



August 4, 2021

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**VIA E-MAIL (angie@cypresscreekequine.com)
AND CERTIFIED – RETURN RECEIPT REQUESTED**

Cypress Creek Equine LLC & Southern Equine Stables
Attn: Mr. Kevin Moody & Mr. Michel Moreno
600 Jefferson St., Suite 1500
Lafayette, LA 70501

Cypress Creek Equine LLC & Southern Equine Stables
Attn: Mr. Kevin Moody & Mr. Michel Moreno
600 Jefferson St., Suite 1401
Lafayette, LA 70503

Re: Insured: Cypress Creek Equine LLC & Southern Equine Stables
Horse: LAOBAN
Date of Loss: May 24, 2021
Claim #: 020211458937
Policy #: DTN1003376-00, Effective 4/8/2021 – 4/8/2022
AND
Claim #: 020211459052
Policy#: DTN1003375-00, Effective 4/8/2021 – 4/8/2022

Dear Messrs. Moody and Moreno,

We represent North America Specialty Insurance Company (“NAS”), who, subject to the terms, conditions, limitations and exclusions thereof, insured the joint interest of Cypress Creek Equine, LLC (“Cypress Creek”) and Southern Equine Stables, LLC (“Southern Equine”) in the 2013 thoroughbred stallion named Laoban under the above-referenced Horse Mortality Policies of Insurance (the “Policies”).

NAS, through the undersigned counsel, has conducted its investigation of Cypress Creek’s and Southern Equine’s claims for the loss of Laoban, who unfortunately died on May 24, 2021. NAS’ investigation has included:

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1. Obtaining relevant documents and veterinary records concerning Laoban's health history and the circumstances of Laoban's death;
2. Obtaining video footage of Laoban's death;
3. Conducting Examinations Under Oath ("EUO's") of the resident veterinarians of Winstar Farm, LLC ("Winstar"), who had care, custody and control of Laoban from the latter part of 2020 through Laoban's death on May 24, 2021; and
4. Consultation with independent Board Certified Veterinarians.

For the reasons explained herein, NAS has concluded that there is no coverage under the Policies in respect of Cypress Creek's and Southern Equine's claims for the mortality loss of Laoban.

SUMMARY INTRODUCTION

The evidence obtained in this investigation supports the conclusion that Laoban died because he was given a risky compounded cocktail injection of four different drugs. Two of the drugs have warnings of anaphylaxis. Three of the drugs were expired; one was expired by nearly nine years and was only indicated for iron deficient anemia relating to baby pigs.

The Winstar veterinarian who administered the cocktail injection failed to read any of the four (4) drug labels. She used the drugs in a manner that was contrary in at least 10 different ways to the label instructions (i.e. wrong species, wrong dosage, wrong route of administration, etc.). The decision to give this cocktail to Laoban and the fact that this veterinarian did not remain by Laoban's side immediately after the injection for at least several minutes to monitor his response are more than sufficient to exclude coverage due to "Improper Care" under the Policies. But as a threshold matter, the death of Laoban is excluded under the Policies, because this injection was not used to prevent or treat any accident, sickness or disease. The injection was given solely in an attempt to increase Laoban's "energy level" so he would

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breed more. This was an unbalanced risk that Dr. Wharton undertook on behalf of Winstar and not a risk that is covered under the Policies.¹

THE CLAIM FACTS

Based upon NAS' investigation as described above, the claim facts that have been developed are as follows:

A. Winstar's Care, Custody and Control of Laoban

Pursuant to a written Purchase and Sale Agreement dated October 18, 2020, Winstar acquired eighteen (18) fractional interests in Laoban from various other entities. Pursuant to a subsequent "Amended Laoban Co-Ownership Agreement," Winstar became the Syndicate Manager of Laoban, with Laoban to stand at stud at Winstar under the supervision and management of Winstar.

As a Syndicate Manager, Winstar maintained physical custody of Laoban, providing this stallion with food, water, shelter, care and veterinary attention. As such, from the time Laoban arrived at Winstar in the latter part of 2020 until the date of his death on May 24, 2021, Winstar had care, custody and control over Laoban.

B. Laoban's Purported Lethargy and Tiredness

On May 22, 2021, Laoban reportedly entered the breeding shed at Winstar "with enthusiasm," but quickly lost interest in breeding. Winstar's breeding records reflect that Laoban mounted three different mares that day but did not complete the breeding act with each such mare.

¹ If Dr. Wharton had testified that the shot was given to Laoban due to an accident, sickness or disease that had been sustained or contracted by Laoban, then NAS would have been entitled under the Policies to have been "immediately" notified of the relevant health problem prior to administration of the injection. Such "immediate" notification requirements in equine mortality policies are strictly enforced and courts have consistently held that failure to give immediate notice forfeits coverage without proof that the insurance company has been prejudiced. See Hauser v. Great Am. Assurance Co., 971 F. Supp. 2d 824 (N.D. Ill. 2013); Jahn v. Great Am. Assurance Co., 2004 WL 765240 (N.D. Ill. Apr. 6, 2004); Hiscox Dedicated Corp. Member, Ltd. v. Wilson, 246 F. Supp. 2d 684, 693-94 (E.D. Ky. 2003); Arigato Stables v. Am. Live Stock Ins. Co., 493 A.2d 584 (N.J. App. 1985).

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Dr. Heather Wharton² (“Dr. Wharton”), the associate resident veterinarian at Winstar, observed these incomplete breedings and, therefore, conducted a physical exam of Laoban’s vital parameters, including his heart rate, respiratory rate, mucous membranes, capillary refill time, gut sounds and temperature. According to Dr. Wharton, all of Laoban’s vitals were within normal limits. However, according to Dr. Wharton, Laoban “seemed lethargic and tired.” In this regard, Dr. Wharton testified at her July 7, 2021 EUO that Laoban “wasn’t as energetic as he normally seemed” and on “that day he just stood there with his head held kind of halfway, uninterested in what was going on around him.”

On the following day, May 23, 2021, Laoban was still unwilling to complete the breeding act with respect to two other mares. According to Dr. Wharton, who also observed these breedings, Laoban mounted the mares, penetrated the mares with his penis, thrust into the mares, but quit before he ejaculated. Upon examination, Dr. Wharton concluded that clinically, Laoban was “well.” Again, she did not find anything wrong with Laoban.

Dr. Wharton was unable to determine any cause or reason for Laoban seeming to be lethargic and tired. She confirmed that she “didn’t consider his health to be threatened,” “didn’t consider him to be suffering” and “didn’t consider him to be in any distress.” She said that Laoban “was not sick.” In fact, she acknowledged the “realistic possibility” that Laoban might have just been “tuckered out from breeding during that season and that’s why he appeared to be lethargic and tired.” In this regard, Winstar’s breeding records reflect that Laoban began the breeding season in the middle of February 2021 and that by May 22, 2021, Laoban had already been bred successfully to 126 mares, impregnating 64% of them.³

² Dr. Wharton completed her veterinary degree in 2015 and began work at Winstar in December of 2020.

³ This was a significant increase compared with only 67 mares that Laoban was bred to during the 2000 breeding season while standing stud at Sequel Bloodstock’s farm in New York.

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C. The Decision To Give Laoban A “Vitamin Shot”

On the afternoon of May 23, 2021, it was decided by David Hanley (Winstar’s farm manager), Larry McGinnis, (Winstar’s stallion manager) and Dr. Wharton to give Laoban a dose of nonsteroidal anti-inflammatories that night. According to Dr. Wharton, David Hanley also came up with the idea of giving Laoban what he characterized as a “vitamin shot” the following morning. Further, according to Dr. Wharton, David Hanley asked her if she thought a “vitamin shot,” specifically something with Vitamin B12 in it, would help increase Laoban’s energy level and she agreed.

D. The “Vitamin Shot” Became The “Black Shot”

At the time it was determined between Dr. Wharton, David Hanley and Larry McGinnis that Laoban would get a “vitamin shot,” Dr. Wharton also decided that she would include more to this “vitamin shot” than just B12. Dr. Wharton decided that the “vitamin shot” would also include Vitamin C, Vitamin B Complex and Iron.⁴ She did not discuss the inclusion of these three other drugs with anyone else. Dr. Wharton thought that these additional drugs would increase Laoban’s energy level. Dr. Wharton’s theory was based upon her limited experience working at racetracks in California. Neither Dr. Wharton nor the managing resident veterinarian, Natanya Nieman, had ever administered this type of shot to a horse at Winstar. Dr. Nieman had never even injected an adult horse with a vitamin let alone a mixture of vitamins with iron dextran added.

Later that day, May 23, 2021, Dr. Wharton went to the Winstar Veterinary Pharmacy to see if she could find the ingredients she wanted to use for Laoban’s cocktail injection, namely, Vitamin C, Vitamin B12, Vitamin B Complex and Iron. Dr. Wharton found bottles in a cabinet, all in injectable liquid form, of the Vitamin C, the Vitamin B12 and Iron Hydrogenated Dextran, as well as a bottle of Vitamin B

⁴ Iron, of course, is a mineral and, therefore, this “cocktail” that Dr. Wharton decided upon was no longer just a “vitamin shot,” once Iron was added.

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Complex in injectable liquid form in the refrigerator. These four drugs can only be purchased by a licensed veterinarian or a technician under a veterinarian's supervision. Likewise, the labels on the bottles of these injectable drugs all state the following:

CAUTION: Federal Law restricts this drug to use by or on the order of a licensed veterinarian.

Dr. Wharton admitted that other than looking at the names of these drugs on their bottles, she did not read anything else on these labels. Without reading the expiration dates, the indications or the warnings on those four bottles, Dr. Wharton simply concluded that she had what she wanted for the following morning's injection to Laoban.

Dr. Wharton arrived back at Winstar at approximately 6:30 a.m. the following morning, May 24, 2021. She went directly to Winstar's Veterinary Pharmacy, took the bottles of the Vitamin C, Vitamin B12 and Iron Hydrogenated Dextran out of the cabinet, as well as the bottle of the Vitamin B Complex out of the refrigerator. Dr. Wharton then drew 10 cc's of the Vitamin C, 10 cc's of the Vitamin B12, 10 ccs of the Vitamin B Complex, and 2 cc's of the Iron Hydrogenated Dextran, from their respective bottles and combined these four drugs into one 35 millimeter syringe, thereby formulating a "compound" of what she has described as the "Black Shot."⁵ She then drove with the syringe containing the Black Shot ingredients to Winstar's stallion complex where Laoban was in his stall.

E. The Administration of the Black Shot to Laoban

Dr. Wharton went to Laoban's stall with a Winstar groom at approximately 6:37.24 a.m. She had the syringe containing the Black Shot in her right hand and at approximately 6:37.40 she occludes the jugular vein in Laoban's neck and injects the Black Shot intravenously using a 19 gauge 1 ½ inch needle.

⁵ In her May 24, 2021 "Calendar Entry" which is part of Winstar's records, Dr. Wharton described this compound that she formulated as the "Black Shot," because the Iron turned all four of the ingredients black in color.

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Less than 25 seconds later, Dr. Wharton turns away from Laoban and then exits his stall with the groom following behind. No one stays in the stall or can be seen outside his stall. Dr. Wharton leaves and drives back towards her Winstar office.

F. Laoban Goes Into Anaphylactic Shock And Dies

Laoban appears normal for approximately 58 seconds following the injection but then abruptly jolts toward a wall and then proceeds to violently roll around for 10 seconds before collapsing in a corner of the stall with his limbs flailing. About 40 seconds after the abrupt jolt, a Winstar groom is the first person to look in on Laoban and then other Winstar employees begin to gather in and around his stall. Larry McGinnis, Winstar's stallion manager, calls Dr. Wharton who was in route back to her Winstar office to inform her that Laoban was down in his stall. Dr. Wharton returns to Laoban around 6 minutes after the injection (at approximately 6:43.45) and assesses the downed stallion.

Dr. Wharton did a clinical assessment of Laoban, observing that he was shaking, his respiratory rate was tachypnea/dyspneic, his heart rate was fast but weak and his mucous membranes were white with prolonged capillary refill time. Based upon these observable clinical signs, Dr. Wharton diagnosed Laoban as being in anaphylactic shock, which is a hypersensitive reaction to something given or ingested.

Dr. Wharton, therefore, left Laoban at approximately 6:44.10, returned to her truck outside the stallion complex, obtained a steroid known as Solu-delta cortef and returned back to the stall at approximately 6:45.17, at which time she administered 500 mg of the Solu-delta cortef intravenously to Laoban in an effort to revive the stallion. The administration, however, had no effect. Figuring that she had given Laoban an insufficient amount of the Solu-delta cortef, Dr. Wharton left Laoban again, went back to her truck, retrieved Solu-Medrol, a similar steroid, returned back to Laoban again at approximately

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6:46.45 and this time, administered 125 mg of the Solu-Medrol intravenously to Laoban. But this administration had no effect either. Laoban died shortly after administration of the Solu-Medrol.

THE BASES OF NAS' DECLINATION OF COVERAGE

Based upon the foregoing facts, and for the reasons explained below, NAS, through the undersigned counsel, has determined that there is no insurance coverage under the above-referenced Policies for the death of Laoban.

1. Unauthorized Medication

We call your attention to coverage form NAS-KHM-POL (12/05), HORSE MORTALITY COVERAGE FORM, Section II of your Policies with NAS, entitled "EXCLUSIONS", which provides in pertinent part as follows:

1. The following exclusions apply to all coverages in this policy. . .

*f. **Unauthorized Medication***

*This coverage does not apply to loss caused by or resulting from inoculation of the **horse** or administration of drugs or medication to the **horse** unless done by and under the direction of a **veterinarian** and certified by him/her to have been of a preventative nature or necessitated by accident, sickness or disease of the horse.*

(emphasis added via underlining).

The first issue to be addressed under this Exclusion is whether the loss (death) was caused by or resulted from the administration of drugs or medication to Laoban.⁶

⁶ Causation in a civil matter does not need to be proven with certainty. It must be proven by a preponderance of the evidence and when expert medical/veterinary testimony is needed to help the trier of fact, it suffices if the expert presents an opinion with "reasonable medical probability." Baylis v. Lourdes Hosp., Inc., 805 S.W.2d 122, 124 (Ky. 1991). Also, in Johnson v. Vaughn, 370 S.W.2d 591, 597 (Ky. 1963), the Kentucky Supreme Court held that "circumstantial evidence may be sufficient to prove reasonable probability or proximate cause where the evidence reasonably established a causal connection between the alleged negligence and the injury."

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Based upon a combination of the video footage of Laoban's death, the clinical symptoms manifested by Laoban, the diagnosis by Dr. Wharton, the post-mortem report, and a lack of any evidence to the contrary, the death of Laoban was caused by anaphylaxis and the anaphylaxis was caused by the Black Shot.

The post-mortem report by Dr. Laura Kennedy of the University of Kentucky relating to the death of Laoban begins by stating that "a definitive cause of death could not be determined in this case". This is not unusual since it is often difficult for a pathology exam alone to determine with 100% certainty what the cause of death is. However, the report goes on to say, "In a postmortem examination, anaphylactic shock is largely a diagnosis of exclusion, meaning that other causes of death are eliminated. **There is no evidence of another disease process that would have resulted in the death of this horse**". (Emphasis added). And Dr. Kennedy's final conclusion in the "Diagnosis Comment" section of the post-mortem report is that "[a] **presumptive diagnosis of anaphylactic shock can be made with a reasonable degree of medico-legal certainty in this case given the clinical history provided, the macroscopic and microscopic findings and elimination of other anatomically perceptible causes of death.**" (Emphasis added).

Furthermore, Dr. Wharton testified in her July 7, 2021 EUO that –

- After the Black Shot, "He [Laoban] went into anaphylactic shock. That is what occurred."
- Laoban "exhibited all the major signs of anaphylactic shock."
- She confirmed that her signed statement shortly following Laoban's death made a diagnosis of anaphylactic shock.
- Based upon all of the clinical signs that she saw Laoban manifest when she attempted to revive him, Dr. Wharton still, as of July 7, 2021, adhered to the diagnosis that Laoban died as a result of anaphylactic shock.
- Dr. Wharton has not seen or learned anything that would cause her to be less sure of her conclusion that Laoban died from anaphylactic shock.

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In this regard, Dr. Wharton provided the following answer under oath to the following question in her July 7, 2021 EUO:

Q. ... [y]ou made or reached that conclusion on May 24, 2021 [that Laoban died of anaphylactic shock], ... have you seen anything or learned anything since that would cause you to be less sure of yourself in terms of what caused this horse's death?

A. No.

Moreover, NAS has consulted with independent Board Certified veterinarians (also referred to as the "Consulting Veterinarians") who have reviewed the totality of the evidence and also concluded with a reasonable degree of medical certainty that Laoban died from anaphylactic shock. In fact, they have concluded that there is no other reasonable explanation for his death.

In view of the foregoing, the evidence in this matter supports the conclusion that Laoban died as a result of anaphylactic shock.

In her July 7, 2021 EUO, Dr. Wharton further admitted that there is no logical explanation for the anaphylactic shock of Laoban other than the Black Shot that she administered to Laoban on May 24, 2021.

In this regard, Dr. Wharton provided the following answer under oath to the following question:

Q.... And as you sit here today, is there any logical explanation- . . . that you have for the anaphylactic shock of this horse other than the injection that you gave it on May 24, 2021?...

A. No.

Dr. Nieman, Dr. Wharton's supervisor and the head resident veterinarian of Winstar, reiterated this conclusion in her EUO testimony on July 8, 2021:

Q.... as you sit here now, can you think of any other logical explanation for the anaphylactic shock other than the shot?

A No.

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Moreover, NAS's Consulting Veterinarians have also concluded with a reasonable degree of medical certainty that Laoban died from anaphylactic shock caused by the Black Shot administered by Dr. Wharton to Laoban on May 24, 2001. They have further concluded that there is no other reasonable explanation for the death other than the Black Shot injection.

Since the evidence in this matter is that Laoban died of anaphylactic shock caused by Dr. Wharton's administration of the Black Shot on May 24, 2021, the next issue to be addressed is whether Dr. Wharton has certified, as required by the above quoted "Unauthorized Medication" Exclusion, that the shot was of a preventative nature or necessitated by any accident, sickness or disease of or to Laoban.

As demonstrated below, the Black Shot administered by Dr. Wharton to Laoban, which caused or resulted in Laoban's death, was not of a preventative nature, nor was the Black Shot necessitated by any accident, sickness or disease of or to Laoban. Dr. Wharton's EUO was under oath so her sworn testimony is "certified."

With regard to whether the injection was of a preventative nature, Dr. Wharton provided the following answers under oath to the following questions:

Q. Was the purpose of your injection to Laoban on May 24, 2021 to prevent this horse from sustaining any kind of injury, accident or disability?

A. No.

Q. And was the purpose of your injection to Laoban on May 24, 2021 to prevent Laoban from becoming sick or ill or from contracting any disease?

A. No.

Later in the EUO, Dr. Wharton reaffirmed that the injection was not for any preventative reason:

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Q. Okay. And I believe you said [the injection] was not a preventive injection; is that right?

A. Correct.

Dr. Wharton's injection of the Black Shot to Laoban on May 24, 2021 was also not necessitated by any illness, sickness or disease. Nor was Dr. Wharton's injection of the Black Shot to Laoban on May 24, 2021 necessitated by any kind of accident, injury or disability. In this regard, Dr. Wharton provided the following answers under oath to the following questions in her July 7, 2021 EUO;

Q. The injection that you gave to Laoban on the morning of May 24, 2021 was not necessitated by any particular illness, sickness or disease, correct?

A. Correct.

Q. And by the same token, the injection that you gave to Laoban on May 24, 2021 was not necessitated by any kind of accident or injury or disability sustained by Laoban, correct?

A. Correct.

Dr. Wharton's only purpose, her only intention, in giving the Black Shot injection to Laoban on May 24, 2021 was to hopefully increase Laoban's energy level, and Dr. Wharton, as well as Winstar's farm manager and Winstar's stallion manager, wanted to increase Laoban's energy level so that Laoban would get back to breeding more mares. In this regard, Dr. Wharton provided the following answers under oath:

Q. [S]o the purpose, the intention, in giving the injection to Laoban that you did on the morning of May 24, 2021 was to hopefully increase his energy level, isn't that correct?

A. Yes

Q. [W]ould it also be correct that you and Larry McGinnis [Winstar's stallion manager] and David Hanley [Winstar's farm manager] wanted to increase Laoban's energy level so that Laoban would get back to breeding

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mares, correct?

A. Yes.

Further confirmation that Dr. Wharton's injection could not have been to treat any accident, sickness or disease is the fact that Dr. Wharton was not aware of any accident, sickness or disease – sustained or contracted by Laoban since his arrival at Winstar in the latter part of 2020 until his death on May 24, 2021. Also, Dr. Wharton did not conduct or order any sort of blood lab testing of Laoban to diagnose any vitamin or iron deficiency. Therefore, it is inconceivable how the drugs administered by Dr. Wharton to Laoban on May 24, 2021 could have had anything to do with a health concern.

In view of the foregoing, the only evidence concerning Laoban's death is that:

1. Laoban died from anaphylactic shock caused by or resulting from the administration of Dr. Wharton's Black Shot injection on May 24, 2021; and
2. Dr. Wharton's May 24, 2021 Black Shot injection was not of a preventative nature in any respect, nor was it necessitated by any accident, sickness, or disease of or to Laoban.

Accordingly, the May 24, 2021 death of Laoban falls squarely within the above-quoted Exclusion to coverage under your Policies with NAS and by reason thereof, no coverage is afforded under those Policies for the loss of Laoban on this basis alone.⁷

⁷ Paragraph IV (1) (c) of the "Conditions" Section of NAS' Policies, entitled, "Concealment Or Misrepresentation," is also applicable to the facts surrounding Dr. Wharton's unauthorized use of drugs to Laoban. This Condition states, "This insurance is void if you, your agents, your employees, any partial owner or any other persons having care, custody and control of your horse(s) intentionally conceal or misrepresent to us or our Managing Underwriter any material fact or circumstance relating to this insurance at any time." The administration of the Black Shot was a material fact especially considering it was not being given to Laoban to address any accident, sickness or disease that NAS normally would have notice of. It was an injection that was being administered contrary to label indications and it was not an injection that had ever been used by Dr. Nieman at Winstar in her 19 years there. Dr. Nieman expressed that she was "mad" that she had not been consulted about the shot before it was given. In a similar vein, NAS had a right to know about the shot in advance and have its own veterinarian weigh in on whether it was safe and appropriate. Failure to communicate this important information to NAS was an intentional concealment of a material fact relating to the insurance.

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2. Failure to Provide Proper Care

We also call to your attention that part of Section II of your Policies with NAS, entitled “EXCLUSIONS,” which provides as follows.

1. *The following exclusions apply to all coverages in this policy.*
 - a. *Failure to Provide Proper Care*
This coverage does not apply to loss caused by or resulting from:
 - (1) *failure to provide proper care and attention for the horse,*
 - or*
 - (2) *malicious, willful or intentional acts or omissions by you, your agents, your employees, any partial owner or others having care, custody or control of the horse.*

With the above-quoted Exclusion in mind, as further explained below, NAS’ investigation has shown that there were numerous acts, errors and omissions on the part of Dr. Wharton that constituted a failure to provide proper care to Laoban, and caused or resulted in this stallion’s death. Indeed, giving the Black Shot to Laoban, in the face of what should have been a known risk to Dr. Wharton, was “unsafe” according to statute, violated FDA regulations and lacked appropriate veterinary justification. Further, the manner in which the Black Shot was administered and Dr. Wharton’s failure to stay by Laoban’s side were additional failures to provide proper care under the circumstances.”⁸

A. Dr. Wharton’s Compounding and Extralabel Use Were Not Permitted By Law

The Animal Medicinal Drug Use Clarification Act (“AMDUCA”) permits veterinarians to prescribe and engage in both extralabel and compounding uses of certain approved drugs for animals under certain circumstances, but there is one significant exception. At the outset, AMDUCA states that its

⁸ It must be emphasized that analysis of this loss under the “Failure to Provide Proper Care” Exclusion is secondary for purposes of this declination of coverage letter. The “Unauthorized Medication” Exclusion cited above strictly excludes coverage because where as here, a veterinarian administers a drug that kills the horse and the drug is not even intended to prevent or treat a health concern that should be reported under the Policy, then that risk falls squarely on the veterinarian and its employer and not the insurance company. Nonetheless, the discussion of the failure to provide proper care will add additional context to just how careless and improper it was to administer this Black Shot.

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purpose “is to establish conditions for extralabel use or intended extralabel use in animals by or on the lawful order of licensed veterinarians of Food and Drug Administration approved new animal drugs and approved new human drugs. **Such use is limited to treatment modalities when the health of an animal is threatened or suffering or death may result from failure to treat.**” 21 CFR Section 530.2 (emphasis added). The Federal Drug Administration’s website explains this portion of the law as follows: “The purpose of FDA’s requirements for extra-label drug use in animals is to limit this use to **situations where an animal’s health is threatened or where the animal may suffer or die without treatment.**” See “The Ins and Outs of Extra-Label Drug Use in Animals: A Resource for Veterinarians.” (Emphasis added).

Section 530.3(a) of AMDUCA states “*Extralabel use* means actual use or intended use of a drug in an animal in a manner that is not in accordance with the approved labeling. This includes, but is not limited to, use in species not listed in the labeling, use for indications (disease or other conditions) not listed in the labeling, use at dosage levels, frequencies, or routes of administration other than those stated in the labeling, and deviation from the labeled withdrawal time based on these different uses.”

The act of “compounding” is also addressed under AMDUCA as a variation of “extralabel use.” The American Veterinary Medical Association (“AVMA”) describes “compounding” as “any manipulation of a drug beyond that stipulated on the drug label. Veterinary drugs should only be compounded based on a licensed veterinarian's prescription, and to meet the medical needs of a specific patient. Manipulation might include mixing, diluting, concentrating, flavoring, or changing a drug's dosage form.” The AVMA specifically states that “mixing two injectable drugs in the same syringe” is an example of compounding. Needless to say, Dr. Wharton’s act of mixing the four (4) drugs she used in her Black Shot was a form of extralabel (and compounding) drug use under AMDUCA.

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Furthermore, “compounding” of an FDA approved drug (if it doesn’t fit the AMDUCA exception) renders the compound an unapproved new animal drug. By definition, a “new animal drug” is one that “is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of animal drugs, as safe and effective for use under the conditions prescribed.” 21 CFR 510.3 (g)(1). Further, the FDA considers such new animal drugs “unsafe” if they have not met the criteria set forth in 21 U.S.C. 360b of the Federal Food, Drug and Cosmetic Act. See also Medical Center Pharmacy v. Mukasey, 536 F.3d 383, 400 (5th Cir. 2005). The Black Shot did not meet the criteria in 21 U.S.C. 360b and was an unapproved new animal drug and therefore is considered “unsafe” by the FDA and according to statute.⁹ According to the FDA, an approved drug, “means the drug is safe and effective when it’s used according to the label. FDA’s approval also ensures that the drug’s strength, quality, and purity are consistent from batch to batch, and that the drug’s label is truthful, complete, and not misleading”.¹⁰ By contrast, an unapproved new animal drug is not considered by the FDA to be safe or effective or to have consistency regarding strength, quality or purity.

The American Association of Equine Practitioners acknowledges through their website in an article entitled “Understanding Risk Associated with Veterinary Compounding Choices” that the risk of problems associated with administering a compounded drug falls squarely on the shoulders of the veterinarian. Specifically, the article states, “As a veterinarian, if you use a compounded product, you assume liability for any adverse effects or efficacy failure.”¹¹

⁹ It should be noted that the Iron Hydrogenated Dextran used by Dr. Wharton is manufactured by Sparhawk Laboratories, Inc. It is an FDA approved animal drug that is listed in the FDA’s “Green Book.” It appears that none of the injectable Vitamins that were part of Dr. Wharton’s Black Shot are approved by the FDA and it is unclear if any of them meet the exceptions under 21 U.S.C. 360b. If not, then each of these drugs are technically “unsafe” under 21 U.S.C. 360b. That only makes Dr. Wharton’s decision here even more improper.

¹⁰ See <https://www.fda.gov/animal-veterinary/safety-health/frequently-asked-questions-about-animal-drugs#market>

¹¹ See “Understanding Risk Associated With Veterinary Compounding Choices,” Scott D. Stanley, PhD. ([https://aaep.org/sites/default/files/issues/proceedings-10proceedings-z910011000008%20\(1\).pdf](https://aaep.org/sites/default/files/issues/proceedings-10proceedings-z910011000008%20(1).pdf))

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What makes Dr. Wharton's compounding of the drugs even more improper is that the administration of the Black Shot was contrary to the label instructions on the Vitamin C, Vitamin B12, Vitamin B Complex and the Iron Hydrogenated Dextran in at least 10 separate ways:

- The Vitamin C label states “**administer intramuscularly** 1 to 10 mL, depending on condition, species and body weight.” Dr. Wharton, however, administered 10mL of Vitamin C in the Black Shot **intravenously**.
- The Vitamin B12 label indicates the dosage for horses to be “1 to 2 mL.” but Dr. Wharton's Black Shot to Laoban contained 10 ml of Vitamin B12 – **five times the recommended dose**.
- The Vitamin B12 label has an **expiration date of February of 2020** - a year and 3 months past its expiration date at the time of the injection.
- The Vitamin B Complex label has an **expiration date of April, 2019** -over two years past its expiration date at the time of the injection.
- The Vitamin B Complex label contains a “Warning: Parenteral administration [which includes intravenous administration as was done by Dr. Wharton] of Thiamine [an ingredient of the Vitamin B Complex] **has resulted in anaphylactic shock. Administer slowly and with caution in doses over 1/3 mL (50 mg of Thiamine).**” (Emphasis added). There are 150 mg Thiamine in each mL. Therefore, Dr. Wharton administered 1,500 mg of Thiamine as part of her Black Shot to Laoban, which is **30 times more than the 50 mg** amount triggering the warning to “administer slowly and with caution.”
- The Vitamin B12 label states, “Indications: As a source of B Complex vitamins for use in the treatment of **deficiencies of these vitamins** in cattle, sheep and horses.” Laoban, however, was **never tested for or diagnosed to have any “deficiency” of the Vitamin B Complex**.
- The Iron Hydrogenated Dextran label has an **expiration date of July, 2012** - nearly nine years past the expiration date.
- The Iron Hydrogenated Dextran label was indicated only for **baby pigs, not horses**.
- The Iron Hydrogenated Dextran label indicated that it was only for **iron deficiency anemia** in baby pigs.
- The Iron Hydrogenated Dextran indicated that administration was to be by **intramuscular injection only**.

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(Emphasis added).

AMDUCA does not give Dr. Wharton carte blanche to engage in any of the extralabel uses that she did when she compounded the four drugs into the Black Shot and injected it into Laoban. Indeed, as noted above, such extralabel use is permissible only in circumstances when the “animal’s health is threatened or where the animal may suffer or die without treatment.” See 21 CFR Section 530.2. In the case of Laoban and the Black Shot, none of these criteria have been met and Dr. Wharton admitted as much in her July 7, 2021 EUO. In this regard, at her July 7, 2021 EUO, Dr. Wharton answered under oath the following questions in the following manner:

Q. Between May 22nd and May 24 of 2021 you didn’t consider his [Laoban’s] health being threatened, did you?

A. No.

Q. You didn’t’ consider him [Laoban] to be suffering, did you?

A. No.

Q. Between May 22 and May 24, 2021 you didn’t consider him [Laoban] to be in any distress, did you?

A. No.

Q. ... Between May 22 and May 24, 2021, you didn’t consider ... Laoban to be in any condition . . . that death would occur, right? Correct?

A. Correct

Q. And between May 22 and May 24, 2021, you didn’t consider him [Laoban] to be in any type of pain to the extent that you were worried about him suffering or death being a possibility, correct?

A. Correct. Those were not considerations.

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In view of the foregoing, Dr. Wharton's extralabel use and compounding of the drugs in her Black Shot was not permissible under AMDUCA and constituted a failure to provide proper care and attention for Laoban resulting in this stallion's death.

B. Wharton Failed To Heed the Warnings of Anaphylaxis And Failed To Do Any Research

As explained below, part and parcel of the failure to provide proper care to Laoban, thereby resulting in its death, was also Dr. Wharton's administration of two drugs, thiamine (as an ingredient of the Vitamin B Complex) and iron dextran. Both drugs have life threatening warnings of anaphylaxis that Dr. Wharton should have been aware of and taken the warnings very seriously.

The Thiamine in the Vitamin B Complex

As referenced above, the Vitamin B Complex that Dr. Wharton utilized as part of her Black Shot to Laoban contains an ingredient called thiamine. There are 150 mg of thiamine in each mL of the Vitamin B Complex. The bottle has a clear statement:

Warning: Parenteral administration of Thiamine has resulted in anaphylactic shock. Administer slowly and with caution in doses over 1/3 ml (50 mg of Thiamine). (Emphasis added).

NAS' Consulting Veterinarians have advised that giving an injection of Vitamin B Complex (with thiamine) intravenously is not a normal practice and particularly not to an adult horse or stallion. These Consulting Veterinarians have reported that when it is administered, it should be mixed with saline and placed in a drip bag/jug and administered very slowly and that the horse should be cautiously monitored for any adverse reaction.

The warning on the label that Dr. Wharton failed to read is self-explanatory. The warning of anaphylactic shock is serious and is triggered by a dose of 50 mg of thiamine. In the case of Laoban, Dr.

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Wharton administered the shot with 30 times that amount (1,500 mg of thiamine). And she administered the shot very quickly and without any caution. She left Laoban the moment the shot was complete.

Research online and in veterinary drug handbooks reveals warnings consistent with those warnings on the label, but which Dr. Wharton chose to ignore. An article by Dr. Joan Norton published in 2013 highlights various risks presented by several equine drugs, including the risk of thiamine resulting in anaphylactic shock. This article states that “[w]hile oral supplementation [of thiamine] is safe, great caution should be taken when it is administered intravenously.” Dr. Norton specifically warns that:

Rapid injection of thiamine intravenously causes collapse of not only the entire horse but also the cardiovascular system. In many veterinary clinics, **thiamine is only administered IV as part of large volume fluid therapy to ensure that the desired dose is diluted and given over a long period of time.** These injections have also been associated with **anaphylactic reactions that immediately affect the cardiovascular and respiratory systems leading to collapse, respiratory distress and even death.**

(Emphasis added). There was no reasonable justification for Laoban being injected with Vitamin B Complex in the first place, and there was certainly no reasonable justification for injecting this volume of thiamine in Laoban quickly and without caution. And even if there was a medical reason that could somehow justify the shot to begin with (such as a vitamin deficiency) there was no reasonable explanation for why Dr. Wharton couldn't have taken the very minimal extra effort of giving the injection as part of a large volume therapy while staying nearby for several more minutes to monitor any adverse reaction.

The Iron Hydrogenated Dextran

As referenced above, the Iron Hydrogenated Dextran (also referred to as “Iron Dextran”) label does not even mention horses. The drug is only for intramuscular injection in baby pigs with iron deficient anemia. The leaflet referenced on the label notes that pigs (albeit rarely) have died following the injection.

Any bit of research on Iron Dextran and horses would have revealed to Dr. Wharton that this drug poses a risk of anaphylaxis. The first thing that pops up when one searches “Horses and Iron Dextran” or

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“Horses and Iron Hydrogenated Dextran” is a summary of a Dutch study that says, “A description is given of three cases in which horses died very shortly after being given an intramuscular injection of iron dextran. **The use of iron dextran in the case of horses is inadvisable.**” (Emphasis added). Likewise, consulting a well-accepted veterinary source such as Plumb’s Veterinary Medicine Handbook, also reveals that horses are not an indicated species at all for any formulation of iron dextran and that anaphylaxis is a risk even when the shot is administered intramuscularly. Specifically, the Plumb’s Veterinary Medicine Handbook section on Iron Dextran warns that there is a “known hypersensitivity to it” and that the “Adverse Effect” includes “anaphylactic reactions.” There is also no FDA approved variation of Iron Dextran that is indicated for intravenous injection in an animal.

NAS’ Consulting Veterinarians do not believe that giving Iron Dextran to a stallion (or any horse for that matter) is appropriate or a common practice. They are aware of the administration of something called “iron sucrose” to horses, but not Iron Dextran. The Consulting Veterinarians cannot understand why Dr. Wharton would have given an iron injection of any sort to Laoban, but particularly when he had not been diagnosed with iron deficient anemia.

Consistent with the Consulting Veterinarians, Dr. Nieman also had never given a horse Iron Dextran in her 19 years at Winstar and she testified in her July 8, 2021 EUO that she did not even know the Iron Dextran was in the Winstar Pharmacy. Dr. Nieman thought it must have been a “misorder.” Moreover, Dr. Nieman testified under oath at her July 8, 2021 EUO that “I don’t give vitamin injections and iron ... this is not something I would have used.” This alone speaks volumes about how unusual and risky this injection was.

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In sum, Dr. Wharton's failure to recognize the serious life-threatening risk of anaphylaxis related to the Black Shot and her failure to do even a modicum of research on the drugs is another component of the failure to provide proper care to Laoban that resulted in his death.

C. The Decision to Give This Injection Lacked Any Reasonable Justification

Dr. Wharton's decision in the first instance to mix the ingredients of the Black Shot and administer the injection in the manner she did is yet another layer of the failure to provide proper care for Laoban, thereby resulting in its death. This was not a situation where Laoban was suffering from an injury, sickness or disease compelling Dr. Wharton to use an approved drug extralabel to save the horse's life. Quite the contrary, here Dr. Wharton said that Laoban was completely healthy, but just "seemed lethargic and tired" during a limited period of two days and as she admitted, there was a "realistic possibility" that Laoban might just have been tired from breeding. However, instead of giving him a week or two off to monitor improvement, and instead of conducting any blood or any other diagnostic tests, she resorted to the Black Shot to press Laoban into further breeding service. NAS' Consulting Veterinarians do not believe that there was any justification or basis for the administration of the Black Shot under these circumstances.

Dr. Wharton suggested in her EUO that this injection was safe because she had administered it to race horses during her limited experience as a race track veterinarian in California. Her claim in this regard is unclear, naïve, dubious and insignificant in light of all the other evidence. She claimed she used this cocktail "many times" previously while she worked under Dr. Melinda Blue for race track trainers in California. She said she used it on race horses so they could "race faster" and "as a recovery from physical exertion to give them a little bit of energy after they were done racing, when they were tired." When pressed about how many times she had used this cocktail, she responded, "I could not say. I cannot recall." When asked to ballpark the number of times she said "likely" more than fifty times. Also, when asked

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what other veterinarians besides her and Dr. Melinda Blue used this cocktail she could not name a single other veterinarian. Consistent with her foggy recall, she conceded that this cocktail might have occasionally used iron sucrose instead of iron dextran and Vitamin B Complex without thiamine as opposed to the Vitamin B Complex with thiamine used on Laoban.

So while Dr. Wharton may have used this cocktail over 50 times without a horse dying or having an adverse reaction she was not even certain how many times she previously used the very two ingredients, which are well documented to present the risk of anaphylactic shock: thiamine and iron dextran. And even if one were to assume she had previously used the exact same four ingredients on numerous race horses, it would in no way negate her obligation to acknowledge all the obvious risks here and follow the warnings from the labels and veterinary drug handbooks. The labels and the veterinary drug handbooks aggregate the collective knowledge of a large number and cross section of veterinarians and scientists. Dr. Wharton's experience, on the other hand, is very narrow and limited. And her prior limited success with the cocktail in no way negates the fact that she was assuming the risk of an adverse reaction by Laoban to her use of a compound cocktail that is by law deemed "unsafe" by the FDA.

In her July 7, 2021 EUO, Dr. Wharton also attempted to shift some of the blame to others at Winstar for her failure to read the labels and expiration dates on the four drugs. For example, she said that Dr. Nieman and other staff are in charge of the Winstar Pharmacy and removing expired bottles. She said it was okay to use the Iron Hydrogenated Dextran because "to my knowledge, it was safe and it was meant to use for horses while we had it in our pharmacy." In this regard, Dr. Wharton testified as follows:

Q. You just assume that every drug in that pharmacy was -- was fine and you didn't have to read any labels on them is that what you -- was that the assumption that you operated on, doctor?

A. Yes, because we have staff that are in charge

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of that.

Q. Okay.

A. Which is not me.

Q. All right. Does that -- does that obviate the necessity or excuse you from looking at labels on [drugs] before you use them?

A. It should. It's already being checked. It's not my responsibility to go through our drug cabinet.

Dr. Wharton also testified that she did not feel she had to consult with or obtain Dr. Nieman's approval to give this injection to Laoban if David Hanley instructed her to do so because "David is Natayna's boss, so his authority supersedes hers."

Dr. Nieman appears to disagree with Dr. Wharton regarding whether this injection should have been brought to her attention. In response to a question regarding whether she expected to be consulted if Laoban was going to receive a vitamin B12 injection from Wharton (at Hanley's direction), Dr. Nieman said that a vitamin B12 shot was "not something I would regularly do" so "I would ... have expected to be consulted with on that matter." Then, when asked if Dr. Wharton had decided to add three more drugs to the injection (without Hanley's involvement) whether she'd expect to be consulted, Dr. Nieman responded simply, "Yes."

In fact, when asked if she was "upset about the manner in which this [injection] was done without even discussing it with [her]" Dr. Nieman responded succinctly, "Yes. I was mad." The following questions and answers then transpired:

Q. ...Were you mad ... about the manner in which the horse was dead? I mean, horses die, but you don't get mad usually unless you're unhappy with the manner in which they died. What were you mad about?

A. I was mad that if something had happened differently, he may not be dead.

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Q. And what in your view should have happened differently?

A. I think I should have been consulted about the shot.

Q. Before it was given?

A. Yes.

Q. So that you could have an opportunity to express your view?

A. Yes.

While Dr. Wharton's excuses for using the drugs, not reading the drug labels and failing to consult with Dr. Nieman about the Black Shot may raise issues relating to possible negligent oversight of Winstar's Pharmacy and possibly improper protocols related to veterinary decisions at Winstar, these issues do not affect NAS' coverage position herein. Determining whether there was contributory negligence on the part of other Winstar employees for the death of Laoban is not necessary for purposes of determining that there was a failure to provide proper care for Laoban which resulted in this stallion's death. The act of administering the shot was a decision made by Winstar (through its employees) and Winstar was the only party who had control over that decision. Whether the failure to provide proper care for Laoban rested entirely with Dr. Wharton or was shared by Winstar management and the head resident veterinarian does not influence the conclusion herein that there was a failure to provide proper care for Laoban and that his death is excluded from coverage under the Policies.

D. Leaving Laoban Following the Shot Was Also Improper Care

While there was no adequate justification for administering the shot in the first place, the fact that Dr. Wharton gave the shot and then left immediately rather than standing by Laoban's side for at least several minutes with anaphylaxis medications nearby was also a significant omission and failure to provide proper care and attention. As explained in previous sections, there were numerous reasons that

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Dr. Wharton should have been aware of the risk of anaphylaxis presented by the Black Shot. Even if the chance of anaphylactic shock was only minimal, the warnings were significant enough (particularly in the manner she quickly administered the shot) that a reasonable veterinarian would have taken several minutes after the shot to observe the horse.

The NAS Consulting Veterinarians have also opined that not only would a reasonably prudent veterinarian under these circumstances have remained present to watch for an adverse reaction, they believe a reasonably prudent veterinarian would have had epinephrine readily on hand, in addition to a steroid like Solu-delta cortef/Solu-Medrol. They believe that epinephrine is the first line of defense for an anaphylaxis reaction such as this. They also believe that if Dr. Wharton had remained by Laoban's side after the shot with epinephrine that there is a possibility his life could have been saved.

The foregoing acts, errors and omissions by Dr. Wharton on behalf of Winstar also constituted a failure to provide proper care and for Laoban. Coverage for the death of Laoban, is therefore, excluded under your Policies with NAS for this reason as well.

3. Sound Health At The Start of Coverage

We also call your attention to coverage form NAS-KHM-POL (12/05), HORSE MORTALITY COVERAGE FORM, Section IV of your Policies with NAS, entitled "CONDITIONS," which provides in pertinent part as follows:

1. The following conditions apply to all coverage in this policy: ...

t. Your Agreement

You agree that on the date coverage starts for any **horse** covered under this policy, the following statements are true:

- (1) The **horse** is in sound health and free from any sickness, disease, lameness, injury or physical disability of any kind and has not been nerved.

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Coverage for the two joint Cypress Creek and Southern Equine Policies began April 8, 2021 pursuant to a new application. The application was signed by the manager for both Cypress Creek and Southern Equine on April 12, 2021. This Application asked Cypress Creek and Southern Equine to confirm that each horse to be insured including Laoban, was “in sound health for its intended use and free from any illness, disease, lameness, injury, significant conformational defect, breeding disability or physical disability of any kind...” The Application also asked Cypress Creek and Southern Equine to confirm that “No Listed horse [including Laoban], is suffering or has previously suffered from any type of degenerative condition such as Laminitis, Navicular Disease, Joint Disease, Arthritis...or any other type of equine malady.” Cypress Creek and Southern Equine’s Application answered “True” to both of these statements and further stated:

I HAVE FIRST HAND KNOWLEDGE OF THE ANSWERS IN THIS APPLICATION OR I HAVE OBTAINED ANSWERS DIRECTLY FROM INDIVIDUALS WITH FIRST HAND KNOWLEDGE.

NAS’ investigation has shown that the aforementioned statements and representations in the Application and as agreed to in the Conditions section of the Policies were not true and correct with respect to Laoban. While the evidence shows that the Black Shot discussed in previous sections was administered only to “increase” Laoban’s “energy level,” and was not in response to any accident, injury, sickness or disease, the investigation of this claim has revealed that Laoban was diagnosed as having “degenerative arthritis” of the “cervical facets at C 5, 6 and 7” as well as impinging spinous process at T2, T13, T14 and T15. The arthritis was revealed by X-rays taken by Dr. Alan Ruggles on or about February 6, 2021 and March 22, 2021. The impinging spinous process was noted by Dr. Larry Bramlage on or about February 5, 2021. Records of both Winstar and Rood and Riddle Equine Hospital also reflect that Laoban

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was having breeding difficulties and/or disabilities prior to the April 8, 2021 commencement date of the Policies.

The Application should have disclosed the degenerative arthritis, the impinging spinous processes and breeding difficulties. Laoban failed to satisfy the above-quoted Condition of NAS' Policies which required that Laoban be in sound health and free of any disease, injury and/or physical disability of any kind as of the April 8, 2021 commencement date of the Policies. By reason of the foregoing, there is no coverage afforded under NAS' Policies for the death of Laoban on this basis as well.

CONCLUSION

Based on the information available and for the reasons outlined above, NAS, through the undersigned counsel, respectfully disclaims coverage and denies any and all liability under the above-referenced Policies for the death of Laoban.

NAS may have other bases upon which the declination of coverage may be based and hereby expressly reserves the right to present additional bases at a later time, if necessary, and hereby further reserves the right to assert any other policy provisions, privileges and defenses that may be available to it. NAS' decision is based upon the investigation into this loss, which includes, but is not limited to, the information supplied by you.

Should you wish to obtain copies of the video footage of Laoban's death and/or the transcripts of the EUO's that we have conducted, please let us know and we will provide these materials to you. Furthermore, should you believe that NAS' decision with regards to your claim is in error, we request that you immediately provide us with the reasons therefore and any information that you have not already provided to us that supports your position. NAS reserves the right to review any additional information that you may submit and amend its decision if warranted.

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Very truly yours,



Harvey A. Feintuch

cc: The Limestone Bank, Inc.
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Micheal Levy of Muirfield Insurance (mlevy@muirfieldinsurance.com)