SUMMARY REPORT ABOUT SORING IN TENNESEE WALKING HORSES Paul C. Stromberg DVM, PhD DACVP

The following is a summary of the points and observations I have made studying the problem of soring in Tennessee Walking Horses (TWH). It outlines what I did for this project and what I have found including testimony of VMOs, USDA training manuals, a review of the scar clinics conducted by VMOs for DQPs my own study and fact finding and most importantly the histopathology from skin biopsies of TWH disqualified for scar rule violations. I have laid out the difference between good science, logic and thinking with what the Horse Protection Act staff of the USDA is doing. It also draws on a popular book by a Harvard physician about the errors doctors make in human medicine and lectures I give about this in veterinary medicine. Examples of these mistakes are found in testimony and the scar clinic transcripts. It builds the case that USDA is doing poor science with inadequate methods and poor logic. This is the essence of the problem with inspecting TWH for scar rule violations. How can you accept the USDA's conclusions if the methods, logic and medical practice are so flawed.

MY QUALIFICATIONS. There is a tendency among lay people to think one veterinarian is like another and I want everyone to understand I am trained and experienced in a specialized area of medicine and the scientific method, how to conduct research and correctly apply logic to judgments and diagnoses. I am not like most DVMs and certainly NOT like the VMOs (Veterinary Medical Officers) who are inspecting TWH for compliance with the HPA (Horse Protection Act).

SPECIALIZATION IN VETERINARY MEDICINE — It is identical to human medicine. More training and experience focused in a narrow area of medicine. Today a "DVM" is the equivalent to a family practice doctor in human medicine. When people need more experience and technical skill, they see a specialist. It's the same in Veterinary Medicine today. There are about 25 different specialties in veterinary medicine, similar to those in human medicine; internists, surgeons, ophthalmologists, dermatologists, oncologists and pathologists among others. You would not seek a family practitioner to read your breast biopsy or perform brain surgery on you. Likewise, if you want to fully understand the complexities of a pathologic process in horses, you would not want to consult a general practice veterinarian but seek the advice of a veterinarian with advanced training and experience in the recognition of disease patterns and the understanding of the mechanisms that produce those patterns.

Generally 3-4 additional years of training and experience are required in the area of specialization after the DVM degree. It is performed in an accredited institution where specialty training is a major activity conducted by experts in that specialty. You complete the training and then must pass a rigorous examination to be accepted as a specialist. Increasingly today most specialties have maintenance of certification programs that promote continuing education to keep the status of your certification active and current. This lets the public know that you have in-depth training in the specialized area of medicine. It is designated by the title "Diplomate" on a diploma. Thus I am a Diplomate of the American College of Veterinary Pathologists or DACVP. The American College of Veterinary Pathologists was the first specialty college organized in veterinary medicine (1949) and was the largest until about 15 years ago when internal medicine became the largest specialty.

WHAT IS A VETERINARY PATHOLOGIST. What do they do? What is their expertise? A veterinarian who has completed additional training in the recognition and interpretation of disease patterns; an expert in the diagnosis of disease in a broad range of animals. Because of the "One Medicine" concept shared by the AMA and AVMA, most are also very knowledgeable about human diseases although they do not diagnose human diseases as part of their practice. They observe, describe and interpret the patterns of pathologic processes and explain how they are caused. Most veterinary pathologists also have a PhD degree during which they are taught to master the scientific method and how to correctly apply it. This entails how to properly perform research in the investigation of disease and understand the mechanisms of disease causation so as to understand how to manage, treat or prevent it.

This takes an additional 4-6 years of training although it is often performed concurrently with the residency training in a medical specialty. Veterinary pathologists comprise only about 2.5% of all veterinarians in the USA today. Veterinary pathologists are employed in the biopharmaceutical industry, government diagnostic and research labs (NIH, FDA, NIEHS, Public Health Service and the military, but not the USDA), academic institutions (both medical and veterinary), zoological parks, wildlife conservation societies, state and private diagnostic labs and in private practice. ACVP Diplomates are employed in 31 foreign countries on all continents. Because the demand for their service and skills is so high and their numbers so low, they enjoy a very robust job market with many opportunities.

THE PATHOLOGY OF SORING INJURIES – A Pathologist's View of the Pathology

Prior to 1970 unscrupulous people inflicted injury and pain on TWH by damaging the skin on their front legs in an attempt to make it more sensitive and hence accentuate their natural gait. The damage was caused by the application of caustic substances that produced a "chemical burn" or irritation that induced epithelial necrosis as well as damage to the deeper dermis. There are 3 distinct phases to soring injury that begin as acute necrosis with the cardinal signs of inflammation. As the wound begins to heal, it forms "granulation tissue" that is pink, moist (edematous) and may have a granular feel to it. If this becomes infected it may change to a more chronic form of inflammation (granulomatous) and possibly (but not necessarily) form discrete areas of such inflammation called "granulomas" depending on the soring agent. As healing proceeds the tissue becomes covered by epithelium (re-epithelialization). The swelling decreases, the tissue becomes pale, drier and firm until a mature white scar forms that may remain. It was the early stages of necrosis and immature granulation tissue that would be sensitive and reputedly help to produce the exaggerated gait trainers hoped for. With extensive necrosis, extensive scar tissue would be less sensitive as nerves are often destroyed and the effect of heightened sensitivity would be diminished. Mature scar tissue likely has no sensation at all as the nerve endings are destroyed.

The lesions affected primarily the cranial aspect of the pasterns. There were no lesions on the posterior aspect of the pastern. Nobody tried to hide this as it was not illegal. After the HPA passed in 1970, USDA enforced the law and disqualified "sored" horses. The detection was not difficult. The skin was ulcerated, acutely inflamed and in chronic cases began to heal by the formation of abundant granulation tissue called "**Proud flesh**" which horses often form in exuberant amounts. Because this tissue is not covered by epidermis, it is open to secondary infection and readily exhibits the classic "Cardinal signs of inflammation" ("*Rubor et Tumor cum Calore et Dolore et functio laesa*"). Visual inspection alone was sufficient to make the diagnosis. Indeed, I talked with some older gentlemen at the 2016 Celebration who told me you could not only see the damaged skin from the grand stand, you could also often smell the lesions! It is likely there are few USDA officials still working today who can remember those days (42 years ago). The HPA has markedly decreased the incidence of this type of lesion which the USDA admits .{ Scar Clinic 2016: page 30, line 4-5; Baker: "...nowadays I don't think there's as much –well, obviously there's not as much soring as there used to be and it's not as bad as it used to be,"}

Although those lesions are rarely seen today, the USDA has shifted their focus around to the back of the pastern and reports high incidences of soring injuries there even though that was not a site of soring lesions before the HPA. In many horses the skin here forms folds and ridges of tissue with mild alopecia (hair loss). These folds are like the folds that form in the palm of your hand as you open and close it. These changes in the skin look very different from the old classic lesions on the anterior aspect of the pastern. They are not ulcerated and do consist of exposed immature granulation tissue that is not reepithelialized yet and they are not mature fibrous scars. But most scar rule violations now are called on these folds yet there has been no attempt to verify that these areas have either acute or chronic inflammation with granulation tissue or mature scar formation.

The microscopic or **histopathology of "soring lesions**" has not been described in the peer reviewed literature. But we know that the reaction ranges from that of a chemical burn to irritant contact dermatitis.

The severity varies with the nature of the chemical. Agents capable of this are strong acids such as carbolic or sulfuric, alkalis, cresol tars, paints, kerosene, turpentine, mustard oil, diesel fuel, antiseptics and insecticides. The reaction varies from acute full thickness epidermal necrosis and ulceration to partial necrosis with vesicles or hydropic degeneration. There is a potent acute inflammatory reaction that varies in its quality from acute suppurative to chronic granulomatous depending on how frequent or persistent the chemical is or how easily it can be cleared from the skin by the inflammatory response. Chronic application or hard to clear substances may invoke a granulomatous response especially if the exposed dermis becomes secondarily infected. When necrosis is extensive the injury heals by granulation tissue formation also called "Healing by 2^{nd} intent." It may or may not form discrete granulomas. Very severe injury or chronic repeated injury destroys adnexal elements such as hair follicles, blood vessels, and nerves in the dermis with filling of the tissue by dense fibrous tissue called "scar tissue." It may leave the skin devoid of hair. Such lesions often have a change in cutaneous pigmentation due to the destruction of melanocytes in the epidermis. Horses in particular among domestic animals, lose pigment in scar tissue so the area is pale to white. The gross and histologic lesions are not etiologically pathognomonic, however. Scar tissue can be easily recognized but the specific cause of the damage is generally not obvious.

THE LANGUAGE OF THE HPA AND SCAR RULE: A pathologist's view of the language The term "proliferating granuloma" or "proliferating granuloma tissue" is nonsense. It has no real meaning and is not language a pathologist or any knowledgeable medical professional would use today. This suggests to me the law was written by a layperson such as a congressional staffer or an administrator without medical training. Its inclusion in the HPA is unfortunate. It is easy for a layperson to be confused by the terms granuloma, granulation tissue and granulomatous inflammation. Two interpretations of the language are possible. One that is centered on the "Proliferating" component of the language would seem to imply the proliferation of granulation tissue or immature scar tissue following necrosis induced by a caustic chemical. This is the common result of injury and normal wound healing. That seems in line with the classic injuries and correlates with old photographs of proud flesh on the pasterns of sored horses. The second is centered on the "Granuloma" component of the language that would recognize a localized nodular form of distinct inflammation with the characteristics of granulomatous inflammation, a mixture of inflammatory cells including epithelioid macrophages, perhaps multinucleated giant cells and sometimes surrounded by fibrosis. The presence of granulomatous inflammation of which granuloma is a specific subtype is also consistent with chronic inflammation characteristic of hard to clear or persistent antigens or repeated injuries and depending on the agent used to cause necrosis might be found in such injuries. It may also signal secondary infection by some microbial agents. It is not unreasonable to conclude that in some cases you might find proud flesh with chronic inflammation in it which is not uncommon in proud flesh on horses injured by other pathogenic mechanisms. To date nobody has verified by histopathology that granulomas form in soring lesions. What should be clear is that granulomas do not proliferate or grow by cell division as a neoplasm does so the term proliferating granuloma tissue is an inaccurate term not in use by pathologists today.

The term "granulation tissue" is derived from the fine nodules or "granulations" on the surface. They are a mixture of newly formed blood vessels, extracellular matrix and fibroblasts with minimal collagen deposition that provides support for wound repair. (See photos from page 184 of "The Pathologic Basis of Veterinary Disease", McGavin and Zachary, 4th Ed, 2017). But there were few English language veterinary pathology textbooks when the HPA was written and no veterinary <u>histopathology</u> textbook in English. The first edition of <u>Veterinary Pathology</u> by Smith & Jones in 1957 may have been consulted.

Instead a German textbook ("Pathologische Histologie" by Georg Pallaske, 2nd Ed, 1960 (See copy of the book cover) might have been used as a reference. It's apparent from translating the German that his use of the term "Special granulation tissue" may have had the same meaning as "Granulomatous tissue" which could easily have been mistranslated as "Granuloma tissue." But "granulomas" do not proliferate

in the same sense as neoplastic or cancer cells do. So the term is confusing as to its real meaning to anyone not familiar with Pallaske's textbook. Granulomas may grow by accretion of inflammatory cells drawn to the injury but not proliferation of cells. The potential confusion was addressed in the 5th Ed of *Veterinary Pathology* by Jones & Hunt published in 1983 (pg 195-196). "*Granulation tissue} must not be confused with granulomatous inflammation described previously. The name comes from the gross appearance of this tissue. The surface, when seen with the naked eye, appears to bear many red "granules" which are actually the blunt ends of loops of new capillaries which are often perpendicular to the surface."*

<u>I believe the language created confusion within the USDA and they do not have a clear idea of what it really means.</u> So they are unsure what to look for in their inspections. This uncertainty is manifested in reading the transcripts of the scar rule clinics which document the disagreement among the VMOs, the changing agency regulations governing how to inspect and the confusion among the DQPs.

The posterior surfaces of the pasterns may show bilateral areas of **uniformly thickened epithelial** tissue if such areas are free of **proliferating granuloma tissue**, irritation, moisture, edema, or other evidence of inflammation.

This is why the VMOs in their testimony are careful to say they observed **non-uniformly thickened epithelium** because uniformly thickened epithelium is allowed. The scar rule is silent about non-uniformly thickened epithelium and does not define it. This raises several questions about how VMO's interpret what they see as scar rule violations:

- 1) What do they mean by non-uniformly thickened epithelium? Does this refer to an area of skin or to the topographic ARRANGEMENT OF THE SKIN LAYERS?
- 2) What informs them the tissue is uniformly versus non-uniformly thickened?
- 3) What has that got to do with chronic inflammation and scar tissue formation?
- 4) And what informs them it is epithelial tissue; scar tissue; or granulomatous inflammation when they feel it with their thumbs?
- 5) What is the objective medical evidence for this besides what they feel which is highly subjective and variable? Indeed, histopathology of these areas conclusively prove the skin is has no inflammation and is not scar tissue.

It is clear to me that the USDA has chosen to interpret the language of the HPA to mean a localized area of inflammation (granuloma). The diagram in their training manual, illustrates this. Their language in the scar clinics teaching the DQPs focuses on this. In private discussion with USDA officials in Ft Lauderdale, FL in 2017 I was told they are feeling for "nodules" in the skin. Therefore, they are looking for "granulomas" and are disqualifying horses on what they think represents granulomas when it is not certain that is the correct meaning of the language "proliferating granulomas" in the HPA. In fact it is likely the correct interpretation is "granulation tissue."

WHAT I HAVE DONE RELATED TO THIS CASE

I evaluated skin biopsies of the putative scar rule violation tissue. In 2014 I peered reviewed the slides and reports of the primary veterinary pathologist at the Kentucky Diagnostic Laboratory. I traveled to Shelbyville in spring of 2015 to clinically evaluate some of these horses. In 2015 and 2016 I attended the Celebration event and evaluated horses called out on scar rule violations and biopsied some of these horses. I have examined a total of 136 skin samples from 68 horses all disqualified for scar rule

violations. <u>All of these samples were independently evaluated by two board certified veterinary pathologists</u>. This include horses owned by Mr. Terry Dotson and The McSwains.

(See the biopsy reports from the Kentucky Veterinary Diagnostic Laborator)

MR. DOTSON'S HORSES

UNIVERSITY OF KENTUCKY VETERINARY DIAGNOSTIC LABORATORY

1) K14012221 "Fenway Finesse" – No apparent healing by second intent. No granulomatous inflammation. No scar tissue. Incidental changes in dermal collagen and scattered lymphocytes and macrophages indicative of immune surveillance. Marked compacted orthokeratotic hyperkeratosis with acanthosis forming deep rete ridges. Telogen phase hair follicles with evidence of traction alopecia. Epidermal Thickness, Lt pastern = $80\text{-}140~\mu m$ (Reference range = $40\text{-}100\mu m$) Epidermal Thickness, Rt pastern = $120\text{-}220\mu m$

2) K14012223 "Catfish Hunter" – No evidence of healing by 2nd intent. No granulomatous inflammation. No scar tissue. Mild irritation/superficial trauma to the epidermis. Mild superficial perivascular dermatitis consistent with immune surveillance.

Epidermal thickness, Lt pastern = 120-170μm Epidermal Thickness, Rt pastern = 160-190μm

THE McSWAIN HORSE "HONORS"

UNIVERSITY OF KENTUCKY VETERINARY DIAGNOSTICF LABORATORY

Report Date 11/3/2015

Accession No.: K15012014

Diagnosis: Bilateral moderate superficial trauma

Diagnosis Comment: Histologic changes suggest superficial trauma with no evidence of healing by

second intent.

Pathologic Anatomic Findings:

HISTOLOGIC EXAMINATION:

Two punch biopsies are submitted, one from the palmer surface of each forelimb pastern. Histologic changes include the following:

RIGHT:

Epidermis – stratum corneum: Mild compact orthokeratotic hyperkeratosis, measuring 30-40μm. The deep strata of the stratum corneum exhibit multifocal pallor and retention of nuclear oputlines ("ghost cells").

Epidermis – viable layers: Moderate acanthosis, measuring between $\underline{90-110\mu m}$ (Control = 40-100) in the interfollicular epidermis, forming deep rete ridges extending into the superficial dermis.

Superficial dermis: Superficial papillary dermis is expanded and interdigitates normally with reticular dermal collagen.

Pigmentary incontinence is not observed. There is <u>minimal</u> superficial to <u>mid perivascular</u> nonsuppurative inflammation.

Follicular adenxae: Hair bulbs are not apparent. Follicular external root sheath epithelia are moderately thickened. Where apparent hairshafts are occasionally misshapen or dimunitive. Several follicles are atrophic.

LEFT:

Epidermis- stratum corneum: Mild compact orthokeratotic hyperkeratosis, measuring 20-30μm.

Epidermis- viable layers: Moderate acanthosis, measuring between <u>70-110µm thick</u> (Control = 40-100) in the interfolllicular epidermis forming deep rete ridges extending into the superficial dermis. Superficial dermis: Superficial papillary dermis is expanded and interdigitates normally with reticular dermal collagen.

Pigmentary incontinence is not observed. **No inflammation is observed**.

Follicular adnexa: Hair bulbs are located 1.4-1.9mm from the epidermal surface. Follicular external root sheath epithelia are moderately thickened. Where apparent, hair shafts are occasionally misshapen or dimunitive. Several follicles are atrophic. Occasional follicles are in anagen.

MY ANALYSIS

I completely agreed with the Kentucky Diagnostic Lab pathologist that none of these skin samples contained evidence of chronic inflammation or scar tissue formation. My conclusion is that **between 2014** and 2016 the VMO's erroneously diagnosed scar rule violations on 136 out of 136 pasterns in my samples of The Celebration material, including Mr. Dotson's and Mr. McSwain's horses. A very high false + rate for a diagnostic test.

The critical findings of the histopathology of the TWH pasterns revealed a **thickened epidermis featuring**:

- 1) Acanthosis,
- 2) Hyperkeratosis
- 3) Deep rete peg formation. (Pseudoepitheliomatos or pseudocarcinomatous hyperplasia)
- 4) A variably thickened epidermis.
- 5) No granulomatous inflammation and no scar tissue.

This is typical of a common nonspecific reaction to mild chronic irritation. Many things can cause it. In this case I believe it is a **mild friction rub** possibly from the action devise but maybe from the orientation of the skin of the pastern in horses with a package and a high stepping gait or rubbing together of the skin folds. There is a lot of flexion and extension in this area which I suspect may be contributing to the friction and the reaction independent of any chain or action device. But it is not causing damage to the skin because there would be blistering, erosion and ulceration if it were. The epidermal hyperplasia is arguably a protective physiologic reaction and not pathologic. **There is no objective evidence these ridges on the caudal aspect of the pastern are scar tissue or granulomatous inflammation and therefore they cannot be scar rule violations and/or proof of soring.**

If the observed changes on the back of the pastern are not scars, what are they and what caused them?

ANATOMY AND PHYSIOLOGY OF EPIDERMAL GROWTH

The skin is composed of a multicellular epidermal layer of cells stacked one upon another like a brick wall and a dermal layer composed of connective tissue. The thickness of the epidermis is determined by a dynamic equilibrium between the basal cell layer that divides and pushes the cells upward toward the surface and the loss of surface cells which are constantly rubbed or sloughed off. When the surface cells are stimulated, they signal the basal cells to increase their rate of cell division to make up for the surface loss. Many stimuli prompt this but physical stimulation like rubbing is a principal cause. (It is the explanation why the skin of our elbows and knees is thicker than the skin on our arms and belly.) Excess cell loss at the surface signals the basal layer to divide and make more cells. If the cell loss is increased, the basal layer increases producing cells faster than they can transit to the surface causing the cells to pile up in the middle of the epidermis and the epidermis gets thicker. This configuration is readily recognized microscopically and termed "acanthosis" which is a sign of increased demand for keratinocytes on the surface and the compensatory supply of new cells. Often the basal cell layer forms long extensions into

the dermis called "rete pegs" or "rete ridges" The dead cells at the surface also build up in a configuration called "hyperkeratosis". These are distinct observations that can be objectively measured. Notice the presence of these terms in the pathology reports from the Kentucky Diagnostic Laboratory.

Callus definition (See exhibits from "<u>The Pathologic Basis of Veterinary Disease</u>", Zachary, 2017 page 1066

<u>Callus</u> = a raised irregular patch of thickened skin that develops because of friction. Secondary folliculitis, furunculosis and ulceration can develop. Microscopically the epidermis and follicular infundibulum are thickened by **hyperkeratosis and acanthosis**. Regular epidermal hyperplasia (**rete peg** and papillary dermal interdigitation) also occurs. The follicular openings can be widened by excessive keratin. Dilated follicles can rupture (a condition called **furunculosis**), releasing bacteria, keratin proteins, and sebum, resulting in secondary pyoderma and endogenous foreign body inflammatory response to released follicular contents (**Callus pyoderma**). *Therefore the gross observation of some of the cardinal signs does not necessarily confirm soring by human action. Histopathology can differentiate these two forms of dermatitis.*

Clinical Appearance: Such areas of hyperkeratosis viewed grossly can appear as plaques, <u>ridges</u> and circular areas. These look thickened, irregular, non-pliable often with a distinct edge and cannot be flattened. **Exactly the description found in the 2017 Inspection regulations on page 38 and 39.

Compare the words from the Kentucky Pathology reports to the definition of a callus above

Exhibits:

- a) Pictogram of epidermal hyperplasia from Zachary, page 1023
- a) Definition of callus from Zachary, page 1066
- b) Pictogram and photograph of a callus from Zachary, page 1049
- b) Pictogram and photograph of lichenification from Zachary

***We could reasonably conclude the areas of thickening on the caudal pastern of Mr. Dotson's Dotson's and Mr. McSwain's horses are homologous to, or actually are, calluses. They are free of granulation tissue and granulomas (indeed any significant inflammation) and therefore are not violations of the scar rule whether you choose the "granuloma" or the "granulation tissue" interpretation of the language in the HPA.

WHAT COULD BE CAUSING THE FOLDS, RIDGES AND WRINKLES ON THE CAUDAL PASTERN?

I am uncertain at this time but there is evidence this is caused by the somewhat unique conformation of TWH, perhaps how the foot fits into the package, improper shoeing, contracted heels (a known problem in TWH and in Saddlebred horses with a high stepping gait). Slow motion video of this area in action reveals exaggerated expansion and flexion of the skin which causes compression of the skin much like the folds in the palm of your hand when you close and open it (flex and extend it). These folds or ridges are slightly elevated and may be subject to friction from the action device or rubbing of adjacent folds which is causing the epidermal thickening. It is significant to note that experienced equine practitioners who work on TWH have seen similar folds and ridges on the pastern of the hind legs where there are no action devices and nobody sores the skin. This alone should have told USDA these changes are NOT likely due to human action. Friction on these folds stimulates the epidermis to proliferate and

produces the thickening and alopecia which could be called a callus. Because calluses are prone to becoming inflamed by furunculosis, simply observing the signs of inflammation is not sufficient to assume it is due to human action (soring). Indeed, I saw suppurative luminal folliculitis in about 5% of the biopsies which is the antecedent lesion to furunculosis. So what the USDA calls scar rule violations are folds of skin produced by multiple factors that are variably thickened because of friction and which in some cases could be called calluses.

WHY DO THE USDA INSPECTIONS HAVE SO MANY FALSE POSITIVES?

The answer in one word...."Pseudoscience" (and bad medical practice).

The USDA is evaluating these pasterns by the same methods as when the HPA was enacted into law. It was not sophisticated then and it did not need to be. The lesions were obvious. But those lesions are extremely rare now because soring is uncommon today. **Scar Clinic 2009**, **page 33**, **line 19-22**: Behre: "..it's no secret that the legs have gotten cleaner and cleaner and cleaner, and we're always told, you know, these horses come so far. Couldn't agree more. It's amazing."

But USDA is trying to apply the same visual inspection method sometimes combined with what they feel with their thumbs to diagnose a change in the skin that none of them understands or have thoroughly investigated. Bob Gibbons remarked to me at the meeting with the VAC in Ft Lauderdale in February 2017 that, "*The skin has changed*." But what has changed? Not the way equine skin reacts to injury! (That hasn't changes for at least 10,000 years). Yet he had no answer when I asked why nobody had ever thought to look at the histopathology of the ridges on the posterior pastern.

To interpret anything else except the classic old lesions by visual inspection alone without verification by histopathology is foolish and inept and would fail peer review. It is a highly subjective, insensitive and inadequate way to diagnose new and unfamiliar skin changes in any species. To do so would be medically negligent at the least and borderline malpractice. In addition they are using poor logic and are making some of the common mistakes doctors make when thinking about what they see. This is the **very definition of pseudoscience, and poor medical practice** and by extension also reflects poor program management by the administrators. The evidence for this conclusion can easily be seen in their training manual, testimony and the transcripts from the scar clinics. Why has the USDA never consulted experts for advice about what they are seeing?

What is "Pseudoscience" and how is different from good science?

THE SCIENTIFIC METHOD = It's a procedure method to gain reliable knowledge about the natural world. It sets rules about hypothesis construction, testing, data collection, analysis, conclusions. The scientific method keeps us tethered to the facts collected by strict guidelines. It prevents us from accepting fanciful notions about the causes of our observations. It pays attention to minute details. It requires calibration of instruments; verifies or **validates its standards**. It seeks corroborative data (testimony). It designs experiments to collect data and test ideas in different ways that come to the same conclusion thereby reinforcing confidence in the conclusion. It involves the correct deductive and inductive logic. Good science relies on objective observations and correct use of both **deductive and inductive logic**. (See supporting documents)

"Fundamentals of Gross Anatomic Pathology."

"How to Interpret What You See."

Dr. Paul C. Stromberg

**Two important principles in the practice of medical or pathologic diagnosis that are pertinent to this case.

<u>Objective vs. Subjective data</u>- Define the difference between Objective and Subjective evaluations and the importance of the difference. The size of cat hearts at autopsy is a good example. (Subjective assessment versus weighing the hearts) A fundamental principle of anatomic pathology and good science in general really, is you always put more emphasis or value on objective observations and data than subjective data.

(VMO's perform only subjective evaluations of horse skin.

See the of the 2017 USDA HPA Reporting Requirements. Conducting the Inspection page 32-45. There is no objective assessment.

<u>Corroborative testimony</u>- I can define and show the importance of doing this when interpreting pathologic changes. The lesions associated with HCM in cats with large hearts

An example of Good Deductive logic = Going from the general condition to the specific

"Every doctor is fallible. No doctor is right all the time."
Sutherland and Baker are doctors,
Therefore they are fallible. They are not right all the time"

An example of bad logic = Aristotle's Fallacy of the Consequent

"When it rains, the street is wet, The street is wet, therefore it's raining"

The error here is in ignoring other causes of wet streets

An example pertinent to this case

"Scar tissue causes horse skin to look and feel thick."

"This horse's skin looks and feels thick, therefore it is scar tissue

AND the horse has been sored by human action." = Double fallacy.

This ignores other causes of thick skin in horses AND then ascribes the false conclusion to human causation without any facts to substantiate it. Classic poor reasoning

An example of bad logic concerning palpation

"Palpating a horse's painful leg will elicit a withdrawal response" This horse reacted when I pressed on its leg, therefore it is painful AND it was caused by humans" = **Double fallacy**

A simple withdrawal response does not always mean pain AND does not always mean pain caused by human action. **Illogical and not supported by any facts**. **Double fallacy again**

VMO's pseudoscientific approach is flawed.

1) All observations are **subjective**. There are no objective evaluations in their protocol. The subjective observations are likely to produce frequent and divergent opinions by the inspectors which is exactly what we see.

{ Scar Clinic 2015, page 24, line 5-7; Baker: "...we call scar rules a lot more than you guys do. So obviously there's either been a lack of training or something."} They know there is inconsistency in judging.

{Scar Clinic 2015: page 30, line 2: <u>DQP</u>: "Why are we so far apart?"}

{Scar Clinic 2015: page 42, line 21-25: <u>DQP</u>: "Who instructs you?" <u>Baker</u>: "Dr. Cezar, Dr Turner. ---I'm trying to think of the other first names that have come in –our attorneys, OGC, Office of General Council."}

None of these people are qualified to teach dermatopathology or verify what you see. This tells me nobody at USDA understands what they are looking at nor do they truly understand what the language of the HPA means.

- 2) Their **logic is not supported by facts** and this leads to incorrect and non-valid conclusions.
- 3) **No verification** that thick skin or withdrawal responses to palpation mean anything else besides scar tissue, granulomatous inflammation AND pain, all of which they think MUST mean the horse was sored by a human.

When the soring lesion disappeared from the anterior aspect of the pastern and USDA began calling out horses based on the ridges on the caudal aspect, why didn't anyone ask the question, "Why have the lesions moved around to the back of the pastern and why do they look different"? And there was no imagination as to what else could have caused these strange new changes other than they must be scars. They do not appear to have the basic understanding of the skin, inflammation, wound healing to think it was anything else besides soring. This is a classic cognitive error of being wedded to prior belief and ignoring facts.

HOW DO DOCTORS MAKE COGNITIVE ERRORS?

See my notes from the following lecture and Groopman's book

"Cognitive Errors in Veterinary Diagnostic Pathology."
"Why We Make Mistakes and How to Manage the Risk."
Dr. Paul C. Stromberg

&

"How Doctors Think"

Dr. Jerome Groopman

"Every doctor is fallible. No doctor is right all the time. Every physician, even the most brilliant, makes a misdiagnosis or chooses the wrong therapy" "Doctors learn by remembering when they were wrong "Identify your mistakes, analyze them, keep them accessible at all times"

VMOs make a diagnosis and never learn if they are right or wrong. They are missing the most important opportunity to learn. Two common errors in thinking pertinent to this case.

<u>ANCHORING</u> = The observer does not consider the multiple possibilities but quickly and firmly latches on to his or her "First Impression" and ignores discrepancies that would argue to reject it. We see only the landmarks we want to see and so become "anchored" in our opinion.

<u>CONFIRMATION BIAS</u> = the tendency to search for or interpret new information in a way that confirms or reinforces your diagnosis and avoid or ignore information that contradicts or would lead you away from prior belief. ***(See the cartoon in my notes)

Scientific Method = "Here are the facts. What conclusion can we reach?"

<u>Pseudoscience</u> = "Here is the conclusion. What facts can we find to support it?"

USDA is "anchored" to the idea that anything abnormal on the pastern = soring without ever verifying their observation or presenting facts to support their conclusion.

Scar Clinic 2015, Page 21, line 4-6: <u>DQP</u>: "If there's anything there, it's out. "Also anchored to the idea that every reaction a horse makes to palpation is proof of pain without considering other explanations. They ignore data that would lead them away from prior belief and see only what they want to see ("Confirmation bias").

Scar Clinic 2016: page 53, line 6-10: Baker: "Half the time when I lift up the foot, I know, I know. Because when you lift up that foot and you see that sunburst or fan pattern, those aren't injury scars. Rarely, rarely are they folds of skin. Because for one thing, a fold of skin if it's in that pattern why would that fold of skin be there?" (He's already made up his mind without palpating anything it's a scar. He is "anchored" and therefore biased to assume everything is a scar rule violation. Also he cannot imagine why a fold of skin would be there! This suggests to me his understanding of the histology, biology and pathology of the skin is at least incomplete. He does not know enough to imagine what else could cause the fold of skin.

{Scar Clinic 2016: page 2-3, line 24-: Baker: "...the agency has determined by defining in this act that that skin that's in that pattern, that abnormal tissue, because it's not normal tissue, that's in that pattern which is a sunburst, that normal---that normal pattern of a scar that is indicative of past soring, that is a scar according to the HPA" } (Offers no proof or verification that it actually is scar tissue). USDA is either incompetent or there is another agenda. Who at the agency is qualified to make this determination?

{Scar Clinic 2016: page 5, line 15-16; Baker: "—they use those four words, uniformly thickened epithelial tissue and they call it a scar....But those scars that run up like a ---in that fan shaped pattern, you have to call them scars." Unidentified speaker: "Abnomal tissue" Baker: "You have to call them out." Unidentified Speaker: "He's obliged to call them a scar because that's what the law says. Even though that's really not what it is, that's what we have to call it."}

Southerland's affidavit:

[&]quot;Lt pastern. I palpated the anterior pastern area and the horse made repeated and consistent <u>pain</u> withdrawal responses."

[&]quot;Rt pastern. I palpated the anterior pastern area and the horse made repeated and consistent pain withdrawal responses".

In both cases he assumes the horse's response to his palpation is due to pain without considering the possibility this is a finicky horse. Every horseman knows if you press hard enough some animals will response. Indeed, every vet knows this about any animal. The DQPs know this

(Scar Clinic 2016, Page. 14, lymph node 12-13; <u>DQP</u>: "Horses react differently to different people").

The fact the response was consistent on both pasterns might make you think this is the case rather than to automatically diagnose a pain response that is equal on both sides which is not necessarily likely. He is looking for bilateral pain because he knows it cannot be sored (By law) unless both sides are affected. In his professional opinion the horse has been sored by chemical and/or action device. But he ignores the data that tells us action devices do not cause injury to the skin. Therefore it must be from a chemical. If it is chemical, it must be a recent or acute injury if there is pain because scar tissue would be less sensitive. But if the injury is acute he ignored the lack of any signs of inflammation (corroborative testimony). He is "anchored" to his prior belief that every response is due to pain and therefore proof of soring. He ignores anything that would lead him away from this prior belief. "Here is the conclusion, what facts can I find to support it?" He has no facts. But in his professional judgment....His professional judgment is flawed, it is illogical and his medical practice is poor.

Sutherland could be considered to be **negligent in his medical practice by relying only on palpation and using a method designed for one purpose** (testing for lameness) **that is inadequate for another** (interpretation of a pathologic or physiologic reaction) as his only means of evaluation. These horses are not lame. But palpation is what he knows how to do. Dr. Sutherland is the equivalent of a family practice physician sent to do brain surgery.

CRITIQUE OF THE USDA INSPECTION PROTOCOL

UNIFORMLY OR NONUNIFORMLY THICKENED EPITHELIUM. DOES IT REALLY MATTER?

I am not sure the VMOs fully understand what they are feeling. I suspect they are feeling the unevenness of the hyperplastic epidermis. I am not certain ANYONE in the USDA understands the histology, the microscopic anatomy or the pathology of this skin. I doubt you can confidently detect the difference between scar tissue, epidermis and inflammation by just feeling it with your fingers. No knowledgeable medical professional would profess to be able to do so with confidence.

Contrast Baker and Kirstin's interpretation. Nodules of granulomas versus uniformly thick pastern skin by area in Kristin's comments. Is it granulations or granulomas Baker feels? (neither). The DQPs don't know what is going on and they are skeptical. (*see scar clinic quotes*). You can't feel granulation tissue thru thickened epithelium or any epithelium for that matter and the folds on the caudal pastern are covered by epithelium, thick epithelium. He described granulomas defined by the agency.

{Scar Clinic 2016: page 50, line 14-22; Baker: "...defines granuloma, and it's a rather large group of fairly distinctive focal lesions, and focal is a localized area, and a lesion is just a pathological or abnormal tissue. So it's a group of very distinctive --- so it could be one of many different types of focal lesions that are formed as a result of an inflammatory action caused by a biological, chemical, or physical agents. And a physical agent is a chain."}. Baker is quoting almost verbatim from the language of the scar rule and not trying to clarify to his class or DQPs what the language means. I think because he himself does not understand what he is looking at. Why is he doing this? Could it be because USDA

administrators have trained him in the language of the law and not the medicine or pathology it was meant to define?

Clearly Baker shows us he is feeling for localized granulomatous inflammation when 1) it has not been determined for sure granulomas form as a result of the application of caustic substances that induce acute necrosis and inflammation. 2) They have not to my knowledge demonstrated the "nodules" they say they feel are in fact "granulomas." Granuloma is a sometime late stage lesion. Not all granulomatous inflammation forms a granuloma. He could be missing earlier stage granulomatous (or any type) inflammation because he cannot feel nodules. **How many false negatives is he passing**. "Definitive Diagnosis by thumbs" is not real medicine.

"TO FLATTEN OR NOT TO FLATTEN, THAT IS THE QUESTION!"

VMOs talk about the importance of "flattening out" or not as the definitive criterion to identify scar tissue. How did they reach that conclusion? The facts are that the skin of these pasterns is thickened by epithelial hyperplasia to a variable degree; from within normal range to 2 times normal thickness. That is quite clear in the KY lab reports and verified by my own observations. Whether or not you can "flatten out" the folds or ridges of skin is in part likely a function of several factors one of which may be epidermal thickness. **Epidermal acanthosis cannot be flattened by any amount of pressure**. They may be calling horses out with more or less epidermal thickness due to epidermal hyperplasia not the presence of granulomas. **No granulomas were detected by histopathology in Terry Dotson's or the McSwain's horses**.

Despite this there is great discussion about whether or not you should use one or two thumbs to spread folds or rub your thumb perpendicularly across the ridge of fold feeling for uniformity or hard nodules or granules that they interpret as evidence of granulomas. None of this is valid or in my opinion matters. It is likely that the ability to flatten the skin folds has more to do with the pliability of the underlying dermis, hydration status of the animal, temperature; has the horse recently warmed up or exercised, age of the horse and the innate genetic variability of the dermal collagen. But in any case it is an erroneous conclusion reached without ever verifying their diagnosis by another method or measure. Now they teach that criterion to others without verifying their standard, a serious breach of good scientific practice, and are passing the error on to others. No wonder there is so much variability in their judging and no wonder so many DQPs doubt what they are being told. A reading of the scar clinics highlight the disagreement between the VMOs and the DQPs. They communicate much uncertainty and disagreement. They are not judging by the same standard. All of which underscores the variability in the result.

THE CARDINAL SIGNS OF INFLAMMATION

The VMOs can all recite the cardinal signs of inflammation such as redness and swelling but do not seem to completely understand the process or that there are other causes of redness and swelling besides inflammation

"Redness & swelling are signs of inflammation

I see redness and swelling in the skin, therefore its inflammation

AND it's caused by human action."

Double fallacy again unsupported by any facts

This ignores other causes of red skin, swelling, heat, moisture. In the ridges, wrinkles and folds of skin on the posterior aspect of the pastern (calluses) any sign of inflammation is **more likely to be related to callus pyoderma than caused by soring.** Therefore not all evidence of inflammation on the folds means the horse has been intentionally injured by humans (sored). The histopathologic lesions of callus pyoderma are common and well known in animals and can generally be easily recognized.

scar clinic quotes

{Scar Clinic page 30, line 15-25: <u>Baker</u>: "So part of the definition of a sored horse is inflammation. and it has to be ---you can't reasonably expect that somebody can't have done something to cause inflammation; and that's pain, which we always look for; redness, which I don't know---its abnormally red, inflamed, then they're REALLY IN VIOLATION of the Horse Protection Act}. What does that mean? Without the inflammation it might not be scar tissue or a violation?)

It is unlikely that they will see the cardinal signs unless there is ulceration, epithelial necrosis, immature granulation tissue (Proud flesh). In other words the acute injury induced by recent injury, not chronic mature scar formation that is composed of dense dermal fibrosis that has re-epithelialized.

THE INSENSITIVITY OF SENSITIVITY

Several years ago my senior resident told me she found a lump in her breast. She was only 30 years old but she was worried. She visited her doctor who palpated her breast and she flinched. Her doctor said, "Yes, you have a lump in your breast. He could have said that her flinching was is a sign of pain (although she told me she was startled but it did not hurt her) and that pain means her breast was inflamed and it is likely caused by cancer. At that point he could have said you should have a radical mastectomy. Or he could have ordered a biopsy; or done nothing. 100 years ago he might have done nothing or performed a mastectomy but today that would be gross negligence and medical malpractice. Fifty years ago around the time the HPA was written he would have performed a biopsy. Fortunately today medicine has advanced and we have less invasive techniques that add reliable data to the inspection protocol for breast cancer and she had radiography and ultrasound. Experienced radiologists interpreted the new data and diagnosed fibrocystic breast disease, a benign condition that is neither painful nor causes inflammation. Her doctor ordered these tests partly because its good medical practice and partly because if he had done nothing and she subsequently was found to have breast cancer, he would have been sued for malpractice and likely lost. Likewise, if he had performed a mastectomy and later found on surgical pathology that the lump was fibrocystic breast disease he would have been sued for malpractice and likely lost. Had the radiologists been suspicious about their findings, she would have had a biopsy performed and the tissue examined by a pathologist who would have definitively diagnosed her condition.

This is essentially what the VMO's are doing when they palpate a walking horse and when it flinches or reacts, they always interpret that as evidence of pain and they conclude the pain is caused by inflammation and that furthermore that inflammation is intentionally caused by a human in the act we call "soring." All of these are conclusions without facts to support them. But unlike my student's doctor who has an incentive to do the right thing, the VMO's diagnosis is final. There is no review or due process. There is no threat of malpractice. So they can diagnose with impunity and have no fear of consequences. Do we not owe these horses the same standard of care we demand of our doctors when they palpate the lump in our own breasts? The sensitivity test is a start but it is not enough to definitively diagnose breast cancer in women or soring in Tennessee walking horses. It was adequate 50 years ago to detect the kind of classic soring injuries that occurred but those injuries are largely not seen anymore. If the horse is really painful due to inflammation, if it is the acute lesion of soring there must be corroborating signs of inflammation present (or the objective detection of a foreign substance applied to the skin) and if so how do they separate that from other causes of inflammation?

WHAT CAN WE CONCLUDE FROM OUR ANALYSIS?

Using **inductive logic** (that is going from the specific to the general), we could conclude that the real incidence of soring at The Celebration is very likely much lower than reported. But the real value of

inductive logic is that it generates testable hypotheses. I could quickly design a simple experiment to generate several important conclusions about USDA's inspection protocol and estimate the true incidence of soring at The Celebration.

THE EXPERIMENT

- 1) Biopsy all horses showing at The Celebration next year and examine them by standard objective histopathology and have the cases peered reviewed.
- 2) Divide the horses into 2 groups;
 - a) Those disqualified for scar rule violation or sensitivity or evidence of soring as defined by
 - b) Those found to have no evidence of soring or sensitivity and allowed to show
- 3) Compare the number of horses found with evidence of soring by histopathology in each of the 2 groups, passed and showed and excused.
- **4)** Perform a simple ANOVA if needed

The experiment would yield a conclusion about the true incidence of soring at The Celebration and by inference about the true incidence of soring in the TWH industry.

- 1) A repeated high false + rate would validate the data collection from 2014-2016. It would also generate the question "Why". Inspectors are either incompetent at interpreting changes in equine skin, establish that their inspection protocol is flawed or they are calling out many horses for another reason. (Perhaps a political agenda)
- 2) A high false rate would highlight the inadequacy and insensitivity of the current **USDA** inspection protocol and force USDA to consider a more objective method of testing if they truly care about protecting horses from soring.
- 3) A low false rate would support the conclusion that soring is much less common than the **USDA** asserts and would call into question all of the past reports in the media of the high incidence of soring at The Celebration. Media could report this error in the popular press.

What would it say about the incidence of soring in the TWH industry in general beyond The Celebration? Nothing conclusively at this point but it would certainly suggest the likelihood that soring is less common industry wide than thought and generate the hypothesis that the HPA has in fact markedly reduced the incidence of real soring in TWH industry. Maybe there is more soring occurring in other shows around the USA. This hypothesis could be tested by widening the sampling process to other TWH events and gather data about soring beyond just The Celebration and test the hypothesis that soring is not as common industry wide as thought.

The outlined experiment is:

- 1) Simple in its design,
- 2) Uses objective, easily applied widely accepted traditional methods to assess soring injury,
- 3) Correctly applies logic
- 4) Reaches valid conclusions.
- 5) Would generate important information however the data turn out

Recognizing the practical difficulties in collecting such a large sample, the experiment could be performed on a much smaller sample. A statistician could advise how many fewer horses are needed in each group and still retain the statistical power of the analysis. In addition it would give us a real estimate of how serious is the soring problem among TWH and should logically lead us to improve our methods of detection to something with a lower error rate. It begs the question, "How many really sored horses is the USDA missing?" To my knowledge there has been no outcome assessment performed by the USDA about how effective their inspection program is. This lack of performance monitoring is another example of poor science and program management. And the public is being hurt by this negligence.

MY OPINION OF THE PROBLEM

This is a sensitive and highly emotionally charged issue. We need a little equanimity here and just look at the facts. The scientific method and good practices are the best way forward.

"A little learning is a dangerous thing, drink deep or taste not the Pierian spring.

There shallow draughts intoxicate the brain, and drinking largely sobers us again."

(Essay on Criticism by Alexander Pope).

I believe government when it uses science to inform its policy decisions, owes its citizens the best, most accurate science possible. Anything less is a betrayal of the trust we place in it and destroys confidence in our institutions. The current inspection protocol is poor science, poor medical practice and does not meet the standard of care we demand in human medicine. The VMOs are exhibiting poor judgment and the classical errors in logic and critical thinking. The continued reliance on inaccurate subjective methods will not solve the problem but it's all they know. ("When all you have is a hammer, all problems tend to look like nails"). It's not sensitive enough to reliably detect anything other than the classic lesions and any conclusion about soring derived from it is fallacious and unsupported by facts. In addition it is poor program management not to know the sensitivity and specificity of your methods or have an outcomes assessment or performance monitoring procedure.

USDA has the wrong orientation. They are focused on how to find the evidence that would reinforce their conclusion that all TWH are sored until proven otherwise and support litigation that everything abnormal as a scar rule violation when they should be asking the question, "How do we solve the problem of soring in TWH." They need help from people outside of the agency who have the skill and knowledge to help. Those people are out there. They are available and they want to help. And I believe the TWH industry wants to solve this problem as much as the public does.

REVIEW AND ANALYSIS OF THE SCAR RULE CLINIC TRANSCRIPTS

These documents are transcripts of the classes or seminars conducted to teach DQPs (Laypeople) how to inspect TWH for evidence of soring. The teachers are USDA veterinarians (VMO) who are supposed to have knowledge, training, experience and understanding of medicine sufficient to teach laypeople. But none of them has any advanced training relevant to this. Indeed I cannot find any evidence that any of them has significant training beyond the DVM degree or they are professionally more than general practitioners. They certainly do not understand the scientific method, do not demonstrate any curiosity or imagination about what they are looking at, are using flawed logic incorrectly and are committing common mistakes that doctors make when thinking about their observations. Yet the USDA uses these individuals to train others in how to inspect horses.

A review of these documents reveals the **inadequacy of visual observation and palpation** as the main and only procedure to detect soring in these horses. **It's entirely subjective**. There is no objective testing.

Much of the conversation illustrates the uncertainty around what they are looking at and feeling. Dr. Baker, Dr. Kirstin and Dr. Baum reveal an incomplete understanding of wound healing, the inflammatory response, basic pathologic mechanisms and the response to injury. They purport to be able to feel with their fingers and make a definitive diagnosis and interpretation of something that is occurring at the microscopic level. This is an absurd statement. If doctors could do this there would be no need for histopathology. I do not think they understand what they are feeling and they have clearly ruled out all other explanations for what they feel except it must be scar tissue and or granulomatous inflammation. The examples they use to teach others are not verified by other means to be what they say they are and they are guilty of false logic. In other words they have not verified their standards. How can you teach or diagnose without a verified standard against which you compare your test subject. (Pseudoscience). No wonder there is so much disagreement among inspectors. They are committing not only errors in logic but making common mistakes doctors make when thinking (anchoring and confirmation bias).

They make no allowance for error. They do not seek any feedback about their diagnosis and so do not ever find out if they are wrong or attempt to learn from their error so as to not make the same mistake over and over again as they are clearly doing. There is no performance monitoring except the VMOs are monitoring DQPs but who monitors the VMOs? This is poor program management. Every medical diagnostic test knows the specificity and sensitivity of its test method. What is the frequency of false + and false - results? The transcripts show that the VMO's are trained by administrators who are not competent to interpret skin lesions in horses. Baker to his credit says if they are being trained incorrectly they need to know that. But he is acting more like a policeman than a trained medical professional that he is supposed to be. It suggests to me he is not thinking for himself but following what he has been told and trying to justify his findings. "Here is the conclusion, What facts can we find to support it" (Pseudoscience and poor medical practice). I suspect they are being told by management what their conclusion should be. As an "investigative reporter" I am asking, "who is training them?"

Participants in the scar rule clinics cannot agree on how to inspect, what to look for and how to interpret what they see and the rules seem to change from year to year. USDA as an agency does not understand the language in the HPA or what it means so they do not know what to look for much less teach others the art. Given the divergence among inspectors in how they have judged horses at Celebration, it's clear they are trying to teach umpires how to "call balls and strikes" without having a clear understanding themselves of "where the strike zone" is. The language clearly illustrates the frustration of the DQPs.

SCAR RULE CLINIC TRANSCRIPTS FROM 2016

Scar Clinic 2016: page 2-3, line 24-: <u>Baker</u>: "...the agency has determined by defining in this act that that skin that's in that pattern, that abnormal tissue, because it's not normal tissue, that's in that pattern which is a sunburst, that normal---that normal pattern of a scar that is indicative of past soring, that is a scar according to the HPA" (Offers no proof or verification that it actually is scar tissue). USDA is either incompetent or there is another agenda.

Scar Clinic 2016: page 3, line 11-14: <u>Baker:</u> "There can't be any granuloma tissue underneath that – underneath that epithelial tissue. You just don't find uniformly thickened epithelial tissue." (So all thickened epithelial tissue is a scar. Anchored)

Scar Clinic 2016: page 4, line 22- to page 5, line 4: <u>Baker:</u> "But if it doesn't look like that or its got those ridges, even if you spread them out, we as agency, that' is a --- its sore according to the scar rule. And if we cut that --- if we took that and took a cut, I don't know how many of those would ever not have granuloma tissue, some sort of tissue change indicative of inflammation." **He is anchored to prior belief**

that it's a scar). Why has USDA never "cut that" and examined it microscopically and looked for the granuloma tissue?

Scar Clinic 2016: page 5, line 15-16; Baker: "—they use those four words, uniformly thickened epithelial tissue and they call it a scar....But those scars that run up like a ---in that fan shaped pattern, you have to call them scars." Unidentified speaker: "Abnomal tissue" Baker: "You have to call them out." Unidentified Speaker: "He's obliged to call them a scar because that's what the law says. Even though that's really not what it is, that's what we have to call it."

Scar Clinic 2016: page 30, line 4-5; <u>Baker</u>: "...nowadays I don't think there's as much —well, obviously there's not as much soring as there used to be and it's not as bad as it used to be," They know the old classic lesions are rare but there is no curiosity about it.

Scar Clinic page 30, line 15-25: <u>Baker</u>: "So part of the definition of a sored horse is inflammation. and its has to be ---you can't reasonably expect that somebody can't have done something to cause inflammation; and that's pain, which we always look for; redness, which I don't know---its abnormally red, inflamed, then they're REALLY IN VIOLATION of the horse Protection Act. What does that mean? Without the inflammation it might not be scar tissue?)

Scar Clinic 2016: page 49, line 6-14: <u>Baker</u>: "The interior and anterior lateral surfaces, which is the sides and the front, have to be free of any granulomatous tissue, any bilateral granulomas has to be on both, any bilateral inflammation or any bilateral evidence of something that's indicating that a soring practice has been done in the past, and the law says such as loss of hair."

Scar Clinic 2016: page 50, line 14-22; <u>Baker</u>: "...defines granuloma, and it's a rather large group of fairly distinctive focal lesions, and focal is a localized area, and a lesion is just a pathological or abnormal tissue. So it's a group of very distinctive --- so it could be one of many different types of focal lesions that are formed as a result of an inflammatory action caused by a biological, chemical, or physical agents. And a physical agent is a chain." Baker is trying to teach DQPs here. Its incoherent.

Scar Clinic 2016: page 51, line 17-23: <u>Baker</u>: "So the posterior surface ---so the backside of the pastern can't have abnormal tissue, the localized swelling, the fluid oozing through the skin, or signs of inflammation which we've all talked about. It can't have non-uniformly thickened epithelial tissue." (Anything abnormal is scar tissue; no other possible explanation.)

Scar Clinic 2016: page 53, line 6-10: Baker: "Half the time when I lift up the foot, I know, I know. Because when you lift up that foot and you see that sunburst or fan pattern, those aren't injury scars. Rarely, rarely are they folds of skin. Because for one thing, a fold of skin if it's in that pattern why would that fold of skin be there?" (He's already made up his mind without palpating anything it's a scar. He is anchored. Also he cannot imagine why a fold of skin would be there! so it MUST be a scar) How does he know that rarely they are folds of skin?

SCAR RULE CLINIC TRANSCRIPTS FROM 2015

Scar Clinic 2015, Page 21, line 4-6: <u>DQP</u>: "If there's anything there, it's out." (Anchoring and confirmation bias)

Scar Clinic 2015, page 21, line 18-20: <u>Baker</u>: "If you have excessive hair loss due to soring on a lateral, anterior and medial, then it's a violation." How does he know the hair loss is due to soring?

Scar Clinic 2015, page 22, line 9-13: <u>Baker</u>: "The proliferating granuloma tissue which are lesions – it's lesions formed as a result of an inflammatory process. And in the red it's – the government has defined granuloma as any one of a rather large group of fairly distinctive focal lesions" Statement makes no sense. Does Baker understand inflammation? Why is the government defining "granuloma?" Shouldn't medical specialists (pathologists or dermatologists) be defining that?

Scar Clinic 2015, page 22-24: <u>Baker</u> is incoherent in this explanation. "If it's edema, it's a swelling, it's just a localized swelling. That could be a loss of function" Baker does not understand the "loss of function" part of inflammation" or that inflammation is not the only cause of swelling.

Scar Clinic 2015, page 24, line 5-7; <u>Baker:</u> "...we call scar rules a lot more than you guys do. So obviously there's either been a lack of training or something." They know there is inconsistency in judging.

Scar Clinic 2015, page 24, line 12-15: Baker: "Those are—it's a granuloma tissue, there's---to use a term fold, there's also that tissue underneath and you run our thumb across it and there's a granuloma tissue." (anchoring and confirmation bias). He does not explain what he feels that he then concludes must be a granuloma. And what about granulomatous inflammation that is not formed into a granuloma. Can he feel that? He could be missing a soring injury that is not yet at the granuloma stage yet.

Scar Clinic 2015: page 27, line 6-16: Policy change on flattening out the folds. No agreement between Baler and DOPs.

Scar Clinic 2015: page 27, line 10-25; <u>Baker</u>: granuloma tissue. "It's a fairly distinctive—they are fairly distinctive in the manner that they are visible. They're fairly distinctive. They have that pattern. They're localized lesions caused by an inflammatory process. That's how we are taught." You can press anything flat or smooth." No you cannot flatten a callus. (Baker sounds uncertain, tenuous understanding of what he is looking at).

Scar Clinic 2015: page 28, line 6-8: <u>Baker</u>: 'The physical, visual, a physical examination, run our thumb perpendicular, we look at them, and that's how we determine if it's a scar rule" **This makes no sense.** Poor teaching, poor medicine and poor science.

Scar Clinic 2015: page 29, line8-9: <u>Baker</u>: "*I don't call anything out if I can't feel it.*" Yet in the 2017 training manual on page 32, "Conducting the Inspection it says:

First visually examine the posterior pastern and assess whether there is clear visual evidence of a scar rule noncompliance

Ask yourself: Is there proliferating granuloma tissue, irritation, moisture, edema, or other evidence of inflammation?

Yes: Horse is noncompliant with the scar rule and is sore

No: Must determine if the skin is uniformly thickened

So you are calling horses out before you even touch it based on visual only. Poor science, poor medicine and poor logic. Borderline medical malpractice.

Scar Clinic 2015: page 30, line 2: <u>DQP</u>: "Why are we so far apart?" The DQP does not understand why there is so much differ3ence between what the VMOs are doing and the DQPs.

Scar Clinic 2015: page 31, line 22-23: Read from a letter from the acting administrator. "..the visual appearance of the tissue alone does not indicate a scar rule violation." Now in 2017 its different? Inconsistent. Based on what. There are no facts anywhere in this.

Scar Clinic 2015: page 32, line 9: <u>DQP</u> "We've just---we've been told by you guys numerous times this year that basically if the horse wasn't perfect he was out. You know, it doesn't have to be the hard fold of skin like we've looked at in the past. At one time we were told that you could visually look at and see anything, he was out" **Anchored to the idea anything abnormal = a scar rule violation.**

Scar Clinic 2015: page 36, line 20: <u>Baker</u>: "I palpate it to see if there is underlying granuloma tissue." He is anchored to the idea anything abnormal or "nonuniform" he thinks he feels is automatically "granuloma tissue" and does not consider any other possibility for what he feels.

Scar Clinic 2015: page 39, line 25- page 40, line 3: <u>DQP</u>: "What about a situation where a VMO calls a horse out because he can feel two or three scar (cells) there. Now me and you both know nobody can feel that." The DQP understands you cannot feel 3 cells. BTW a custodian told me this very quote in 2015 while we biopsied his horse.

Scar Clinic 2015, page 40-41, line 19-24 and line 1-21: Baker: "If we're interpreting and been trained wrong, we need to know that. If I've been training you guys wrong, which is pretty much the same thing, right? You guys that have been here, it's the same – actually it's almost the exact same presentation except photos. So if we're not doing it right, we need to know. If I can't get the information to you guys, then I need to know. And that's why we have our trainers here to – not critique me but to make sure that the information is going from me to you guys. DQP: "In last year's training—do you remember last years training? Whenever we got to the scar rule part of it you told us in this room that this is the new way we're going to look at the scar rule. If I can see it, it's out. It was the new way. "You didn't say, "If I can feel it, its out.?"

Scar Clinic 2015: page 42, line 7: Baker: "This is not a very good training."

Scar Clinic 2015: page 42, line 21-25: <u>DQP</u>: "Who instructs you?" <u>Baker</u>: "Dr. Cezar, Dr Turner. --- I'm trying to think of the other first names that have come in -out attorneys, OGC, Office of General Council." None of these people are qualified to teach you dermatopathology or verify what you see. What are attorneys doing there and how do they help interpret the language in the scar rule? This tells me nobody at USDA understands what they are looking at. Poor program management.

SCAR RULE CLINIC TRANSCRIPTS FROM 2009

Scar Clinic 2009, page 6, line 20-23: <u>Kirstin</u>: "...some of the horses and especially with long hair, you just won't see the scar but you certainly can feel them." So you can make a definitive diagnosis of scar tissue, granulomatous inflammation or epithelial thickening just by feeling it.

Scar Clinic 2009, page 7 line 3-23: Behre: He makes an erroneous comparison of uniformly thickened tissue (he does not use the word "epithelium") between horses and the wrinkled skin of Shar Pei dogs. He goes further to say that fibroblasts & capillary buds and things that are responding to either physical compression, thermal or chemical injury. This is also fuzzy thinking. Granulation tissue does not form in response to compression but to necrosis. He goes on to say, "it still looks like there's something embedded in that skin tissue and that would be proliferating granuloma tissue which you see in part B of the scar rule." There are no facts to support this assumption. He is anchored to prior belief this must be inflammation and therefore a scar rule violation.

Scar Clinic 2009, page 33, line 19-22: Behre: "..it's no secret that the legs have gotten cleaner and cleaner and cleaner, and we're always told, you know, these horses come so far. Couldn't agree more. Its amazing."

Scar Clinic 2009, page 21, line 16-18: <u>Kirstin:</u> "And the question you must be asking is did a person engage in a practice that caused these scars to form?" Kirstin is assuming he is looking at scar tissue and that scar tissue must be caused by a human. No facts.

Scar Clinic 2009, page 23, line 9-23: Behre: "There's no way a person examining the horse can know how the tissue occurred, whether it happened due to a horse (??), due to the horse having a caustic chemical applied to it, having chain, (?) chain, how the horse is shod, the inspector doesn't have the benefit of all that background to be able to explain away (?) tissue changes. So we can't tell the difference between a sweat crack and of course (?) you're talking about that has some type of chemical applied, but we don't have the benefit of that history. We can't tell the difference. We can only tell whether or not the horses' tissue is in compliance under the regulation the way it's written."

Scar Clinic 2009, page 25-26, line 25 to 8: <u>Kirstin</u>: "...but once you have applied than chain and then they have been in the ring and they have had the grit and grease and the friction of the chain, this tissue can swell. And here you are seeing a post-show limb, not an uncommon appearance here, and indicative with this swelling of the inflammatory response as you would expect swelling to be one of the signs, and redness, of this---of inflammation."

Scar Clinic 2009, page 26, line 14-15: <u>Kirstin</u>: "Again, was evidence of these ridges being turgid, swollen, <u>possibly red</u>."

Scar Clinic 2009, page 32, line 2-5: Behre: "..And put your thumb back underneath it, a lot of times you will feel a ridge of proliferating granuloma tissue and I've had a couple of VMO's point those out to me that I missed in the last two (?) clinics." How can you know by just feeling with your thumb what kind of tissue you are feeling?

REVIEW AND ANALYSIS OF THE TESTIMONY OF THE USDA

Case 1:16-cv-01234-RWS Document 12-3 Filed 05/09/16 Page 2 of 4 Jeffery Baker

August 24, 2013. Preshow inspection at The Celebration of the McSwain's horse, "Honors".

I observed the horse walking and noticed **no abnormalities**. I examined and palpated the poster area of the left pastern and got **withdrawal reactions that were not consistent**. I did identify non-uniformly thickened areas of epithelial tissue along the posterior area of the left pastern as annotated on the 7077. **I palpated the lesions and determined that they were scars.** I moved the foot forward, examined and palpated the anterior, lateral, and medial aspects of the left pastern. I did not identify any reactions or abnormalities on the anterior, lateral, and medial aspects of the left pastern.

I then moved to the right side of the horse. I examined and palpated the posterior area of the right pastern. The horse exhibited consistent withdrawal responses as I palpated the medial heel bulb and the area just above the medial heel bulb. I also identified non-uniformly thickened areas of epithelial tissue along the posterior area of the right pastern as annotated on the 7077. I palpated the lesions and determined that they were scars. I moved the foot forward, examined and palpated the anterior, lateral, and medial aspects of the right pastern.

I placed the horse next to the inspection area to be inspected again after approximately ten minutes. During the second inspection I found the same scars and consistent withdrawal symptoms as the first inspection.

I sent the horse to the radiograph station. The radiographs were normal.

In my opinion this horse was sore as defined by the Horse Protection Act and should be called as unilateral sore and also for scar rule.

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Jeffery Baker

July 26, 2014.: Post Show inspection at the Red Carpet Shoe of the South of the McSwain Horse "Honors"

- 2. I observed the horse walking and noticed **no abnormalities**. I examined the posterior area of the left pastern and identified non-uniformly thickened areas of epithelial tissue as indicated on the form 7077. The area was scarred with thickened ridges of skin that originated near the sulcus and radiated upward and outward. These scars were hard to the touch. I palpated the posterior pastern and did not elicit any movement from the horse. I moved the foot forward, examined and palpated the anterior, lateral, and medial aspects of the left pastern. I did not identify any reactions or abnormalities.
- 3. I then moved to the right side of the horse. I examined the posterior area of the right pastern and identified non-uniformly thickened areas of epithelial tissue as indicated on the form 7077. The area was scarred with hard, thickened ridges that originated near the sulcus and radiated upward and outward. I palpated the posterior pastern and did not elicit any movement from the horse. I moved the foot forward, examined and palpated the anterior, lateral, and medial aspects of the right pastern. I did not identify any reactions or abnormalities.
- 4. In my opinion this horse was sore as defined by the Horse Protection Act and should be excused because of the scar rule.

Case 1:16-cv-01234-RWS Document 12-5 Filed 05/09/16 Page 7 of 31 Jeffery Baker

August 23, 2014. Pre-show inspection at the Celebration event of the McSwain horse "Honors"

- 2. I observed the horse walking and noticed **no abnormalities**. I examined the posterior area of the left pastern and <u>identified non-uniformly thickened areas of epithelial tissue</u> as indicated on form 7077. The area was <u>scarred</u> with thickened ridges of skin that originated near the sulcus and radiated upward and outward. These <u>scars</u> were hard to the touch. I palpated the posterior pastern and elicited strong, consistent, and repeatable <u>pain</u> responses as evidenced by the horse withdrawing its foot-when I palpated the medial and lateral heel bulbs and just above each heel bulb. I moved the foot forward, examined and palpated the anterior, lateral and medial aspects of the left pastern. I elicited strong, consistent, and repeatable **pain** responses- as evidenced by the horse withdrawing its foot and flexing its shoulder muscles- when I palpated the left lateral pastern at the coronary band and mid pastern
- 3. I then moved to the right side of the horse. I examined the posterior area of the right pastern and <u>identified non-uniformly thickened areas of epithelial tissue</u> as indicated on the form 7077. The area was <u>scarred</u> with hard, thickened ridges that originated near the sulcus and radiated upward and outward. I palpated the posterior pastern and elicited strong, consistent, and repeatable pain responses- as evidenced by the horse with drawing its foot when I palpated the lateral heel bulb. I moved the foot forward,

examined and palpated the anterior, lateral and medial aspects of the right pastern. **I did not identify any reactions or abnormalities.**

4. In my opinion this horse was sore as defined by the Horse Protection Act and should be excused because it was bilaterally sore and bilaterally scarred.

ANALYSIS: Baker described non-uniformly thickened epithelial tissue in every case. He uses the term almost as if it were from a macro. Pathologic lesions have a variable range of expression. Every granuloma and scar it not alike yet his description is. He considers no other possible interpretation for the thickened tissue. But scar tissue is not epithelial tissue. He has made a mistake in interpretation proved by biopsy and histopathology. Also the withdrawal responses are not consistent. He assumes every withdrawal response means pain and also that it must mean pain inflicted by a human (soring). He has no objective evidence to support this conclusion. Animals may exhibit withdrawal responses when people pick up their feet for other reasons beside pain. Many animals are finicky about their feet. Palpation to elicit a response is a technique used in the examination for lameness in horses. It is intended to look for areas of deep pain around bone and joints that is the location and source of the lameness. But these horses are not lame. Therefore this technique, while a start, it not the optimal and certainly not a definitive method to determine the presence of pain. He does not look for corroborating evidence of such as ulceration, necrosis, immature granulation tissue etc. which would explain the withdrawal response as caused by pain. Where does he think the "pain causing lesions are?" In a soring lesion the lesions will be on the surface or a necrotic or ulcerated skin, not deep in the tissue. In addition, how can he jump to the conclusion that a withdrawal response means pain induced by humans rather than another spontaneous pathologic process such as callus pyoderma?

He demonstrated his bias and that he is anchored to the prior belief that everything he sees means a soring injury by his statement that areas of skin he described are "scars" or scarred. A fundamental tenet of descriptive anatomic pathology is ," *Describe first, then interpret.*" He is essentially saying that there are scars on the skin, therefore the skin is scarred. A classic error in logic. Look at his statement in the scar clinic **Scar Clinic 2015**, **Page 21**, **line 4-6**: <u>DQP</u>: "If there's anything there, it's out." (**Anchoring and confirmation bias**).

THE WAY FORWARD

The forgoing report and analysis has focused on defining and documenting the errors the USDA has made in their inspection protocol which is fundamentally unchanged from the days when TWH were openly abused and sored. But I would like to focus on what we can do going forward. I stated above the USDA's approach is wrong. Instead of trying to refine their inspection technic and protocol to confirm the presence of soring, we should be asking the question,

"How do we solve the problem of soring in the TWH industry?"

The accompanying document (**The New Tissue Rule Proposal**) was written several years ago at the request of council for the Veterinary Advisory Committee to the TWH industry to propose a new approach to the scar rule. It outlines a new approach to the tissue component of the soring problem. This would be implemented in coordination with drug testing of blood samples or skin swabs, radiographs and other inspection and monitoring modalities to more objectively detect and discourage the practice of soring. Many of these ideas are in a preliminary stage of development and need a broader discussion by experts, government officials and industry representatives as to what is feasible, practical, economical and would bring objective "Bang for the buck" in discouraging and detecting soring of TWH. Other broader

programs could be discussed such as continuing education for USDA inspectors and PR information campaign to reach the public informing including trainers and owners about soring and/or encourage them to abandon the practice. I support the harshest of penalties for offenders but we must base convictions on accurate objective proof of guilt. Many of the people whose horses I evaluated at The Celebration events know they are not soring their horses. To be accused of this based on seemingly capricious judgments and flimsy subjective evidence without due process erodes their faith in our institutions and reflects badly on our science and the profession of veterinary medicine. We need a fresh approach to solve this problem with new ideas and cooperation of horse owners, the TWH industry, the government and educate the public.