THE NEW TISSUE RULE PROPOSAL

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Mr. G. Thomas Blankenship has asked me to outline a new approach to evaluating the tissue component of an integrated surveillance protocol for the Tennessee Walking Horse industry. This new approach should promote good management, protect the health of horses and discourage illegal attempts to enhance performance in the show ring by the use of performance enhancing drugs (PED), "soring", heavy shoeing etc that are detrimental to the health and welfare of horses and violate the Horse Protection Act (HPA). The protocol should rely on accurate objective scientific procedures grounded in evidence based medicine recognized to have broad acceptance in the field of veterinary medicine. The procedures should encompass definitions that are definable, teachable and enforceable. The ideas set forth in this document should be considered to be tentative proposals to be reviewed and discussed with the other members of the Veterinary Advisory Committee (VAC) and judged as to their feasibility, desirability and potential effectiveness to accomplish the goals. Success will depend heavily on USDA's acceptance of the new procedures and may require congressional assistance and/or the force of law to implement.

THE "SCAR RULE"

Before beginning a definition of a new "Tissue Rule" we should be clear what the present status is with regard to "tissue" in the HPA as the language from a medical or pathological point of view is in part inaccurate, vague and less than desirable. Below is the language from the HPA

Sec 11.3 Scar Rule

The scar rule applies to all horses born on or after October 1, 1975. Horses subject to this rule that do not meet the following scar rule criteria shall be considered to be "sore" and are subject to all prohibitions of section 5 of the Act. The scar rule criteria are as follows:

- (a) The <u>anterior and anterior-lateral</u> surfaces of the fore pasterns (extensor surface) must be free of bilateral granulomas, other bilateral pathological evidence of inflammation, and, other bilateral evidence of abuse indicative of soring including, but not limited to, excessive loss of hair.
- (b) The <u>posterior surfaces of the pasterns</u> (flexor surface), including the sulcus or "pocket" 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.

The term **Granuloma** is defined as any one of a rather large group of fairly distinctive focal lesions that are formed as a result of inflammatory reactions caused by biological, chemical, or physical agents.

A citation from the Federal Register Vol 43, No. 83: dated 04/28/1978 provides some additional clarification:

"The proposed "scar rule" allows for normal changes in the skin that are due to friction. These changes would allow thickening of the epithelial layer of the skin in the pastern area (much like a callous on a workman's hands) and the moderate loss of hair in the pastern area caused by the friction generated by an action device. The "scar rule" would not allow bilateral granulomas, other bilateral pathological evidence of inflammation, or excessive hair loss on the anterior and anterior-lateral surface of the fore pasterns, and would prohibit all proliferating granulation tissue or other evidence of tissue inflammation."

These definitions are acceptable and germane to the issues surrounding the soring of horses. It is the detection methods used to judge the presence of such lesions that are inaccurate, subjective, open to bias and unfairly applied without due process. Any person seeking an open and honest evaluation of soring would recognize we have to change what we are doing.

THE "STATE OF THE UNION"

The term "Proliferating Granuloma Tissue" is an incorrect and poor choice of words. One wonders if this was an unrecognized typographical error or misunderstanding of terminology by a lay person crafting the wording in the document. **Granulomas** are a discrete form of chronic inflammation that do not "proliferate" in the medical sense that cells are dividing and increasing in number resulting in growth or enlargement in size. Although granulomas may increase in size by accretion of additional inflammatory cells, they do not significantly enlarge as a result of cell division or "cellular proliferation" in the same way a neoplasm (cancer) does. Granulation tissue (easily confused by lay people with "granuloma") is the fibrous scar tissue that is evidence of prior tissue damage (necrosis or death of cells and tissue) and repair. This process is driven by the proliferation of *fibroblasts* that secrete and form the fibrous scar tissue accompanied by capillary proliferation that feeds the growing reparative tissue; a condition also referred to as "healing by 2^{nd} intent". This process tends to either fill in the area of damage or surround and contain an area of chronic inflammation to "wall off" isolate or protect the host from further damage. When formed in uncontrolled excess, (more common in horses than in other domestic species) it is known as "Proud Flesh" so named for its tendency to form an elevated or protruding mass raised above the level of the adjacent tissue or surface of the skin. Early in its formation, there are abundant capillaries in granulation tissue so it is soft, red or pink and edematous (moist). With time it matures and has more dense fibrous tissue and fewer capillaries so it appears white, dry and has a smooth firm feel to the touch. As it matures it contracts and exerts tension on the adjacent tissue resulting in depressions and irregular, often stellate, scars. Although the wording in the scar rule is improper medical terminology, any experienced veterinary pathologist would understand it to mean granulation that contains chronic inflammation. Granulomatous inflammation is a response to antigens that are complex and difficult to clear away or remove by the normal inflammatory and immune responses allowing the tissue to return to a normal state. It can be thought of as a sort of "Inflammatory Over-Drive" whereby the host's normal resistance shifts into high gear in order to overcome these persistent antigens to normal clearance mechanisms. Granulomatous inflammation may follow acute

inflammation if the offending antigens are not cleared by the initial inflammatory response. As granulomatous inflammation matures it may become more limited and localized and be termed a granuloma. **Granulomas** are often surrounded by scar tissue. The pattern has distinctive microscopic features recognizable to any trained pathologist examining biopsy samples. The reaction was commonly seen in sored horses because the soring agents used were caustic substances such as mustard oil, diesel fuel and kerosene that when applied to the pasterns, heel bulbs or coronary bands caused blistering, chemical burns or other forms of cell death and loss (necrosis). These chemicals were difficult to clear, persisted for a long time on the skin and so induced granulomatous inflammation. Because topically applied soring agents destroyed the epidermis, the epithelium did not cover the damage and healing occurred by 2nd intent, often visible as "proud flesh" and eventually as scar tissue formation. Severe lesions typical of the classic soring injuries that were easily recognized before the 1970's may persist for long periods of time as areas of white scar tissue with loss of adnexae (sweat glands, sebaceous glands and hair follicles). Because hair follicles were destroyed, the scared areas of skin were devoid of hair and if the injury was severe enough, the scar could be permanent. Less severe injuries that may have induced less proud flesh could eventually heal and the affected skin returned to normal with regrowth of hair. This type of chemical injury is analogous to 1st, 2nd and 3rd degree thermal burns with the clinical outcome depending upon the depth and severity of the thermal damage. First degree burns (sunburn) heal completely with no scar formation while 3rd degree burns that destroy the regenerative stem cells in the hair follicles may leave a permanent scar.

The USDA, over the years since the HPA was implemented, has attempted to modify the definition of "Scar" to include such terms as "abnormal dermis", loss of pigment, "fibrous tissue", "button lesions", "sweat cracks", ulceration, "wart-like growths", abnormal thickening where the skin is corrugated and ridged, "clusters of exuberant growth" and "deep furrows and nodules". However, all of these definitions while "colorful and descriptive" are imprecise, vague, not grounded in scientific or meaningful medical terminology recognized by pathologists, These terms are not defined either grossly (clinically) or histopathologically. If in conversation with a colleague I mentioned I found "button lesions" or "sweat cracks" they would have no clue what I was describing. Therefore, the use of these criteria to identify evidence of soring is neither definable or teachable. Most importantly they are not found in the language of the HPA definition of a scar that constitutes the definable standard against which inspections are compared.

The evaluation for soaring that produces granulomatous inflammation and scar tissue formation should be focused on the detection of processes defined in the language of the HPA, widely understood in the veterinary medical community and grounded in real evidence-based medicine. In this regard, the classic lesions induced in the industry prior to the HPA are easily recognized by any competent licensed equine veterinarian and all board certified veterinary pathologists or dermatologists. Currently these classic lesions seem to be rare and I believe that as far as tissue evaluation for scar formation goes, they are not seen very often today by practicing veterinarians. Indeed on my first visit to Shelbyville, I asked local area practitioners if they could show me some "sored horses" so I could see a positive standard for reference to compare horses against. They answered they could not because they knew of none. Since then other equine practitioners I have spoken with who work with TWH have confirmed the scarcity of such cases. We should perhaps be so bold to conclude that the HPA has had the intended effect of markedly reducing

soring in its classic manifestation. It's possible that innovative, unethical and corrupt individuals have conceived new ways to illegally induce damage and pain in horses to accentuate the foreleg action of TWH that does not produce the overt classic soring lesions of chronic granulomatous inflammation and scar tissue formation which is why we seek to establish better more objective mechanisms to police the industry and protect horses.

In its apparent zeal to police violations of the HPA and discourage trainers from perpetuating this practice, USDA has relied on using modified definitions of the scar rule language but this relies on unreliable, subjective and sometimes ludicrous assertions that have resulted in a very large number of false positives and have unfairly and erroneously disqualified many horses for scar rule violations when in fact there was no scar or evidence of chronic inflammation that could be ascribed to human causation. Digital palpation with flattening of skin folds, callous formation, mild alopecia due to friction are clearly not violations of the language in the HPA. What is needed are better more accurate objective methods that can be consistently applied that will protect horses from soring, be fair to horse owners and provide some due process for disqualified horses.

During a legal action in federal court in Atlanta which I attended as an expert witness on May 10^{th} , 2016 (Keith McSwain and Dan McSwain v. Tom Vilsack United States Secretary of Agriculture and the United States Department of Agriculture) the presiding United States District Judge (Richard W. Story) was sympathetic to the complaint that horses disqualified from competition had no opportunity for appeal. In his opinion he found for the plaintiffs that the enforcement of the HPA violated the Due Process clause of the Fifth Amendment of the US Constitution and granted a motion for the plaintiffs for preliminary injunctive relief. He urged both the plaintiffs and the government to find a way to address this without weakening the HPA. So there may be an opportunity to find a way through this dilemma and institute a better system.

THE 2014 AND 2015 CELEBRATION STUDIES

On April 4th, 2015 I received histopathology slides of equine skin biopsies taken from TWH that attended the 2014 Celebration event in Shelbyville, TN along with the pathology reports performed at the Kentucky Diagnostic Laboratory. The material consisted of 58 total samples taken from 29 horses. The samples were of both Rt and Lt flexor surfaces of the fore pasterns of horses disqualified from competition for scar rule violations as defined in the HPA. Review of these samples found mild orthokeratotic hyperkeratosis and mild to moderate acanthosis consistent with the so-called "dermatitic reaction". This is a nonspecific proliferative epidermal response to mild chronic irritation, a common pattern seen in the skin of most animals. It is seen in a wide variety of chronic skin disorders of different causes. Many horses also exhibited a very mild perivascular infiltration of lymphocytes, scattered macrophages and occasional neutrophils. This pattern is seen in most locations of horse skin and is indicative of a normal functioning immune surveillance responding to antigenic challenge. Most importantly there was no evidence of necrosis, ulceration, granulomatous inflammation, granuloma formation, granulation tissue (scar tissue) either immature or mature, or so-called "proud flesh" that would indicate damage to the skin or healing by second intent. Occasionally there was evidence of mild folliculitis, a common and often subclinical problem caused by bacteria,

dermatophytes (ringworm) or follicle mites (<u>Demode</u>x sp.). Some samples contained evidence of telogenized hair follicles at the end of their growth cycle and occasionally an atrophied follicle. My own study of the samples agreed completely with the primary pathologist at the Kentucky Laboratory that the samples reflect mild chronic irritation. Neither of us found any of the lesions listed in the HPA as so called "scar" nor did we find evidence of acute inflammation suggesting chemical burns as might be seen with the application of a caustic substance.

On July 22, 2015 I traveled to Shelbyville to clinically examine some of these horses and consult with local veterinarians. I looked at about 8 of the horses of the 29 biopsied from the 2014 Celebration. The anterior and lateral aspects of the pasterns were completely normal. There were linear skin folds on the flexor surfaces of many pasterns with variable degrees of mild alopecia (hair thinning or loss) associated with these folds. The skin generally did not feel thickened although this was a subject evaluation. There was clearly no evidence of scar tissue or granulomatous inflammation that would reflect a scar rule violation. I asked if they could show me a scared horse for reference and was told there aren't any.

Based on the histopathology and my clinical examination of these horses the thickening and mild hair loss are interpreted to be the result of mild chronic friction rubs or irritation, similar to a **callus**; a condition permitted in the scar rule language of the HPA. To have disqualified these horses for scar rule violations is clearly a misdiagnosis and false positives.

To improve my experience I commented to Mr. Inman that I would welcome the opportunity to prospectively examine and biopsy additional horses. Accordingly I was invited to attend the 2015 Celebration in Shelbyville from Sept 4-6th. Together with Dr. C.R. Johnson DVM, DACVS of Versailles, KY and other local veterinarians and members of the Veterinary Advisory Committee (VAC) we set up a separate examination station and notified owners and trainers that we would examine any horses disqualified from competition and give a separate although unofficial opinion. We examined 25 horses immediately after they were disqualified and recommended skin biopsies of both pasterns. We found no gross or clinical evidence of soring or scar tissue formation on any of the 25 horses. Eighteen horses returned the following morning and 36 samples were collected from both fore pasterns. Each was photographed. Biopsies were acquired and the samples were sent to the Kentucky Diagnostic Laboratory with the same protocol as the 2014 samples. I peered reviewed the original pathology reports and examined the histopathology slides. Neither the original pathologist nor I found any evidence of chronic granulomatous inflammation, "proliferating granulomas", granulation (scar) tissue or healing by second intent in any of the 36 samples.

The primary pathologist measured the thickness of the epidermis in each horse and compared it to pastern skin from 5 control horses. The control skin ranged from 40-100µm thick. Of the 36 skin samples from the 18 disqualified horses, about ¼ had thickening within the control range; ½ were about 50% thicker and about ¼ were 100% thicker. This thickening was generally not equal in severity between the Rt and Lt pasterns. The normal basket weave configuration of the *stratum corneum* layer was compacted (orthokeratotic hyperkeratosis). In these samples given the history I interpreted this to be due to friction caused by the package or action device on the hooves.

The clinical observation of mild hair loss was corroborated by the microscopic observations of telogenized and atrophied hair follicles. I favor an explanation of hair loss by chronic friction or possibly traction alopecia. Given the 50-100% increase in epidermal thickness in ¾ of the horses, I think this could have caused a feeling of thickening detectable by manual palpation. This is sometimes accompanied by a "sandpaper-like" feel to the surface which is caused by the stubble of re-growing hair. In most cases this led inspectors to erroneously diagnose scar tissue and therefore proof of soring by humans. But the histopathology of the biopsies clearly established relatively normal skin without evidence of inflammation or scar tissue. And the alternate interpretation of chronic friction driven epidermal thickening and hair loss is the scientifically correct conclusion and pathogenesis for the observations. **Histopathology has clearly demonstrated to be the most objective and reliable method to evaluate the pastern skin of TWH for evidence of soring.** It is widely accepted by the medical community, has been and remains the mainstay of medical diagnosis for over 160 years and has the virtue of being accurate, sensitive and relatively inexpensive. It is far superior to simple visual inspection and manual palpation alone which is inaccurate, highly subjective and liable to bias.

Over the course of two years a total of 96 skin samples from 47 TWH disqualified from the Celebration event for scar rule violations have been shown by histopathology to be misdiagnosed by inspectors. Not a single horse was shown to actually have scar tissue or chronic inflammation as defined by the HPA. This is clearly an unacceptably high rate of false positives. Disqualifications based on simple visual inspection and manual palpation have been shown to be sloppy science and poor medical practice. Such a high rate of false positives in a medical diagnostic procedure on humans would not be tolerated or approved by the FDA, Medicare or any private health insurance company. One could ask why is there such a high false positive rate or why is the USDA using inferior methods? Government owes its citizens the best most accurate, objective science to inform its policy decisions. The current methods employed by the USDA to police the TWH industry are woefully inadequate, unjustifiable and have the effect of eroding the confidence and trust between the government and its citizens.

"TSA PRE-CHECK-LIKE PROGRAM"

We clearly need to do something different, better and more objective to ensure accuracy in our medical diagnosis. Above all it must continue to protect the health and welfare of horses but also be fair to the majority of horse owners who are not soring their horses. It must also provide some redress, appeal or due process for subjective diagnoses that are inaccurate and result in disqualification. It should eliminate bias and mitigate the effects of subjectively collected data but fit within the culture of the TWH industry. It should have the capability to be implemented in a timely manner and expedite the inspection process, yet discourage the practice of soring. Such a program should provide behavioral incentives for compliance, consequences or penalties for violations, and feedback for mistakes and errors so that everyone involved in the process can learn and improve their skills. It must also be definable, teachable and enforceable.

An appropriate model might be found in the TSA PreCheck Program for US airline passengers that pre-approves individuals for an expedited security screening at airports. Certain baseline personal information is provided on line for a background check. The applicant then presents

him or herself in person to a designated representative, usually a private contractor or approved facility where the information is verified and the traveler is finger printed. If cleared, the traveler is issued a Traveler's ID number that he/she inputs into airline webpage profiles when purchasing tickets. There is a small fee for this registration that is required to maintain the pre-approved status for 5 years. When boarding passes are issued they bear the "TSA PreCheck" logo and passengers holding such boarding passes are cleared through a separate line at the airport with an expedited screening procedure although they still pass through a metal detector.

A similar "Precheck Card Program" could be established for TWH competing in shows across the USA. Horses wishing such a PreCheck Program Card would present their horses to a qualified equine practitioner who would perform a soundness examination evaluating the parameters recommended by the VAC. But this would include a thorough inspection of the pasterns for evidence of scar rule violations or other evidence of soring. Anything the veterinarian is uncertain of or is suspicious of would be biopsied and sent to a diagnostic laboratory or board certified veterinary pathologist for examination and diagnosis. The results would become part of the permanent record of that horse. Perhaps such horses could be tagged with a microchip and their data record be accessed remotely.

This PreCheck examination would be good for a finite period time to be determined. Given that the show season is about 6 months long I would preliminarily suggest 6 months requiring each horse to be checked by a veterinarian at least once a year. This would need to be discussed and an appropriate period of time agreed upon. Other aspects of this PreCheck examination could be required if deemed necessary and effective; i.e. radiography of the hoof or lower leg, shoeing, drug testing etc. Each horse is then issued a "Card" with the microchip number or document certifying his soundness to compete and compliance with the parameters in the HPA. We will need some association (A TWH association?) to maintain and update the data record of each horse. We could require that participating equine veterinarians be pre-approved by a CE process or information disseminated by a professional organization (AVMA, AEP etc) reminding the veterinarian of the issues surrounding soring and how to detect it properly. This would ensure they are correct in their definitions of lesion although I think most are competent in this task.

THE PRE-CHECKED HORSE INSPECTION PROTOCOL

Upon attendance at show competitions, Prechecked horses would present their document, have the horse's ID verified by scanning the microchip and undergo an expedited inspection process. That process could look something like this:

Each horse is inspected separately by 2 DQP's without knowledge of the horses' history except that he has been PreChecked. Following the inspections, the DQP's would compare their evaluations. If both agree the horse has no evidence of 1) scar rule violation and 2) is not sore, the horse is admitted to the show ring. If the DQP's disagree, the USDA VMO and an outside equine veterinarian hired by the show are then brought in to inspect the horse, again independently. After this, the 4 individuals compare notes and the horse is scored (4-0, 3-1, 2-2, 1-3, scar/sored vs. qualified). For all horses in which at least one inspector diagnosed soreness or scar, that horse is biopsied after the show. If the decision is unanimous (4-0 for scar) that horse is preliminarily disqualified pending the results of the biopsy. In all split

decisions (3-1,2-2 and 1-3 for soreness or scar), the horse is scheduled for a biopsy but is provisionally qualified and competes. The outcome of his performance depends on the results of the biopsy.

The opinion of each evaluator is recorded. If the biopsy shows objective evidence of scar or active inflammation (soreness) the horse's performance is vacated and owner pays for the biopsy. If the biopsy does not reveal objective evidence of scar or soreness, the USDA pays for the biopsy. The rationale here is that the USDA is professionally responsible for properly recognizing and interpreting the pathological lesions correctly. In addition the USDA trains the DQPs so they are also responsible for their performance.

THE BIOPSY PROCEDURE

All horses being biopsied should have a description and location of what was biopsied. I presume both Rt and Lt and fore pasterns would be biopsied because sored horses are supposed to have evidence of bilateral soring but if not, then which leg was sampled and exactly where. This should be entered into the individual animal data record (IADR).

DATA TRACKING

The show keeps track of all horses ruled to have scar violations or diagnosed as sore and what the diagnosis was of each person making that evaluation. When the results of the biopsy are known, the show compiles a record of how well each inspector is performing in this task and how accurate they are. If there is a consistent pattern of false positives among the inspectors there could be a provision for counseling or some form of continuing education for individuals who have an unacceptable rate of false positives or negatives. By this mechanism over time the feedback would assist the entire community to remove some of the subjectivity and bias from this system of inspections. There may need to be some provision for CE or remedial education here to insure the recognition and the proper diagnosis is being taught. If USDA is training DQPs to diagnose as scar changes permitted in the skin of horses by the HPA, that will need to be corrected because in the PreCheck program DQPs will be shouldering much of the burden ensuring soring is not being practiced. After discussions with some DQPs I anticipate that many horses currently being disqualified falsely will be properly interpreted by these people and qualified. Their confidence may be bolstered by the fact that an equine vet has already evaluated these horses and found them sound and not scared. A scar can form in 6 months but more attention should be focused on the detection of acute soring lesions and substances applied to the pasterns.

Post-Show Inspection Protocol

The inspection would follow what is usually done for winning entries. With respect to scar rule violations, a similar protocol would be followed as the preshow inspection. First the 2 DQPs would make the inspection independently but under the supervision of the independent equine vet who would ensure that no illegal substance was applied to the horse. In his case the inspection is less centered on detecting scar since that was determined prior to entering the show

ring because it is not medically possible for a scar to form in such a short time. The inspection should emphasize the detection of acute soring injuries.

At this time other parameters could be evaluated such as weight of chains or shoes, radiographs taken for evidence of P3 rotation (although this was performed within the last 6 months by the PreCheck vet), etc. The presence of any illegal substance found on the swab or in the blood would lead to disqualification and a penalty (to be discussed). The cost of the testing would be borne by the horse owner as part of the penalty.

[I need some help here. Who pays for the drug screening and swabbing now? Who do we bill if the blood test and swab are clean? How do we monitor drugs applied to the pastern that are water soluble and might not be detected by visual inspection? Do we do random swabs? But it should go without saying that if we find anything on the pastern your horse is disqualified. We could discuss a penalty here for this violation if there is not already one because this should be an objective finding. It might accelerate compliance with the rules and protect horses from being sored right before or during competition.

If the 2 DQP's are in agreement and there is no evidence of illegal activity, the horse is clear and remains the winner. If there is disagreement, the VMO and outside vet are brought in and inspect the horse for signs of acute soreness and pain. The 4 inspectors as before discuss their findings and interpretations and score the horse. The preshow and post show results are compared. If the horse has not already been required to have a biopsy, the disagreement will result in a biopsy. The results of the biopsy determines who pays the bill; the owner if there is objective evidence of soring and the government if there is not or whoever covers this cost now. (The show? The TWH industry?)

All of this result is entered into each horse's IADR along with the biopsy results and the interpretations of each inspector. The IADR would contain all information about previous competitions, the results of his inspections and the results of any biopsies. This information would NOT be available to inspectors prior to showing to avoid bias but would be used to compile a record of compliance or disqualifications. We will need to design some data storage and tracking system for this data so it is accessible. Is there a national database for TWH in existence and could it be used for this purpose. During one phone discussion with Mike Inman, he indicated the TWH Industry or registry might be used in this capacity. This will need to be fleshed out.

Non PreChecked Horses

For horses that are not entered into the "PreCheck Program" the current inspection protocols would be used. Data would be available to compare the false positive rate among the traditional inspection system and the new system. If the PreCheck Program is successful I could see how eventually all inspections would be done this way and every horse interested in competition would sign up for the program.

I think that if fairly applied and rigorously monitored, this PreCheck Program would markedly decrease the number of false positives. It would also discourage anyone from soring their horses

and it would increase the sensitivity by which we identify and punish violators. As long as the means by which we disqualify horses is sensitive, objective, accurate, and fair I advocate harsh penalties for individuals who sore their horses. The nature of the penalty should be determined in consultation with industry representatives. The program needs to be seen as rigorous so as to discourage soring. Because more of the inspections would be performed by DQP's and external veterinarians, this would ease the burden on the USDA VMOs and perhaps stretch their resources to cover more shows.

Surgical biopsy is the best and most definitive way to detect physical anatomic evidence of soring. The procedure is relatively inexpensive. By using any of the commercial veterinary diagnostic labs or contract with one or several individual veterinary pathologists to read all of the samples, it can be more rapid (several days) than what we have experienced the last 2 years with the Celebration material. And it can be done by any experienced board certified veterinary pathologist without requiring any additional rigorous training. Each individual biopsy does not need to have the detailed analysis provided by the Kentucky lab for the Celebration material. A simple evaluation of the sample and description of any inflammation or granulation tissue present would be sufficient to establish the presence of a scar rule violation, evidence of acute soring injury or most importantly the lack of it.

SUMMARY

A new definition of soring and scar in horses is proposed to be based on histopathology not just visual inspection and digital palpation. While this will delay the final diagnosis it has the unqualified advantage of being far more accurate than simple gross visual inspection and palpation. It also provides some due process for disqualified horses and maintains the presumption of innocence by allowing the horse to compete and be recognized until definitively shown to be in violation. With time, the ability to correlate each inspector's clinical impression with a definitive histopathologic diagnosis provides a learning experience in clinical diagnosis. The new tissue standard is easily and objectively **definable** by a more accurate, widely accepted standard method.

The success of failure of the program could be rapidly determined by tracking the false positive rates at shows. The program decreases the subjectivity and bias from the simple visual inspection criteria that are used now. Horses would no longer be barred from competing because the inspector could not "flatten out" skin folds, because the inspector could "feel 3 cells" by digital palpation or other undefined subjective criteria presumed to be evidence of scar rule violations without corroborative evidence. There would be a clear incentive for owners to register their horses for the PreCheck Program. There is some increase in cost of this program (the annual veterinary soundness exams and potential testing). But this alone would result in an increase in the health and welfare of TWH as they would be getting consistent, at least annual, medical evaluations and establishing permanent medical IADRs. The rigor of the program would discourage trainers from soring horses. (A trainer would have to be insane to injure a horse that will almost certainly be objectively and unambiguously discovered under this program). This could be accelerated by more severe penalties for clear and unambiguous violations but requires vigilance that everyone is doing their jobs correctly. There are consequences defined in the program for individuals who have been shown to sore their horses and consequences for

inspectors who inaccurately diagnose soring and scar rule violations. There is an immediate incentive for the government to ensure the VMO's and DQP's are making correct and accurate diagnosis because they foot the bill for mistakes. Privately hired show veterinarians with an unacceptable error rate would simply not be hired again for duty. Likewise, owners will pay the cost of the testing if they sore horses or potentially apply anything to the patterns of the horses.

Evaluation of horses while blinded to their prior history should reduce bias and the independent evaluation by all inspectors should mitigate the subjectivity in visual inspection and interpretation of findings. A winning horse will have been inspected by 3 vets and 2 DQPs prior to showing and potentially 4 additional individuals after the show making it highly unlikely a sored horse will slip through the process. By relying on histopathology of skin biopsies (read by anonymous unbiased 3rd parties) as the final unbiased arbiter we are providing a better **teachable definition** of soring and scar rule violations. We could reduce the false positive rate and increase the recognition of real violators. The feedback from histopathology would form the basis for teaching the recognition and proper interpretation of gross or clinical changes seen on visual inspections, a sort of "On-the-job continuing education" opportunity. This should improve their diagnostic skills, decrease their false positive and negative rates and thereby meet the **teachable** criterion required of the new standard. Reliance on more objective methods, data tracking and the ability to impose strict penalties fairly along with the provision of due process for suspected violations in the form of provisional qualification to compete pending results of biopsy and other testing (the presumption of innocence instead of presumption of guilt) the program is better accepted by the public and therefore more **enforceable**. Such a program could restore confidence and trust in the government, reassure the concerned public, improve the standing of the TWH industry and better protect the health and welfare of horses. It meets the criteria of being definable, teachable and enforceable. The success of the new standard will require acceptance and compliance of the USDA and may need the force of law to acquire it.