BEFORE THE INDIANA HORSE RACING COMMISSION

DR. DUANE WILCOX, Petitioner, v. INDIANA HORSE RACING COMMISSION STAFF, Respondent.	In Re: Administrative Complaint No. 218002 (as amended)

BRIEF IN SUPPORT OF COMMISSION AFFIRMATION OF PROPOSED FINDINGS OF FACT, CONCLUSIONS OF LAW, AND RECOMMENDED ORDER OF ADMINISTRATIVE LAW JUDGE

The Indiana Horse Racing Commission Staff ("Staff" or "Commission Staff") respectfully submits this brief in support of its request that the Commission affirm the Proposed Findings of Fact, Conclusions of Law, and Recommended Order of Administrative Law Judge Michael Buker ("ALJ Buker") dated May 2, 2019 ("Recommended Order")[1], attached as Exhibit A, which is submitted pursuant to the Chairman's May 22, 2019, Notice of Opportunity to Present Briefs and Oral Argument in the above-referenced matter.

I. INTRODUCTION

1. On March 28, 2018, Commission Staff issued an exclusion notice against Dr. Wilcox, which excluded him from all tracks and satellite wagering facilities under

[1] ALJ Buker's Recommended Order was issued with respect to Paragraphs 12, 14, and 16-20 of Administrative Complaint No. 218002 (as amended) and incorporated his Recommended Order Regarding Summary Judgment and Ancillary Motions ("Summary Judgment Order") issued on January 14, 2019, attached as Exhibit A1, with respect to Paragraph 9 of Administrative Complaint No. 218002 (as amended). Recommended Order herein refers to ALJ Buker's May 2, 2019, Recommended Order and the incorporated section of his January 14, 2019, Summary Judgment Order.

the jurisdiction of the Indiana Horse Racing Commission ("Commission" or "IHRC").

2. Dr. Wilcox timely requested a hearing on the exclusion. ALJ Buker was assigned to the matter.

3. On March 27, 2018, the IHRC issued Administrative Complaint No. 218002, attached as Exhibit B, finding in pertinent part, that:

    a. Dr. Wilcox violated Ind. Code § 4-31-12-21 "Veterinarians; controlled substances and injection instruments; handling and disposal" which provides, in pertinent part, that track veterinarians must use proper disposal techniques for hypodermic needles and syringes.

    b. Dr. Wilcox violated 71 IAC 5.5-1-28 "Cooperation with Investigations" which provides that a licensee must cooperate with all commission investigations and inquiries made by commission representatives.

    c. Dr. Wilcox violated 71 IAC 5.5-1-29 "Reporting known or suspected irregularities and rule violations" which provides that a licensee with knowledge of rule violations must report those violations or incidents to Commission Staff.

    d. Dr. Wilcox violated 71 IAC 8.5-1-1.5 "Medication" which prohibits participation in, recommendation of, and knowledge of administration of substances, other than furosemide, to horses within 24 hours prior to the scheduled post time.

    e. Dr. Wilcox violated 71 IAC 8.5-1-2 "Foreign substances prohibited" which prohibits participation in, recommendation of, and knowledge of multiple

occurrences of administration of prohibited foreign substances to horses participating in a race in Indiana.

f. Dr. Wilcox violated 71 IAC 8.5-1-5(7) "Furosemide as a permitted foreign substance" which provides that a horse scheduled for furosemide administration must be timely treated.

g. Dr. Wilcox violated 71 IAC 8.5-1-5(7) "Furosemide as a permitted foreign substance" which prohibits the administration of furosemide to a horse not scheduled to receive furosemide.

h. Dr. Wilcox violated 71 IAC 8.5-1-5(8) "Furosemide as a permitted foreign substance" which prohibits a veterinarian from failure to allow observation of drawing of furosemide from a sealed bottle.

i. Dr. Wilcox violated 71 IAC 8.5-4-3 "Single use syringes" which requires veterinarians to properly dispose of or destroy hypodermic needles and syringes.

j. Dr. Wilcox violated 71 IAC 8.5-4-5 "Records of treatment" which requires veterinarian licensees to keep records up to a standard set forth in the rule and also requires veterinarian licensees to provide those records to commission staff within a given time period following a request.

k. Dr. Wilcox violated 71 IAC 8.5-4-12 "Contact with entered horses" which prohibits contact with entered horses within twenty-four (24) hours of scheduled races (not including administration of furosemide).

l. Dr. Wilcox violated 71 IAC 8.5-4-12.1 "Stable area access" which prohibits a veterinarian from accessing stable areas without an association

escort from five (5) hours before the first race post until four (4) hours before post time of the last race.

m. Dr. Wilcox violated 71 IAC 8.5-5-1 "Ban on possession of drugs" which prohibits veterinarians from selling injectables and other substances without proper prescription and labeling of the substance.

n. Dr. Wilcox violated 71 IAC 8.5-5-2(j) "Prohibited practices" which prohibits the sale of prescription medications to trainers and stables without proper prescription and labeling.

o. Dr. Wilcox violated 71 IAC 5.5-1-14(b)(4), 71 IAC 5.5-1-14(b)(10), and 71 IAC 5.5-1-14(b)(16), which provide that the commission may suspend a licensee or otherwise penalize a licensee if:

> (4) The person has violated or attempted to violate a provision of this article, these rules, or a law or rule with respect to horse racing in a jurisdiction.
>
> (10) The person has engaged in conduct that is against the best interest of horse racing or compromises the integrity of operations at a track or satellite facility.
>
> (16) The person has interfered with or obstructed a member of the commission, a commission employee, or a racing official while performing official duties.

(IHRC Staff Administrative Complaint No. 218002).

4. Dr. Wilcox requested a hearing pursuant to 71 IAC 10-3-20(d).

5. The case was subsequently assigned to ALJ Buker to hear and decide the issues framed by the Administrative Complaint.

6. On July 11, 2018, ALJ Buker issued the Fourth Scheduling Order, ordering that the hearing requested on the exclusion of Dr. Wilcox be stayed pending the resolution of Administrative Complaint No. 218002.
7. The parties conducted discovery under the supervision of ALJ Buker and pursuant to the Pre-Hearing Orders and Scheduling Orders issued in this matter.
8. On September 3, 2018, ALJ Buker issued an Order granting Commission Staff's motion to compel, attached as Exhibit C, requiring Dr. Wilcox to correct a number of discovery deficiencies, including a requirement for Dr. Wilcox to submit to Commission Staff, a list of the contents of his "plus" substance, and a sample for testing.
9. On September 18, 2018, Commission Staff deposed Dr. Wilcox, attached as Exhibit D. At that time Dr. Wilcox provided a bottle of "P-Bloc" and indicated to Commission Staff that this was an exact sample of the substance used to create his "plus" formula.
10. On September 21, 2018, Commission Staff issued the Amended Administrative Complaint No. 218002 ("Amended Complaint"), attached as Exhibit E.
11. The Amended Complaint included additional charged violations, finding in pertinent part that:
    a. Dr. Wilcox violated 71 IAC 8.5-5-2(c) "Prohibited practices" which prohibits the possession of a drug, substance, or medication on the premises of a facility under the jurisdiction of the Commission that had not been approved by the United States Food and Drug Administration

("FDA") for any use (human or animal) nor granted prior permission by the Commission.

b. Dr. Wilcox violated 71 IAC 8.5-5-2(e)(2) "Prohibited practices" which prohibits possession of a compounded drug made from non-FDA-approved drugs.

c. Dr. Wilcox violated 71 IAC 8.5-5-2(e)(3) "Prohibited practices" which prohibits possession of a compounded drug where there are FDA-approved, commercially available drugs that can appropriately treat the horse.

d. Dr. Wilcox violated 71 IAC 8.5-5-2(e)(4) "Prohibited practices" which prohibits possession of a compounded drug that does not meet the labeling requirements in 71 IAC 8.5-5-29(j).

e. The Amended Complaint also removed charged violations of 71 IAC 5.5-1-29, 71 IAC 8.5-1-5(8), 71 IAC 8.5-4-3, 71 IAC 8.5-4-12, and 71 IAC 8.5-4-12.1.

12. On September 27, 2018, ALJ Buker issued an Order granting Commission Staff's request to amend Administrative Complaint No. 218002.

13. On November 5, 2018, the parties submitted cross-motions for partial summary judgment.

14. On December 14, 2018, ALJ Buker issued an order granting Commission Staff's summary judgment motion with respect to the charged violation of 71 IAC 5.5-1-28 "Cooperation with investigations" and denying summary judgment with regard to all other charges.

15. On January 31, 2019, and February 1, 2019, ALJ Buker conducted a hearing in this matter. The Commission Staff was represented by IHRC Deputy General Counsel Noah Jackson and Counsel Dale Lee Pennycuff. Respondent was represented by his counsel, David P. Murphy of David P. Murphy & Associates.

16. The parties agreed to the authenticity, relevance, and admissibility of the following exhibits:

    a. Dr. Wilcox's 2016 IHRC application for a Practicing Veterinarian License, dated March 9, 2016.

    b. Dr. Wilcox's 2017 IHRC application for a Practicing Veterinarian License, dated April 7, 2017.

    c. 2017 Checklist – Practicing Veterinarians IHRC License signed by Dr. Wilcox on April 7, 2017.

    d. Administrative Law Judge Assignment Letter to the Honorable Michael Buker, dated May 4, 2018.

    e. Request for Hearing filed by Dr. Wilcox's counsel, David P. Murphy, dated May 2, 2018.

    f. Transcript of Dr. Wilcox deposition taken on September 18, 2018.

    g. Transcript of Penny Loudermilk deposition taken on September 27, 2018.

    h. Transcript of Roy Moore deposition taken on September 27, 2018.

    i. Transcript of Saul Perez deposition taken on September 27, 2018.

    j. Final Order of the Indiana Horse Racing Commission re: Administrative Complaint No. 217004, dated September 15, 2017.

k. Photographs of "P-Bloc" formula container and substance supplied at Dr. Wilcox's deposition.

l. Exhibit Nos. 2-6 identified on the Final Exhibit List of Petitioner.

17. The parties agreed to the following stipulations of fact:

a. At all times relevant Dr. Wilcox was a licensee of the Indiana Horse Racing Commission holding Commission License No. 960449.

b. Dr. Wilcox was, at all times relevant, subject to the rules and statutes regulating pari-mutuel horse racing in the State of Indiana.

c. Dr. Wilcox was a practicing veterinarian at Indiana Grand Racing & Casino located at 4300 N. Michigan Rd., Shelbyville, IN, 46176.

d. Indiana Grand is a property under the jurisdiction of the Commission.

e. In 2016, Dr. Wilcox was disciplined (Stewards Ruling #16594) for administering furosemide ("Lasix") to a horse not scheduled to receive it and for failing to timely administer Lasix to a horse that was scheduled to receive it. He was fined $1,000 and paid the fine. He did not appeal.

f. On September 15, 2017, Dr. Wilcox was disciplined for failing to keep proper treatment and billing records. A Final Order finding in favor of Commission Staff in Administrative Complaint No. 217004 was issued by the Commission in which Dr. Wilcox was fined $1,000. He paid the fine and did not appeal.

g. Trainer Penny Loudermilk and Roy Moore were clients of Dr. Wilcox during the 2016 racing season and used him to administer Lasix to horses under their care.

h. In 2017, Dr. Wilcox administered a substance he described as "plus" (or "+") in injectable form to horses under his care.

i. A bottle of "P-Bloc," labeled by the compounding pharmacy, Rapid Equine Solutions of Aston, PA, was provided to Commission Staff at the deposition of Dr. Wilcox on September 18, 2018.

j. Dr. Wilcox never sought permission from stewards or Commission Staff prior to administering the "plus" to horses under Commission jurisdiction.

k. Dr. Wilcox withheld the contents of the "plus" formula from Commission Staff during an interview, conducted on April 4, 2018, by former Commission counsel Holly Newell.

l. Dr. Wilcox stated that the formula was proprietary in explaining his decision to withhold its contents from Holly Newell.

m. At his deposition, Dr. Wilcox stated that the proprietary nature of the formula was how it was put together with Vetalog or Predef.

18. The Commission Staff presented the testimony of expert witness Dr. Scot Waterman, DVM, IHRC Executive Director Michael Smith, and Dr. Wilcox, DVM. Hearing transcript In the Matter Of: Duane J. Wilcox, DVM v. Indiana Horse Racing Commission Staff, and accompanying exhibits, held on January 31, 2019, and February 1, 2019, attached as Exhibit F.

19. Dr. Wilcox testified in his own defense. He also called Dr. Jerre Rorick, Mrs. June Rorick, and Dr. Michael Mann as witnesses. Finally, Dr. Michael Ross, DVM appeared as Dr. Wilcox's expert witness.

II. RELEVANT LAW

The Indiana Horse Racing enabling statute is at Title 4, Article 31 of the Indiana Code (Pari-mutuel Wagering on Horse Races). Pursuant to the authority established in Title 4, Article 31, the IHRC has promulgated rules to regulate horse racing in Indiana. Those rules are codified at Title 71 of the Indiana Administrative Code. As an administrative agency, the IHRC also derives authority from and is restricted by the Administrative Orders and Procedures Act ("AOPA") (Indiana Code Title 4, Article 21.5).

In 1989, the Indiana state legislature charged the IHRC with ensuring that pari-mutuel wagering on horse races in Indiana will be conducted with the highest of standards and the greatest level of integrity. (*See* Ind. Code 4-31-1-2).

The following IHRC rules are most relevant to the Dr. Wilcox disciplinary action:

> **IC 4-31-13-1 Disciplinary actions of judges and stewards; sanctions; maximum civil penalty**
>
> Sec. 1. (a) The commission may issue orders under IC 4-21.5 to:
>
> ...
>
> (2) impose civil penalties, in addition to any other penalty imposed by the commission on a person who violates this article or a rule or an order of the commission.
>
> (b) The commission or the commission's designee, as determined under the rules of the commission, on its own motion or in addition to a penalty assessed by the stewards and judges, may issue orders under IC 4-21.5 to rule a person off one (1) or more permit holders' premises, if necessary in the public interest to maintain proper control over recognized meetings.
>
> (c) A civil penalty imposed against a licensee under subsection (a)(2) may not exceed five thousand dollars ($5,000). For purposes of subsection (a)(2), each day during which a violation of this article or a rule or an order of the commission continues to occur constitutes a separate offense.
>
> (d) Civil penalties imposed under this article shall be deposited in the state general fund.
>
> **71 IAC 5.5-1-28 Cooperation with investigations**

Sec. 28. (a) All licensees shall cooperate fully with all investigations and inquiries made by commission representatives or association security, or both.

(b) All licensees shall obey instructions from commission representatives or association security, or both.

71 IAC 8.5-1-5 Furosemide as a permitted foreign substance

Sec. 5. Furosemide may be administered intravenously to a horse, which is entered to compete in a race. Except under the instructions of the official veterinarian or the racing veterinarian for the purpose of removing a horse from the veterinarian's list or to facilitate the collection of a post-race urine sample, furosemide shall be permitted only after the official veterinarian has placed the horse on the furosemide list. In order for a horse to be placed on the furosemide list, the following process must be followed:

...

Time of treatment. Horses qualified for medication and so indicated on the official bleeder list must be treated at least four (4) hours prior to post time.

...

71 IAC 8.5-4-5 Records of treatment

Sec. 5. (a) Every veterinarian licensed by the commission who treats any horse or performs other professional services within the enclosure of an organization licensee during a race meeting, or treats horses off the grounds that are actively participating at a race meeting, shall be responsible for maintaining treatment records or a log book on all horses for which they prescribe, administer, or dispense medication or perform other professional services. The treatment records or log book information shall include, but not be limited to, the following:

(1) The date and time of treatment service.
(2) Name of race track.
(3) The veterinarian's printed name and signature.
(4) The registered name of horse.
(5) The trainer's name.
(6) The barn number or location of horse.
(7) The race date and race number, if any.
(8) The medication and dosage.
(9) The reason for treatment or services.

These records shall be current at all times and available to the commission and the stewards upon request. These records shall be retained for at least one (1) year after the conclusion of the race meet and be made available to the commission and stewards upon request. Such records shall be delivered to the commission either upon demand or within twenty-four (24) hours of the request.

(b) Practicing veterinarians shall retain duplicate copies of bills or statements to trainers or owners which shall be retained for at least one (1) year and made available to the commission upon request. Such records shall be delivered to the commission within forty-eight (48) hours of the request.

(c) Any drug or medication which is used or kept on association grounds and which, by federal or state law, requires a prescription, must have been validly prescribed by a duly licensed veterinarian and be in compliance with the applicable state statutes. All such allowable medications must have a prescription label which is securely attached and clearly ascribed to show the following:

(1) The name of the product.

(2) The name, address, and telephone number of the veterinarian prescribing or dispensing the product.

(3) The name of each patient (horse) for whom the product is intended or prescribed.

(4) The doses, dosage, duration of treatment, and expiration date of the prescribed or dispensed product.

(5) The name of the person (trainer) to whom the product was dispensed.

71 IAC 8.5-5-2 Prohibited practices

Sec. 2. ...

(c) The possession and/or use of a drug, substance, or medication on the premises of a facility under the jurisdiction of the commission that has not been approved by the United States Food and Drug Administration (FDA) for any use (human or animal) is forbidden without prior permission of the commission. For purposes of this rule, the term "drug" is any substance, food or nonfood, that is used to treat, cure, mitigate, or prevent a disease, is any nonfood substance that is intended to affect the structure or function of the animal, and includes any substance administered by injection, other than vaccines licensed by the USDA.

...

(e) Notwithstanding subsection (c), veterinarians may possess compounded drugs with the restrictions listed below.
Compounding includes any manipulation of a drug beyond that stipulated on the drug label, including, but not limited to, mixing, diluting, concentrating, and/or creating oral suspensions or injectable solutions:

...

(2) compounded drugs may only be made from other FDA-approved drugs;

(3) veterinarians may not possess compounds where there are FDA-approved, commercially available drugs that can appropriately treat the horse; and

(4) compounded drugs must be in containers that meet the prescription labeling requirements in subsections (i) and (j).

Combining two (2) or more substances with pharmacologic effect constitutes the development of a new drug. This may only be done in accordance with state and local laws and must contain FDA approved medications, if available.

...

(h) A veterinarian shall not possess any drug that is not labeled pursuant to the requirements of subsection (i) or (j).

(i) Drugs possessed by practicing veterinarians on the premises of a facility under the jurisdiction of the commission which have not yet been prescribed or dispensed to horses with which the veterinarian has a veterinarian-client-patient relationship must be affixed with the manufacturer's label which must include:

(1) recommended or usual dosage;

(2) route for administration, if it is not for oral use;

(3) quantity or proportion of each active ingredient;

(4) names of inactive ingredients, if for other than oral use;

(5) an identifying lot or control number;

(6) manufacturer, packer, or distributor's name and address; and

(7) net quantity contents.

If any information as described herein is not included on the manufacturer's label, but instead is on the manufacturer's package insert, the package insert must be maintained on the veterinarian's truck.

(j) When issuing a prescription for or dispensing a drug to a horse with which the veterinarian has a veterinarian-client-patient relationship, the veterinarian must affix or cause to be affixed a label that sets forth the following:

(1) Name and address of the veterinarian;

(2) Name and address of the client;

(3) Name of the horse;

(4) Date of prescription and/or dispensing of drug;

(5) Directions for use, including dose and duration directions, and number of refills;

(6) Name and quantity of the drug (or drug preparation, including compounds) prescribed or dispensed;

(7) For compounded drugs, the established name of each active ingredient; and

(8) Any necessary cautionary statements.

III. ANALYSIS

As a licensee in 2016 and 2017, Dr. Wilcox knowingly subjected himself to the jurisdiction of the IHRC and explicitly agreed to know, and abide by, the rules of pari-

mutuel horse racing in Indiana. As a track veterinarian, Dr. Wilcox was given significant autonomy and expected to comply with rules in order to insure the integrity of horse racing. As a licensee Dr. Wilcox is obligated to know and follow the IHRC rules on cooperation with investigations, timely treatment of horses with furosemide (Lasix), maintaining medical and billing records, and prohibited practices. Instead, Dr. Wilcox was uncooperative with an ongoing investigation, failed to timely administer Lasix on race day, did not maintain adequate records, and violated multiple prohibited practices rules.

Dr. Wilcox refused to disclose the contents of the Plus formula during an interview with former Deputy General Counsel Holly Newell and failed to provide to Commission Staff, as ordered by ALJ Buker, what he eventually claimed was the Plus formula (P-Bloc made from the sarracenia purpurea plant)[2]. Dr. Wilcox failed to present sufficient evidence to refute his failure to timely treat a race horse scheduled to receive Lasix. Further, Dr. Wilcox admitted that his records were not maintained according to Commission regulations, but were in what he termed "substantial compliance." Nor did Dr. Wilcox present evidence sufficient to overcome the preponderance of the evidence standard with regard to violating multiple prohibited practices rules, i.e. 71 IAC 8.5-5-2(c), 71 IAC 8.5-5-2(e)(2-4), and 71 IAC8.5-5-2(h).

IV. ARGUMENTS

A. Petitioner's request for appeal does not properly preserve objections to the recommended order of the administrative law judge because Petitioner's stated claims are not reasonably particular as required under AOPA.

[2] At his deposition, Dr. Wilcox provided a bottle of P-Bloc made with ammonium chloride, instead of sarracenia purpurea, and testified that is was an exact sample of the formula that he used for Plus. (Exhibit D, pg. 55, lines 21-25).

Pursuant to Ind. Code § 4-21.5-3-29(d), "[t]o preserve an objection to an order of an administrative law judge for judicial review, a party . . . must object to the order in a writing that: (1) identifies the basis of the objection with reasonable particularity . . ." In Petitioner's Notice of Objection to the Order of the Administrative Law Judge Dated May 2, 2019 [sic] and Request for Appeal to and Review by the Indiana Horse Racing Commission ("Dr. Wilcox's Objection"), dated May 16, 2019, Dr. Wilcox states five claims as the bases for his objection to ALJ Buker's Recommended Order. Three of those claims are general statements including no context or citation to any part of ALJ Buker's Recommended Order and are thus not reasonably particular to preserve Dr. Wilcox's objection to ALJ Buker's Recommended Order under AOPA.

First, Dr. Wilcox's Objection states that ALJ Buker's Recommended Order is, "(a) Arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law[.]" Dr. Wilcox's Objection does not provide any further context or make any further claim under which the Commission or Commission Staff could properly respond. Further, it is unclear based on the pleading whether Dr. Wilcox intends to allege that all or part of the forty page Recommended Order is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.

Second, Dr. Wilcox's Objection states that ALJ Buker's Recommended Order is, "(c) Unsupported by substantial evidence[.]" Again, no additional context is provided nor evidence cited to form a basis for Dr. Wilcox's pleading. ALJ Buker's Recommended Order spanned forty pages and disposed of eight separate charges in separate paragraphs and subparagraphs, each explaining, at length, the evidence relied upon and the basis for the recommendation. Dr. Wilcox has simply provided a general statement that ALJ

Buker's Recommended Order is unsupported by substantial evidence and has neglected to provide even a single sentence as context or evidence to which the Commission Staff might respond.

Finally, Dr. Wilcox's Objection states that ALJ Buker's Recommended Order is "(d) In excess of statutory jurisdiction, authority, or limitations, or short of statutory right[.]" ALJ Buker's recommended sanctions are based upon a totality of numerous charges against Dr. Wilcox. ALJ Buker's Recommended Order explains in great detail how ALJ Buker reached his recommendations. Pursuant to 71 IAC 10-3-20, the executive director is delegated the authority to prepare and issue administrative complaints. 71 IAC 10-3-20(b) states that, "the amount of the penalty may not exceed five thousand dollars ($5,000) for each violation." Additionally, it states that "each day or occurrence that a violation continues may be considered a separate violation." Dr. Wilcox has failed to identify, with reasonable particularity, how ALJ Buker's Recommended Order is in excess of statutory jurisdiction, authority, etc. where Title 71 of the Indiana Administrative Code clearly allows the IHRC to assess sanctions against a licensee that would include the ten year suspension and ten thousand dollar fine given that the charged violations include hundreds of injections and activities that spanned at least two years.

Dr. Wilcox failed to preserve his right to appeal ALJ Buker's Recommended Order on the three claims listed above. General statements made without context or citation to the Recommended Order or other evidence do not provide a basis for Commission Staff to respond, nor to reasonably interpret what is at issue in Dr. Wilcox's Objection. Although Commission Staff believes that Dr. Wilcox has not properly preserved his right of appeal in the above-listed subsections of Dr. Wilcox's Objection,

Commission Staff has provided arguments in the alternative below, if the Commission considers Dr. Wilcox's request sufficient under Ind. Code § 4-21.5-3-29(d).

B. The recommended penalty in Administrative Complaint No. 218002 (as amended) is reasonable and appropriate given Dr. Wilcox's violations regarding cooperation, Lasix administration, record keeping, and prohibited practices and; therefore, not arbitrary and capricious, an abuse of discretion, or otherwise not in accordance with law.

In Dr. Wilcox's Objection, Dr. Wilcox fails to state a claim as to why ALJ Buker's Recommended Order is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law. Therefore, we will review the Recommended Order considering the legal standard. "A decision is deemed arbitrary and capricious when it is 'patently unreasonable and is made without consideration of the facts and in total disregard of the circumstances. . . .'" *Ind. Alcohol & Tobacco Comm'n v. Spirited Sales, LLC*, 79 N.E.3d 371, 380 (Ind. 2017) (*citing A.B. v. State*, 949 N.E.2d 1204, 1217 (Ind. 2011) (internal quotations omitted)). "Such a decision will also lack any basis which might lead a reasonable person to the same conclusion." *Id.* "In other words, '[a]n action of an administrative agency is arbitrary and capricious only where there is no reasonable basis for the action.'" 79 N.E.3d 371, 380 (*citing Breitweiser v. Ind. Office of Envtl. Adjudication*, 810 N.E.2d 699, 702 (Ind. 2004)).

In rendering his Recommended Order ALJ Buker was required to weigh the credibility of witnesses with regard to the matters in which they offered testimony, including each witness's interest, if any, in the outcome of the matter; consider the administrative record; conduct a hearing with evidence and testimony presented by both parties; and consider the arguments of counsel. ALJ Buker's Recommended Order is incorporated by reference herein.

ALJ Buker clearly lays out the facts and circumstances in his Recommended Order, which contribute to his findings on all of the violations pursued at the administrative hearing, and in summary judgment. A review of the facts and circumstances as laid out by ALJ Buker would lead a reasonable person to reach the same conclusion, and; therefore, is not patently unreasonable, nor arbitrary or capricious.

"An abuse of discretion may occur if the trial court's decision is clearly against the logic and effect of the facts and circumstances before the court, or if the trial court has misinterpreted the law." *Tapia v. State*, 753 N.E.2d 581, 585 (Ind. 2001) (*citing McCullough v. Archbold Ladder Co.*, 605 N.E.2d 175, 180 (Ind. 1993)). ALJ Buker's Recommended Order clearly demonstrates his findings follow the logic and effect of the facts and circumstances presented to him. The statute and regulations in question are clearly set forth and there is no evidence of a misunderstanding or misstatement of the law or regulations. Further, Petitioner fails to provide any citation to any alleged misunderstanding or misinterpretation of law or regulation. Therefore ALJ Buker's findings are not an abuse of discretion or otherwise not in accordance with law.

C. The recommended penalty in Administrative Complaint No. 218002 (as amended) does not violate Dr. Wilcox's constitutional rights with regard to the Eighth and Fourteenth Amendments to the Constitution of the United States, nor Article One, Section Sixteen of the Constitution of the State of Indiana.

Dr. Wilcox's Objection fails to state a claim as to why ALJ Buker's Recommended Order is contrary to constitutional right, power, privilege, or immunity, including but not limited to the right of Dr. Wilcox to be free from excessive fines and punishments as guaranteed by the Eighth and Fourteenth Amendments to the Constitution

of the United States and Article One, Section Sixteen of the Constitution of the State of Indiana. We will review the Recommended Order considering the legal standard.

Excessive Fines Clause

In *Timbs v. Indiana* the Supreme Court held that the Fourteenth Amendment incorporates the Eighth Amendment's protection against excessive fines, thereby applying the protection against excessive fines to the States. 139 S.Ct. 682, 687 (Ind. 2019).

While the Eighth Amendment does apply to the States, it primarily applies to criminal proceedings and civil *in rem* forfeiture proceedings which are based on criminal proceedings. This instant case does not involve said civil *in rem* forfeitures. *See Browning-Ferris Indus. v. Kelco Disposal*, 492 U.S. 257, 275 (1989) (Supreme Court refused to apply Excessive Fines Clause of the Eighth Amendment to punitive damages in private civil cases.). While the dicta in *Browning-Ferris* indicates the Court might be willing to apply the Excessive Fines Clause to fines imposed by, and payable to, the government in a civil context, a search failed to turn up such a ruling from the Court. Even if such a ruling were to be issued, it would likely apply to a civil proceeding and not to an administrative proceeding as the Court tends to make narrow rulings in general.

Assuming *arguendo* that the Excessive Fines Clause does apply, the $10,000.00 fine in ALJ Buker's Recommended Order is not excessive. The legislature granted the Commission the power to "issue orders under [Ind. Code] § 4-21.5 to[] impose civil penalties, in addition to any other penalty imposed by the commission on a person who violates this article or a rule of or an order of the commission." Ind. Code § 4-31-13-1(a)(2). Subsection (c) limits the civil penalty for a violation to a maximum of

$5,000.00. Subsection (d) requires all civil penalties to be deposited in the state general fund.

ALJ Buker found that Dr. Wilcox violated multiple regulations, with several regulations violated numerous times. Dr. Wilcox was found to have violated 71 IAC 5.5-1-28 for failing to cooperate with an investigation. As a practicing veterinarian, Dr. Wilcox was given more autonomy than most licensees to perform his job duties. Being a practicing veterinarian also comports conduct to a higher standard and failure to cooperate is a serious violation. (*See* Exhibit F, pg. 151, lines 10-22). As of the date of this filing, Commission Staff has not been provided with a true sample of the Plus substance as ordered by ALJ Buker. (Exhibit C, pg. 3, ¶ 4).

Dr. Wilcox was found to have violated 71 IAC 8.5-1-5(7) for failing to timely administer Lasix to the horse Dashin' Spirit in the Race No. 2 on June 4, 2016, resulting in a late scratch. Timely Lasix administration is important to the owner, trainer, and the betting public, in addition to effecting the betting pools. (Exhibit F, pg. 154, lines 5-16). ALJ Buker found that Dr. Wilcox failed to maintain treatment records as required under 71 IAC 8.5-4-5. Proper record keeping is of critical importance to allow Commission Staff to examine a veterinary record and discern what treatment and medications have been provided to the horse. (Exhibit F, pg. 157, lines 15-25; pg. 158, lines 1-16). Dr. Wilcox was previously fined $1,000.00 for the same violation in Administrative Complaint No. 217004, effectively putting him on notice that his treatment records were not in compliance. In addition, ALJ Buker found that Dr. Wilcox injected horses with a substance that was not approved by the Food and Drug Administration (the "FDA") in violation of 71 IAC 8.5-5-2(c), said substance being the Plus formula.

ALJ Buker found Dr. Wilcox violated 71 IAC 8.5-5-2(e)(2) by possessing a compounded drug that was not made from other FDA-approved drugs, i.e. the Plus substance. Further, ALJ Buker found that Dr. Wilcox was in possession of and injected horses with a compounded drug when other FDA-approved drugs are commercially available that can appropriately treat the horse in violation of 71 IAC 8.5-5-2(e)(3), said drug being the Plus formula. For the three previously listed violations, 71 IAC 8.5-5-2(c), (e)(2), and (e)(3), Dr. Wilcox admitted in his deposition to injecting horses with the Plus substance more than one hundred times and admitted that Plus was administered at Indiana Grand. (Exhibit D, pg. 53, lines 9-25).

ALJ Buker found that Dr. Wilcox violated 71 IAC 8.5-5-2(e)(4) for possession of a compounded substance (Rapid Equine P-Bloc) at the track that does not satisfy the labeling requirements of 71 IAC 8.5-5-2(i), which requires seven enumerated items on the label. (Exhibit A, pg. 33). The bottle of Rapid Equine P-Bloc supplied to the Commission Staff by Dr. Wilcox contained only two of the required seven items on the label. Lastly, ALJ Buker found that Dr. Wilcox violated 71 IAC 8.5-5-2(h) for possession of a Rapid Equine P-Bloc at the track, a drug that does not comply with the labeling requirements of 71 IAC 8.5-5-2(i), which requires seven enumerated items to be printed on the label. (Exhibit A, pgs. 33-34). The bottle of Rapid Equine P-Bloc supplied to the Commission Staff by Dr. Wilcox contained only two of the required seven items on the label. Dr. Wilcox, like all other licensees who face discipline, had the opportunity to reach a settlement agreement with the Commission Staff, but no such agreement was reached.

Dr. Ross Russell ("Dr. Russell") was charged with violations of 71 IAC 5.5-1-28 (Cooperation of investigations), 71 IAC 8.5-4-5 (Treatment records), and 71 IAC 8.5-5-2 (Prohibited practices) similar to Dr. Wilcox, along with five other rule violations. For those eight charges dealing with cooperation, medication, records, and prohibited practices, Dr. Russell's recommended penalty was a suspension of twenty years and a fine of $20,000.00. Dr. Russell reached a settlement agreement with Commission Staff that included a suspension of 9 years, an agreement not seek licensure for an additional three years, an acknowledgement that a future license was not guaranteed, and a fine of $12,000.00.

Dr. Joseph Baliga ("Dr. Baliga") is charged with violations of 71 IAC 8-1-1.5 (Medication), 71 IAC 8-1-2 (Foreign substance prohibited), 71 IAC 8-5-5 (Records of treatment), and 71 IAC 8-5-12 (Contact with entered horses) for allegedly injecting a horse with a substance other than Lasix within 24 hours of the scheduled post time. For the one injection violation, and a record keeping violation, Dr. Baliga's recommended penalty is a suspension of 5 years and a $20,000.00 fine.

The Commission Staff has been consistent in its recommended penalties based on the circumstances of the violations. The $10,000.00 fine recommended by ALJ Buker was based on the totality of the circumstances and precedence. Commission Staff does not benefit from the fine as it goes to the state general fund, and therefore; has no incentive to levy an excessive fine even though the statute allows a maximum fine of $5,000.00 for each violation. Therefore, the fine in ALJ Buker's Recommended Order is not excessive.

Cruel and Unusual Punishment Clause

"An examination of the history of the [Eighth] Amendment and the decisions of this Court construing the proscription against cruel and unusual punishment confirms that it was designed to protect those convicted of **crimes**." *Ingraham v. Wright*, 430 U.S. 651, 664 (1977). (emphasis added). "The primary purpose of [the Cruel and Unusual Punishments Clause] has always been considered, and properly so, to be directed at the method or kind of punishment imposed for the **violation of criminal statutes**...." *Id.* at 667 (*citing Powell v. Texas*, 392 U.S. 514 (1968)). (emphasis added). The penalty in the instant case is administrative and not criminal. Therefore, an objection based on the Eighth Amendment's Cruel and Unusual Punishments Clause is moot.

As to Section Sixteen of the Constitution of the State of Indiana, the Indiana Supreme Court has stated that "Section 16 applies 'only when a **criminal penalty** is not graduated and proportional to the nature of an offense.'" *Conner v. State*, 626 N.E.2d 803, 806 (Ind. 1993) (*citing Hollars v. State*, 259 Ind. 229, 236, 286 N.E.2d 166, 170 (Ind. 1972)) (emphasis added). The penalty in the instant case is an administrative penalty, not a criminal penalty. Therefore, an objection based on Section Sixteen is moot.

Assuming *arguendo* that the Cruel and Unusual Punishment Clause does apply, the ten-year suspension in ALJ Buker's Recommended Order does not constitute cruel and unusual punishment. A review of the recommended penalties for Dr. Russell and Dr. Baliga, *supra*, support the recommend suspension of Dr. Wilcox. Dr. Russell's recommended suspension was twenty years for a similar amount of violations and Dr. Baliga's recommended suspension was for five years for four violations. The possession of a machine, also known as an electronic instrument, buzzer, or shocking device, is

considered by Commission Staff as being of the same severity as injecting horses with an unauthorized substance. In fact, it is one of limited number of violations that appear in the Indiana Code and, therefore; specifically considered and adopted by the legislature. *See* Ind. Code § 4-31-12-20(b)(3). Multiple jockeys (Ruben Serna, Dean Sarvis, Juan Guerrero, and Didiel Osorio) who violated the machine regulation have had a ten-year suspension as a recommended penalty. In the last two machine cases, Juan Guerrero and Didiel Osorio each received a ten-year suspension for possession of a machine. Commission Staff has been consistent in asking for a ten-year suspension for severe violations. Therefore, the recommended suspension in ALJ Buker's Recommended Order does not constitute cruel and unusual punishment.

D. The recommended penalty in Administrative Complaint No. 218002 (as amended) is not unsupported by substantial evidence.

The standard of evidence ALJ Buker must follow is stated in Title 71 of the Ind. Admin. Code. 71 IAC 10-2-6(c) provides: "The burden of proof is on the person bringing the complaint to show, by a **preponderance of the evidence**, that the licensee has violated or is responsible for a violation of the Act or a commission rule." (emphasis added). In discussing the preponderance of the evidence standard, the Indiana Supreme Court stated "... it would essentially mean that the State must show that the defendant **'more likely than not'** committed the crime ...." *Fry v. State*, 990 N.E.2d 429, 448, (Ind. 2013), LEXIS 475, 2013 WL 3193328. (emphasis added). The substantial evidence standard is different than the preponderance of the evidence standard. "Substantial evidence is **more than a scintilla, but something less than a preponderance of the evidence**." *State v. Carmel Healthcare Management*, 660 N.E.2d 1379, 1384 (Ind. Ct.

App. 1996) (*citing Department of Natural Resources v. Lehman*, 177 Ind. App. 112, 378 N.E.2d 31, 36 (Ind. Ct. App. 1978)). (emphasis added).

Again, Dr. Wilcox's Objection fails to state a claim as to why ALJ Buker's Recommended Order is unsupported by substantial evidence. We will review the Recommended Order considering the legal standard. The Indiana Supreme Court "give[s] deference to an administrative agency's findings of fact, if supported by substantial evidence." *Huffman v. Ind. Office of Envtl. Adjudication*, 811 N.E.2d 806, 809 (Ind. 2004) (*citing LTV Steel Co. v. Griffin*, 730 N.E.2d 1251, 1257 (Ind. 2000); *Luthern Hosp. of Ft. Wayne v. State Dep't of Public Welfare*, 571 N.E.2d 542, 544 (Ind. 1991)). "Under [the substantial evidence] standard, the reviewing court may vacate a board's decision only if the evidence, when viewed as a whole, demonstrates that the conclusions reached by the board are clearly erroneous." *Regester v. Indiana State Bd. Of Nursing*, 703 N.E.2d 147, 151 (Ind. 1998) (*citing City of Indianapolis v. Hargis*, 588 N.E.2d 496, 498 (Ind. 1992)).

ALJ Buker's Recommended Order was based on testimony from seven witnesses, including Dr. Wilcox, each of whom was subject to cross examination by opposing counsel; the consideration of numerous exhibits, joint stipulations, and judicial notice; and after hearing all of the evidence and weighing the credibility of the witnesses and exhibits provided, ALJ Buker determined that the substantial credible and reliable evidence indicated that Dr. Wilcox did, in fact, violate the administrative rules and statutes that Staff, in the hearing, alleged were violated. For each rule violation ALJ Buker found Dr. Wilcox had violated, ALJ Buker precisely details the evidence and reasoning for holding the rule was violated in his Recommended Order.

E. The recommended penalty in Administrative Complaint No. 218002 (as amended) is not in excess of statutory jurisdiction, authority, or limitations, or short of statutory right.

Again, Dr. Wilcox's Objection fails to state a claim as to why ALJ Buker's Recommended Order is in excess of statutory jurisdiction, authority, or limitations, or short of statutory right. We will review the Recommended Order considering the legal standard. The Indiana legislature granted the Commission the power to adopt rules that prescribe fines and penalties and any other regulation that the commission determines is in the public interest in the conduct of recognized meetings and wagering on horse racing in Indiana. Ind. Code § 4-31-3-9.

The Commission promulgated a regulation that all proceedings, other than disciplinary hearings conducted by the Stewards, "conducted on behalf of the commission shall be conducted in accordance with [Title 71, Article 10 *et seq.*] and with [Ind. Code § 4-21.5, AOPA]." 71 IAC 10-1-1. Another regulation provides for a Commission appointee to serve as an administrative law judge ("ALJ") for a commission proceeding. 71 IAC 10-3-7. A further regulation provides "[a] person shall not participate in pari-mutuel racing under the **jurisdiction** of the commission without a valid license issued by the commission." 71 IAC 5.5-1-1(a) (emphasis added). It further provides that the license categories shall include practicing veterinarians. 71 IAC 5.5-1-1(a)(1).

The parties stipulated to the fact that, all times relevant, Dr. Wilcox was a licensee of the IHRC and held IHRC License No. 960449. The parties further stipulated Dr. Wilcox was, at all times relevant, subject to the rules and statutes regulating pari-mutuel horse racing in the State of Indiana; Dr. Wilcox was a practicing veterinarian at Indiana

Grand Racing and Casino located at 4300 N. Michigan Rd., Shelbyville, IN, 46176 ("Indiana Grand"); and that Indiana Grand is a property under the jurisdiction of the Commission. Therefore, based on the power granted the Commission by the Indiana legislature, the adopted regulations under Title 71 *et seq.*, AOPA, and the stipulations of the parties; Dr. Wilcox was under the statutory jurisdiction and authority, in addition to any legal limitations provided to him (Dr. Wilcox) by law, of the Commission, AOPA, and ALJ Buker. Furthermore, ALJ Buker granted Dr. Wilcox all rights he was due under Indiana law, including AOPA, by faithfully following the statutes and regulations.

F. The recommended penalty in Administrative Complaint No. 218002 (as amended) does not require the effective date of the penalty or consideration of Dr. Wilcox having been under suspension since the Commission proceedings were not criminal in nature and ALJ Buker is not the ultimate authority.

Dr. Wilcox's Objection fails to state a claim as to why ALJ Buker's Recommended Order requires the effective date of the penalty or is required to recognize Dr. Wilcox has been suspended. First and foremost, administrative law hearings are intended to be more informal in nature than criminal or even civil hearings. The Commission promulgated a regulation that all proceedings, other than disciplinary hearings conducted by the Stewards, "conducted on behalf of the commission shall be conducted in accordance with [Title 71, Article 10 et seq.] and with [Ind. Code § 4-21.5, AOPA]." 71 IAC 10-1-1. AOPA does not reference Indiana Code Title 35, Criminal Law and Procedure, which has requirements to advise the person of the number of days of pretrial confinement. AOPA references the Indiana Rules of Trial Procedure for specific rules only dealing with discovery, summary judgment, and special judge selection.

Even Trial Rules dealing with judgment entry do not apply. *See Family Dev., Ltd. v. Steuben County Waste Watchers*, 749 N.E.2d 1243, 1252 (Ind. Ct. App. 2001) ("An administrative agency may elect to follow the Trial Rules, but Indiana courts have long held that the Trial Rules are not mandatory rules of procedure for administrative agencies. Proceedings before administrative boards ... are not required to be conducted like judicial proceedings, even when such proceedings are judicial in nature. Accordingly, the Trial Rules which govern procedure and practice in courts do not apply to proceedings before administrative agencies nor to the proceedings requisite to invoking the jurisdiction of reviewing judicial authority."). *See also Josam Mfg. Co. v. Ross*, 428 N.E.2d 74, 77 (Ind. Ct. App. 1981) ("It seems clear that Trial Rules 26 through 37 are intended to be an exception to the general rule that the Indiana Trial Rules are inapplicable to administrative agencies.").

Furthermore, ALJ Buker is not the ultimate authority in the proceedings. The Commission issues the final order after considering any briefs, oral argument, and the Recommended Order. The Commission has the ultimate authority to set the dates of Dr. Wilcox's suspension. However, there is no provision in AOPA or Title 71 of the Indiana Admin. Code requiring the advisement of the number of days of suspension before a final order is issued.

Therefore, ALJ Buker did not err in omitting the effective date of the penalty nor recognizing the number of days Dr. Wilcox has been suspended.

V. CONCLUSION

Dr. Wilcox's objections to the ALJ's well-reasoned and fully supported Recommended Order are without merit. Accordingly, Commission Staff respectfully

requests that the Commission enter a Final Order affirming in all respects ALJ Buker's Recommended Order of May 2, 2019, and that it impose the penalties recommended therein.

Respectfully submitted,

Noah Jackson, No. 32642-49
Dale Lee Pennycuff, No. 34731-49
Indiana Horse Racing Commission
1302 North Meridian, Suite 175
Indianapolis, IN 46204

Counsel for Indiana Horse Racing Commission Staff

CERTIFICATE OF SERVICE

I hereby certify that before noon on June 21, 2019, I served the following parties with the foregoing Brief electronically, via email:

David P. Murphy
David P. Murphy & Associates, P.C.
504 West Main Street
Greenfield, IN 46140
DPMurphy504@outlook.com

The Honorable Michael Buker
Administrative Law Judge
11185 Windermere Boulevard
Fishers, IN 46037
mbukeralj@gmail.com

Deena Pitman
1302 North Meridian Street, Suite 175
Indianapolis, IN 46202
dpitman@hrc.in.gov

Paper copy available upon request.

Dale Lee Pennycuff

Dale Lee Pennycuff
Counsel
Indiana Horse Racing Commission

AN APPEAL TO THE INDIANA HORSE RACING COMMISSION FROM A RECOMMENDED SANCTION ENTERED BY ADMINISTRATIVE LAW JUDGE THE HONORABLE MICHAEL BUKER APPOINTED BY THE INDIANA HORSE RACING COMMISSION

DR. DUANE WILCOX, Petitioner, v. INDIANA HORSE RACING COMMISSION STAFF, Respondent.	)	In Re: Administrative Complaint No. 218002

BRIEF OF PETITIONER IN SUPPORT OF HIS OBJECTION TO THE ORDER OF THE ADMINISTRATIVE LAW JUDGE DATED MAY 2, 2019

Comes now the Petitioner, Dr. Duane Wilcox ("Dr. Wilcox"), by counsel, and for his Objection to the proposed order of the Administrative Law Judge dated May 2, 2019, and his Request for an Appeal to and a Review by The Indiana Horse Racing Commission says:

I.

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Austin v. United States,
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O'Daniel v. State,
188 Ind. 477, 123 N.E.241, (IND.1919)

Constitutional References:

Indiana Constitution
Article I Section 16

United States Constitution
Amendment Eight
Amendment Fourteen

Statutes:

I.C.4-31-3-1

Administrative Regulations:

71 IAC 5.5-1-3 Multi-state licensing information

71 IAC 5.5-1-15 Reciprocity

III
Statement of the Issue

Whether the recommended sanction of the ALJ to suspend Dr. Wilcox from practicing veterinary medicine at race tracks under the supervision of the Indiana Horse Racing Commission ("The Commission") for a period of ten (10) years violates Amendments 8 and 14 of the United States Constitution and/or Article I, Section 16 of the Indiana Constitution?

IV
Statement of the Case

This case began when the Indiana Horse Racing Commission Staff ("The Staff"), by its Executive Director, Michael D. Smith ("Smith") filed a "Notice of Exclusion" on March 28, 2018 barring Dr. Wilcox from the premises where Indiana Grand Casino and Race Track is located near Shelbyville, Indiana, ("The Track"). The reason cited in the Notice of Exclusion was "X Other".

On April 3, 2018 counsel for Dr. Wilcox served notice on Smith and Holly Newell ("Newell"), counsel for the Staff, of Dr. Wilcox' appeal of the Exclusion Notice and his request for hearing.

On April 5, 2018, The Honorable Michael Buker was appointed by the Indiana Horse Racing Commission ("The Commission") to serve as Administrative Law Judge and hear the appeal.

Judge Buker scheduled a telephonic Pre-hearing Conference for April 10, 2018 at 9:00 am; during that conference counsel and Judge Buker began to formulate the ground rules and the schedule for the appeal by Dr. Wilcox.

Before any substantial progress had been made toward resolving the issues raised in the Exclusion Notice, Smith filed Administrative Complaint No. 218002 on April 27, 2018 seeking to ban Dr. Wilcox from The Track for a period of ten (10) years and fine him $10,000; the Administrative Complaint, under the "Findings of Fact" section, in paragraphs numbered 8 – 21, charged Dr. Wilcox with fourteen (14) separate violations of Indiana Law and the Indiana Administrative Code.

The ALJ took judicial notice of the Notice of Appeal which Dr. Wilcox had filed in the Exclusion Notice case and allowed that Notice of Appeal to serve as a Notice of Appeal in the Administrative Complaint case.

On May 4, 2018, the Parties began Pre-trial Discovery. Over the following five months the Parties conducted pre-trial discovery. In addition, Dr. Wilcox took nine (9) Depositions and the Staff deposed one person, Dr. Michael Ross, the Doctor of Veterinary Medicine identified by Dr. Wilcox as the expert who would testify at trial during his case in chief.

While Discovery was in progress the Staff, on September 21, 2018, filed a "Motion to Amend Administrative Complaint No. 218002". The Amended Complaint also sought to ban Dr. Wilcox from The Track for a period of ten (10) years and to fine him $10,000. In the Amended Complaint the Staff alleged that Dr. Wilcox had violated thirteen (13) separate sections of Indiana Law and the Indiana Administrative Code. The

ALJ ruled that the Notice of Appeal filed by Dr. Wilcox as to the original Administrative Complaint would serve as a Notice of Appeal to the Amended Complaint.

While Discovery was in progress, on or about June 24, 2018, Mr. Michael Morris ("Morris"), the investigator assigned by Smith to prepare the case against Dr. Wilcox, filed a "Consumer Complaint" against Dr. Wilcox with the Attorney General of Indiana which seeks to suspend the license of Dr. Wilcox to practice veterinary medicine in the State of Indiana.

On July 11, 2018, Judge Buker stayed Dr. Wilcox' appeal of the Exclusion Notice pending a resolution of the Administrative Complaint.

The ALJ set the case for trial on December 11, 2018 with two (2) days reserved for the presentation of evidence.

Due to scheduling difficulties trial was not commenced until January 31, 2019 and concluded on February 1, 2019.

At the conclusion of the trial, the ALJ ordered the Parties to submit their purposed Findings of Fact and Conclusion of Law and "a brief with respect to whether or not the use of Sarracenia in this case was appropriate, not appropriate, whether (sic: it) is was grandfathered or not. What I want to know is what is the current state of the law with respect to grandfathered drugs...I'm looking for the legal standard so to the extent you can support it with policy reasons or something, that's fine. I don't want a treatise on this, by any means. I'm looking for the legal standard I need to apply with respect to what constitutes a grandfathered drug".

The ALJ also ordered that recommended orders containing findings of fact, conclusions of law, ultimate findings, and recommended orders should be delivered to him no later than March 4, 2019, at 5:00 PM.

On May 2, 2019, the ALJ entered his findings, Conclusions and Judgment which stated

> **RECOMMENDED ORDER**
>
> Commission Staff may recommend penalties and an administrative law judge may accept, reject or modify the recommended penalty. 71 IAC 10-3-12(f). The ten (10) year suspension and fine of Ten Thousand Dollars ($10,000) recommended against Dr. Wilcox in the Amended Complaint are each reasonable in light of the substantial, credible and reliable evidence presented during the Hearing. Having considered all of the facts and evidence presented by the parties, including facts in mitigation, I hereby recommend that a Final Order be entered by the Indiana Horse Racing Commission in favor of the Indiana Horse Racing Commission Staff and against Dr. Wilcox affirming Administrative Complaint No. 218002 (as amended) in all material respects with respect to Paragraphs 9 (as set forth in the Summary Judgment Order), 12, 14 and 16-20 and sanctions be adopted recommending that Dr. Wilcox:
>
> (a) Be suspended for a period of ten (10) years, and
>
> (b) Be fined in the amount of Ten Thousand Dollars ($10,000).
>
> Pursuant to I.C. § 4-21.5-3-29(d), Dr. Wilcox has fifteen (15) calendar days following receipt of this Recommended Order

to file written exceptions with the Indiana Horse Racing Commission.

On May 16, 2019, Dr. Wilcox filed this appeal and request for review by the Commission.

V

Statement of the Facts Relevant to the Issue

The Staff filed an Administrative Complaint against Dr. Wilcox on April 27, 2018, charging him with violations of Indiana Code and the Indiana Administrative Code in fourteen separate paragraphs.

On September 21, 2018 the Staff filed an Amended Complaint against Dr. Wilcox charging him with violations of Indiana Code and the Indiana Administrative Code in thirteen (13) separate paragraphs.

On November 5, 2018 The Staff and Dr. Wilcox filed Motions for Summary Judgment and for Partial Summary Judgment, respectively.

On January 14, 2019, the ALJ granted paragraph 9 of the Staff's Motion and denied the balance of its Motion. The ALJ denied Dr. Wilcox' Motion completely. During the trial, the Staff withdrew paragraphs 8, 10, 11 and 15 of the Amended Complaint and failed to present any evidence regarding paragraph 13. The ALJ considered paragraph 13 to be withdrawn.

Dr. Wilcox testified at trial and the transcript of his Deposition taken on September 18, 2018 was entered into evidence and considered by the ALJ. (See

proposed "Findings of Fact, Conclusion of Law and Recommended Order" by the ALJ dated May 2, 2019, Page 6).

Dr. Wilcox presented evidence that at the time of trial he was 57 years old (Record page 252, lines 12-13), had been practicing veterinary medicine since he graduated from Purdue in 1986 (Record, page 253, lines 16-19) and had specialized in treating large animals (Deposition Transcript of Dr. Duane Wilcox Page 7, Lines 23-25;Record, page 253, lines 2-4). He testified that he had been suspended for the previous year, 2018, from practicing veterinary medicine at any track supervised by the IHRC. He estimated his lost income at approximately $300,000. (Record Page 271, Lines 8-9). Dr. Wilcox also testified that he had borrowed $278,000 from his life insurance since March of 2018 and paid more than $15,000 in credit card interest, "trying to survive". (Record Page 271, Lines 10-14).

Dr. Wilcox testified that he lived on a farm near Homer Glenn, Illinois (Record Page 260, Lines 9-15), that his family consisted of a wife and teenage son who was a sophomore in high school at the time of trial (Record Page 264, Lines 15-22) and raised Percheron draft horses (Record Page 260, Lines 23-25; Page 261, Lines 1-25).

Dr. Wilcox further testified that after the Notice of Exclusion he tried to find work at Churchill Downs, Kentucky but could not because of the continuing "unresolved issue in Indiana". He testified that the Stewards at Churchill Downs were going to abide by all of Indiana's rulings and that he was not allowed to be on the grounds or to treat horses off the grounds that were shipping in to race at Churchill Downs. (Record Page 271, Lines 17-25; Page 272, Lines 1-2; Page 1-15). Dr. Wilcox testified that he had lost more

than $100,000 because of the Kentucky's reciprocal enforcement of Indiana's Notice of Exclusion. (Record Page 272, Lines 16-20).

Dr. Wilcox testified that most of his work was outside the state of Indiana (Deposition Transcript of Dr. Duane Wilcox Page 10, Lines 1-4). He also testified that prior to the Notice of Exclusion, he had worked at The Track in the summer and at Turfway Park in Kentucky in the winter, living in a camper near Shelbyville when he was working at The Track. (Record Page 264, Lines 21-23; Page 265, Lines 12-25; Page 266, Lines 1-5). He also testified that his son wants to become a large animal veterinarian. (Record Page 264, Lines 24-25; Page 265, Line 1).

Dr. Wilcox testified that he was licensed to practice veterinary medicine in Indiana, Illinois, Kentucky, Georgia, Florida (Deposition Transcript of Dr. Duane Wilcox Page 9, Lines 15-20).

Dr. Wilcox also testified that if he is suspended for ten (10) years from practicing at The Track because of the reciprocal agreement between Indiana and other states with racetracks allowing pari-mutual betting, he could not work at any race-track in Illinois, Kentucky, Georgia, and Florida until he was 67 years old. (Record Page 272, Lines 21-25; Page 273, Lines 1-3).

Finally, Dr. Wilcox also testified that after the Staff filed its original Complaint, the Staff Investigator, Michael Morris, filed a "Consumer Complaint" against him with the Attorney General of Indiana which seeks to suspend his license to practice veterinarian medicine in Indiana. (Record Page 273, Lines 16-25; Page 274, Lines 1-13). Dr. Wilcox testified that any such suspension of his license to practice veterinary medicine in

Indiana would render him completely unemployable because any such suspension likewise be reciprocally enforced by other states. (Record Page 274, Lines 14-25; Page 275, Lines 1-4).

The Staff did not present any evidence to rebut the accuracy of Dr. Wilcox' testimony.

The Staff argued that the evidence presented in support of the charges contained in paragraphs 9, 12, 14, 16, 17, 18, 19 and 20 supported its recommended penalty of a $10,000 fine and a suspension from facilities supervised by the IHRC for a period of ten (10) years. (Record Pages 374-375)

Following trial, the Parties submitted proposed Findings, Conclusions and proposed Orders.

On May 2, 2019 ALJ entered Proposed Findings of Fact, Conclusions of Law and Recommended Order in favor of the Staff as to the charges contained in paragraphs 9 (as set forth in the Summary Judgment Order) 12, 14 and 16- 20. The ALJ also recommended that sanctions be adopted recommending that Dr. Wilcox:

(a) Be suspended for a period of ten (10) years, and,

(b) Be fined in the amount of $ 10,000 dollars

VI

Summary of Argument

A

Amendments 8 and 14 of the United States Constitution prohibit the imposition of excessive fines and penalties in civil cases where a State has the power to extract payments, whether in cash or in kind, as punishment for some offense.

B

The Commission is an agency of the State of Indiana.

C

The United States Supreme Court in the case of *Timbs v Indiana*, 139 S. Ct. 682 (2019) decided February 20, 2019, held that the State of Indiana may not forfeit a vehicle worth only $42,000 in a case where the maximum penalty which could be imposed upon the defendant was only $10,000 because the amount of any penalty imposed by a State must be proportionate to the violation charged.

D

Article One, Section 16 of the Constitution of Indiana also prohibits the imposition of excessive fines by the State of Indiana.

E

Indiana is a Participating Jurisdiction with the Members of the Interstate Compact on Licenses of Participants in Horse Racing with Pari-Mutuel Wagering ("Compact").

F

The uncontradicted evidence established that at the time of trial Dr. Wilcox was 57 years old, married, the sole support for this Wife and his teenage son and had been a practicing a large animal veterinarian for more than thirty (30) years. The Staff did not offer evidence to rebut Dr. Wilcox' testimony that he has lost approximately $300,000 in income as a result of the suspension, both at racetracks in Indiana and in other states. Nor did the Staff offer evidence to challenge Dr. Wilcox' evidence that the reciprocal enforcement of the Indiana suspension by the Members of the Compact has prevented him from working at any racetrack in twenty-two (22) other states.

G

Suspending Dr. Wilcox from The Track for a period of ten (10) years has the effect of also suspending him for a period of ten (10) years from all racing establishments controlled by Members and Participating Jurisdictions of the Compact. A 10-year suspension from The Track, reciprocally enforced by Participating Jurisdictions and Members of the Compact is not reasonably related to any legitimate objective of the Staff in Indiana and is purely punishment. Such a broadly applied sanction violates the prohibition against Excessive Fines and Penalties Clauses contained Amendments 8 and 14 of the United States Constitution and Article 1, Section 16 of the Indiana Constitution.

VII

Argument

A

Amendment 8 to the Constitution of the United States provides:

> Excessive bail shall not be required, **nor excessive fines imposed**, nor cruel and unusual punishments inflicted. (**Emphasis** supplied.)

Amendment 14 of the Constitution of the United States provides:

> All persons born or naturalized in the United States, and subject to the jurisdiction thereof, are citizens of the United States and of the State wherein they reside. **No State shall make or enforce any law which shall abridge the privileges or immunities of citizens of the United States; nor shall any State deprive any person of life, liberty, or property, without due process of law; nor deny to any person within its jurisdiction the equal protection of the laws.** (**Emphasis** supplied.)

The United States Supreme Court has specifically applied this prohibition against "excessive fines" to all the States and very recently to Indiana in particular through the Due Process Clause of Amendment 14.

B

The Commission is an agency of the state of Indiana, having been created by an Act of the General Assembly. That statute is found at I.C. 4-31-3-1 and provides that

> "The Indiana horse racing commission is established. The commission consists of five (5) members appointed by the governor".

As an agency of the State of Indiana the limitation contained in Amendments 8 and 14 of the U.S. Constitution and Article 1 Section 16 of the Indiana Constitution apply to orders it issues. *Timbs v State of Indiana* (supra) at page 687 of the Supreme Court Reporter.

C

On February 20, 2019, in the case of *Timbs v. State of Indiana*, (139 S.Ct. 682), (2019) the United States Supreme Court, by a vote of 9-0, reversed a decision of the Indiana Supreme Court and which had approved the forfeiture of a motor vehicle valued at $42,000 from a defendant in a criminal case where the maximum fine could only be $10,000.

That defendant, Tyson Timbs, had pleaded guilty in the Grant Superior Court to dealing in a controlled substance and conspiracy to commit theft. That Court sentenced Timbs, pursuant to a plea agreement, to six years' incarceration, with one year executed in community corrections and five years suspended to probation. Timbs also agreed to pay police costs of $385, a drug interdiction fee of $200, court costs of $168, a bond fee of $50 and a $400 certified court program fee after undergoing a drug and alcohol assessment with the probation department. The maximum monetary fine assessable against Timbs for his drug conviction was $10,000. The State then sought to forfeit the defendant's vehicle, a 2012 Land Rover LR2, which he had purchased with

the proceeds of a life insurance policy on his late father. The Trial Court denied the State's application and determined such a forfeiture would be grossly disproportionate to the gravity of the defendant's offense, and therefore unconstitutional under the Eighth Amendment's Excessive Fines Clause. The Indiana Court of Appeals agreed and affirmed the trial court's denial of forfeiture.

The Court of Appeals held that

> "Forfeiture of the Land Rover, which was worth approximately four times the maximum permissible statutory fine, was grossly disproportionate to the gravity of Timbs' offense" *State v. Timbs,* 62 N.E.3d 472,477 (Ind.Ct.App. 2016).

The State sought transfer to the Indiana Supreme Court.

On transfer, the Indiana Supreme Court reversed the decision of the Court of Appeals and held that

> "Indiana is a sovereign state within our federal system, and we elect not to impose federal obligations on the State that the federal government itself has not mandated. An important corollary is that Indiana has its own system of legal protections, including constitutional, for its citizens and other persons within its jurisdiction. Absent a definitive holding from the Supreme Court, we decline to subject Indiana to a *federal* test that may operate to impede development of our own excessive-fines jurisprudence under the Indiana Constitution." *State v. Timbs*, 84 N.E.3d 1179,1183,1184) (Ind. 2017) (*Emphasis* by the Indiana Supreme Court.)

The U.S. Supreme Court accepted an appeal from Timbs and reversed the decision of the Indiana Supreme Court. In a unanimous decision, the U.S. Supreme Court held

"Like the Eighth Amendment's proscriptions of "cruel and unusual punishment" and "excessive bail," the protection against excessive fines guards against abuses of government's punitive or criminal-law-enforcement authority. **This safeguard, we hold, is "fundamental to our scheme of ordered liberty," with "deep roots in our history and tradition.**" *McDonald v. Chicago*, 561 U. S. 742, 767, 130 S. Ct. 3020, 177 L. Ed. 2d 894 (2010). The Excessive Fines Clause is therefore incorporated by the Due Process Clause of the Fourteenth Amendment...."

Continuing, the U.S. Supreme Court held that

"Under the Eighth Amendment, "excessive bail shall not be required, nor excessive fines imposed, nor cruel and unusual punishments inflicted. " **Taken together, these Clauses place "parallel limitations" on "the power of those entrusted with the criminal-law function of government.**" (citing cases) **Directly at issue here is the phrase "nor excessive fines imposed," which "limits the government's power to extract payments, whether in cash or in kind, 'as punishment for some offense'".** The Fourteenth Amendment, we hold, incorporates this protection....

The Excessive Fines Clause traces its venerable lineage back to at least 1215, when Magna Carta guaranteed that "[a] Freeman shall not be amerced for a small fault, but after the manner of the fault; and for a great fault after the greatness thereof, saving to him his contenement . . . ." (citing authorities). As relevant here, Magna Carta required that economic sanctions **"be proportioned to the wrong" and "not be so large as to deprive [an offender] of his livelihood."** *Browning-Ferris*, 492 U. S., at 271. See also 4 W. Blackstone, Commentaries on the Laws of England 372 (1769) ("**No man shall have a larger amercement imposed upon him, than his circumstances or personal estate will bear.**") ...

In short, the historical and logical case for concluding that the Fourteenth Amendment incorporates the Excessive Fines Clause is overwhelming. **Protection against excessive**

> **punitive economic sanctions secured by the Clause is, to repeat, both "fundamental to our scheme of ordered liberty" and "deeply rooted in this Nation's history and tradition."**
> (**Emphasis** supplied.)

Indiana has long observed the same prohibition against excessive fines.

D

As early as 1919, the Supreme Court of Indiana held that Article One, Section 16 of the Indiana Constitution prohibited excessive fines. In the case of *O'Daniel v. State*, 188 Ind. 477, 123 N.E. 241, (IND.1919) the Defendant appealed a judgment of the Marion Criminal Court which convicted him of arson under § 2260 Burns 1914, Acts 1905 p. 584, § 371. The only evidence of ownership and value of the building was a stipulation at the outset of the evidence. That stipulation did not fix any time of ownership. Defendant himself could have been the owner. The lack of evidence as to ownership and value at the time in question was fatal to the conviction. The Indiana Supreme Court reversed the judgment of conviction and remanded the case for a new trial, holding that

> The questions arise on motion for a new trial: (1) Error in permitting evidence of insurance and proof of loss concerning certain personal property which appellant had in the building. **(2) That the evidence does not show in dollars and cents what damage was done to the building, and therefore did not authorize a fine of $ 1,000.** (3) That the ownership and value of the building, on December 10, 1916, is not shown by the evidence...

> As the law now stands, the fine may be double the value of the structure, **subject always, however, to § 16 of the Bill of Rights (Art. 1, § 16, Constitution of Indiana), against excessive fines.** (**Emphasis** added.)

Dr. Wilcox respectfully contends that in this case, the 'excessive' nature of the fine, (i.e. the suspension) is found in its almost nationwide application.

E

Indiana is a Participating Jurisdiction (not a Member) in the "Interstate Compact on Licenses of Participants in Horse Racing with Pari-Mutuel Waging". The Compact is an agreement among fifteen (15) states pursuant Article 1, Section 10, Subsection 3 of the United States Constitution.

The member states are Arizona, California, Delaware, Florida, Kentucky, Louisiana, Maryland, Nebraska, New Jersey, New Your, Ohio, Oklahoma, and West Virginia. Each of these states has enacted legislation allowing it to enter into an agreement with the other states for the purpose of, among other things, "establishing uniform requirements among the Party states for the licensing of participants in live racing with pari-mutuel waging".

Indiana is one (1) of eight (8) states who "participates" in the activities of the Compact, the other participating states being Arkansas, Illinois, Iowa, Michigan, Pennsylvania, Texas and Wyoming. In order to "participate" in the Compact, Indiana has enacted several sections of the Indiana Administrative Code which permit that participation.

The reciprocating regulations which have been enacted by Indiana include:

> (1) 71 IAC 5-1-2 Fingerprinting and Licensing Reciprocity, which allows the Commission to license persons holding valid permanent (not temporary) licenses issued by ARCI member racing jurisdictions in North America. Prior to being licensed, the person must comply with other various requirements set forth in the statute;
>
> (2) 71 IAC 5.5-1-3 Multi-state licensing information, which allows the Commission to accept an ARCI Multi-State License and Information Form and the National Racing Compact form and license in lieu of a license application from this jurisdiction; and
>
> (3) 71 IAC 5.5-1-15 Reciprocity provides that if a person is suspended, expelled, or ruled off, or if his or her license is revoked or his or her application for a license has been denied, or he or she is under any other current penalty pursuant to the rules of the racing authority of any other state or country or of the gaming commission, such person shall stand suspended, expelled, ruled off, or denied a license at all tracks and satellite facilities operating under the jurisdiction of the Commission until the ruling has been withdrawn by the originating authority.

It is Indiana's status as a "Participating Jurisdiction" which requires states such as Kentucky to deny Dr. Wilcox a license to practice veterinary medicine at any racetrack under the supervision of the Kentucky Racing Commission, including Churchill Downs for so-long as this Commission suspends him from any racetrack under its supervision.

F

The sanction recommended by the ALJ did not take into account the economic penalty already suffered by Dr. Wilcox, nor did it consider the economic hardship Dr. Wilcox will suffer for the next ten (10) years if this Commission sustains the recommendation by the ALJ. At trial, when Dr. Wilcox began to present the evidence of

his lost income caused by the Notice of Exclusion, the following exchange occurred between counsel and the ALJ:

> Q Can you estimate for us how much income you have lost solely from not being able to work at Indiana Grand in the 2018 meet?
>
> A May I refer to some papers.
>
> Q If you wish, yes, please do.
>
> MR. JACKSON: Your Honor, I object that this is not relevant to the charges at hand.
>
> MR. MURPHY: We're contending that the penalty proposed is draconian and totally out of line. And one of the ways of measuring that is how much he has already been punished, the loss he has already suffered.
>
> **ADMINISTRATIVE LAW JUDGE BUKER: Let's not go far down this road.**
> (**Emphasis** supplied)
>
> See page 270, lines 8-21 of the Record.

With all due respect, that comment, coupled with the omission from the Findings and Conclusions Law concerning the economic hardship already suffered and to be suffered by Dr. Wilcox is evidence that the ALJ ***did not consider*** what the Supreme Court found to be of paramount importance in *Timbs* (supra) concerning the due process requirement that the punishment must fit the crime. At page 687 of the Supreme Court Reporter the Supreme Court held

> As relevant here, Magna Carta required that economic sanctions "be proportioned to the wrong and not be so large as to deprive [an offender] of his livelihood....No man shall have a larger amercement imposed upon him, than his circumstances or his personal estate will bear. "

Dr. Wilcox provided a detailed description of himself, his professional practice, his history in the practice, his focus on large animals, particularly horses, his family and financial obligations to his wife and son and, finally, his age. The Staff did not present any evidence in rebuttal, instead choosing to stand on the argument that a severe penalty is appropriate for the sake of being a severe penalty. With all due respect, that is the same argument made by the State of Indiana in *Timbs* (supra) which was rejected by the U.S. Supreme Court by a vote of 9-0.

What makes the proposed ten (10) year suspension an "excessive fine" in violation of the Constitutions of the United States and the State of Indiana is the reciprocal effect the suspension will have in at least twenty-two (22) other states.

G

As established by Dr. Wilcox' testimony, the decision of the Stewards at Churchill Downs, not to allow Dr. Wilcox to practice there or at any other track supervised by the Kentucky Racing Commission, is based on the decision of the Indiana Commission to suspend Dr. Wilcox from race tracks in Indiana. All other Members and Participating Members of the Compact can be expected to follow that decision and to ban Dr. Wilcox from their tracks until his suspension in Indiana is lifted. This undeniable fact was not mentioned by the ALJ in his Proposed Findings, even though the Staff did not challenge Dr. Wilcox' testimony on this point.

Clearly, the Commission must consider this entirely predictable result when it renders a decision in this appeal. A suspension of Dr. Wilcox from tracks supervised by

the Commission in order to enforce its rules and regulations is reasonable. A suspension of Dr. Wilcox from racetracks in twenty-two (22) ***other*** states is not reasonable. It is punitive and an obvious example of an "excessive fine" of the type struck down by the U.S. Supreme Court in *Timbs v State of Indiana*. It is significant that the decision in *Timbs (supra)* was rendered on February 20, 2019, only three (3) weeks after the trial in this case concluded. It is also important to remember that only a $42,000 automobile was at stake in *Timbs (supra*). In this case the ability of Dr. Wilcox to earn a living and support his family is at stake. The ten (10) year suspension proposed by the ALJ is, in effect, an economic forfeiture of Dr. Wilcox' right to practice veterinary medicine at racetracks outside of Indiana.

In 1215 when the English barons forced King John to end his rule of tyranny, one of the most important paragraphs in the Magna Carta established for all time in the Western world the principle that "economic sanctions must be proportioned to the wrong and not be so large as to deprive an offender of his livelihood" and that "no man shall have a larger amercement (sic: crippling economic punishment) imposed upon him than his circumstances or personal estate will bear". The U.S. Supreme Court in *Timbs (supra)* chose to incorporate that language in its decision in order to emphasize that "protection against excessive punitive economic sanctions" is "fundamental to our scheme of ordered liberty and deeply rooted in this nation's history and tradition"

Any sanction imposed on Dr. Wilcox must not include a ten (10) year suspension of employment at racetracks supervised by the Commission.

VIII

Conclusion

Dr. Wilcox has been suspended from practicing veterinarian medicine at any racetrack supervised by the Commission since March 2018. Given that it is unlikely this case will be concluded before the end of the racing season in 2019, Dr. Wilcox will have lost income for that year as well. The uncontradicted evidence is that his loss of income for these two (2) years will be approximately $600,000. The longer the suspension remains in force the more of an economic penalty he will suffer. The most severe penalty however, as detailed above, is the reciprocal enforcement of the Notice of Exclusion by the twenty-two (22) other states who are Members of the Compact. There is no reasonable relationship between the violations established at trial and the necessity for a ten (10) year, nearly nationwide suspension from the practice of veterinary medicine at racetracks by Dr. Wilcox.

Dr. Wilcox respectfully requests that any suspension imposed by the Commission be effective as the date of the Notice of Exclusion and terminate on December 31, 2019. Anything more severe, with all due respect, violates the general prohibitions against excessive fines contained in the Constitutions of the United States and State of Indiana and the specific holding of the United States Supreme Court in *Timbs* (supra).

Respectfully submitted,
DAVID P. MURPHY & ASSOCIATES, P.C.

By: /s/David P. Murphy, 9388-30
Counsel for Petitioner

CERTIFICATE OF SERVICE

I hereby certify that a copy of the above and foregoing has been served upon the following via e-mail and US Mail, first class, postage pre-paid this 21st day of June 2019.

Deena Pitman
dpitman@hrc.IN.gov

Michael Buker
Administrative Law Judge
11185 Windermere Blvd
Fishers, IN 46037
mbukeralj@gmail.com

Dale Lee Pennycuff
Indiana Horse Racing Commission Staff
1302 N. Meridian, Suite 175
Indianapolis, IN 46202
DPennycuff@hrc.IN.gov

Noah Jackson
Indiana Horse Racing Commission Staff
1302 N. Meridian, Suite 175
Indianapolis, IN 46202
NJackson1@hrc.IN.gov

By:/s/David P. Murphy, 9388-30
Counsel for Petitioner

DAVID P. MURPHY & ASSOCIATES, P.C.
Attorneys at Law
504 West Main Street
Greenfield, IN 46140
317.462.2222
Dpmurphy504@outlook.com

BEFORE THE INDIANA HORSE RACING COMMISSION

2019 MAY 22 P 2:25

INDIANA HORSE RACING COMM

DR. DUANE WILCOX,

Petitioner,

v.

INDIANA HORSE RACING COMMISSION STAFF,

Respondent.

In Re: Administrative Complaint No. 218002 (as amended)

NOTICE OF OPPORTUNITY TO PRESENT BRIEFS AND ORAL ARGUMENT

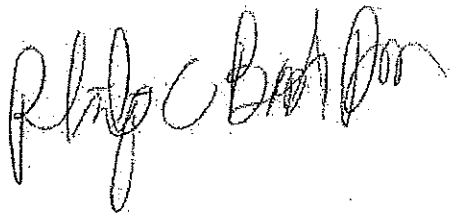
This matter is pending before the Indiana Horse Racing Commission ("Commission") on the Recommended Administrative Penalty against Dr. Duane Wilcox ("Dr. Wilcox"). On May 2, 2019, the Administrative Law Judge designated by the Commission, Michael Buker ("ALJ Buker"), issued his Proposed Findings of Fact, Conclusions of Law, and Recommended Order ("Recommended Order") in this case. On May 16, 2019, the Commission received Dr. Wilcox's Objections to ALJ Buker's Recommended Order.

Notice is hereby given that the Commission will afford both parties an opportunity to present briefs concerning the filing of Dr. Wilcox's objections and the merits of this case. Any briefs filed by Dr. Wilcox or the Commission Staff must be received in the offices of the Commission by noon on June 21, 2019. The Commission will accept electronic filing at dpitman@hrc.IN.gov. No late filings will be accepted and/or considered.

After the submission of briefs, the Commission will also consider oral argument at its meeting to be held on TBD. The oral argument will be limited to ten minutes per side.

SO ORDERED, 22nd day of May, 2019.

THE INDIANA HORSE RACING COMMISSION



By:_____

Philip C. Borst
Chairperson
Indiana Horse Racing Commission

Copies forwarded by electronic mail on May 22, 2019:

Noah Jackson
Deputy General Counsel
Indiana Horse Racing Commission
1302 North Meridian, Suite 175
Indianapolis, Indiana 46202
NJackson1@hrc.IN.gov

Dale Lee Pennycuff
Counsel
Indiana Horse Racing Commission
1302 North Meridian, Suite 175
Indianapolis, Indiana 46202
DPennycuff@hrc.IN.gov

David P. Murphy
David P. Murphy & Associates, P.C.
504 West Main Street
Greenfield, Indiana 46140
DPMurphy504@outlook.com

BEFORE AN ADMINISTRATIVE LAW JUDGE
THE HONORABLE MICHAEL BUKER
APPOINTED BY THE INDIANA HORSE RACING COMMISSION

2019 MAY -2 P 3:55

DR. DUANE WILCOX	)	
	)	
Petitioner,	)	In Re: Administrative
	)	Complaint No. 218002
v.	)	(as amended)
	)	
INDIANA HORSE RACING	)	
COMMISSION STAFF,	)	
	)	
Respondent.	)	

PROPOSED FINDINGS OF FACT, CONCLUSIONS OF LAW, AND RECOMMENDED ORDER

This matter came before the Administrative Law Judge, the Honorable Michael Buker for hearing on Administrative Complaint No. 218002, issued by the Indiana Horse Racing Commission Staff ("Commission Staff") against Petitioner, Dr. Duane Wilcox, DVM. On January 31, 2019 and February 1, 2019, ALJ Buker conducted a hearing in this matter (the "Hearing"). The Commission Staff was represented by IHRC Deputy General Counsel Noah Jackson and Counsel Dale Lee Pennycuff. Respondent was represented by his counsel, David P. Murphy of David P. Murphy & Associates. The ALJ, having considered the administrative record, the arguments of the parties, having conducted the Hearing, and being in all respects duly advised, now issues the accompanying Findings of Fact, Conclusions of Law, and Recommended Order.

BACKGROUND AND PROCEDURAL SETTING

Dr. Wilcox is a practicing veterinarian who was at all times relevant licensed by the Indiana Horse Racing Commission ("IHRC") to practice at its race tracks in Indiana. On April 27, 2018, IHRC Staff filed Administrative Complaint number 218002 against Wilcox under 71 IAC 10-3-

20 alleging a number of violations of the IHRC rules governing horse racing activities in Indiana.[1] Wilcox timely requested a hearing under 71 IAC 10-3-20(d). On September 21, 2018, IHRC Staff moved to amend its original complaint, which was granted (the "Amended Complaint").[2] The Amended Complaint included thirteen alleged violations by Wilcox set forth generally as Paragraphs 8-20[3] thereof. The Amended Complaint recommends that Dr. Wilcox (1) be suspended and remain ineligible for licensure for a period of ten years and (2) be fined in the amount of $10,000.

Following discovery, both IHRC Staff and Wilcox timely filed motions for partial summary judgment to resolve certain allegations set forth in the Amended Complaint. A Recommended Order Regarding Summary Judgment and Ancillary Motions ("Summary Judgment Order") was issued on January 14, 2019, granting Commission Staff's motion with respect to Paragraph 9 and denying summary judgment with respect to all other charges.[4]

The parties agreed to the authenticity, relevance, and admissibility of the following exhibits:

A. Dr. Wilcox's 2016 IHRC application for a Practicing Veterinarian License, dated March 9, 2016.

[1] The Executive Director of the IHRC filed an Exclusion Notice against Wilcox on April 3, 2018, for which Wilcox timely requested a hearing. IHRC Staff filed an Administrative Complaint on April 27, 2018, alleging many of the violations on which the Exclusion Notice was based, and to which Wilcox was deemed to have filed a timely request for hearing. On July 11, 2018, based on agreement of all parties, the resolution and further prosecution of the Exclusion Notice was stayed pending resolution of the this matter (during which time the Exclusion Notice order remains in effect). Because the two actions were pursued concurrently while settlement was attempted, the captioning of this matter remained as it was originally filed under the Exclusion Hearing matter (i.e., Wilcox as Petitioner and IHRC Staff as Respondent) in order to reduce confusion.

[2] Wilcox was granted an opportunity to object to the Amended Complaint, which he elected to not do. His timely request for hearing with respect to the original complaint was treated as a timely request for hearing with respect to the Amended Complaint.

[3] References to Paragraph(s) herein are to paragraph(s) in the Amended Complaint.

[4] A copy of the Summary Judgment Order is hereby incorporated and made part of this Recommended Order.

B. Dr. Wilcox's 2017 IHRC application for a Practicing Veterinarian License, dated April 7, 2017.

C. 2017 Checklist – Practicing Veterinarians IHRC License signed by Dr. Wilcox on April 7, 2017.

D. Administrative Law Judge Assignment Letter to the Honorable Michael Buker, dated May 4, 2018.

E. Request for Hearing filed by Dr. Wilcox's counsel, David P. Murphy, dated May 2, 2018.

F. Transcript of Dr. Wilcox deposition taken on September 18, 2018.

G. Transcript of Penny Loudermilk deposition taken on September 27, 2018.

H. Transcript of Roy Moore deposition taken on September 27, 2018.

I. Transcript of Saul Perez deposition taken on September 27, 2018.

J. Final Order of the Indiana Horse Racing Commission re: Administrative Complaint No. 217004, dated September 15, 2017.

K. Photographs of "P-Bloc" formula container and substance supplied at Dr. Wilcox's deposition.

L. Exhibit Nos. 2-6 identified on the Final Exhibit List of Petitioner.

Not all of these exhibits were offered at the Hearing.

The parties agreed to the following stipulations of fact:

A. At all times relevant Dr. Wilcox was a licensee of the IHRC and held IHRC License No. 960449.

B. Dr. Wilcox was, at all times relevant, subject to the rules and statutes regulating pari-mutuel horse racing in the State of Indiana.

C. Dr. Wilcox was a practicing veterinarian at Indiana Grand Racing & Casino located at 4300 N. Michigan Rd., Shelbyville, IN, 46176 ("Indiana Grand").

D. Indiana Grand is a property under the jurisdiction of the Commission.

E. In 2016, Dr. Wilcox was disciplined (Stewards Ruling #16594) for administering furosemide ("Lasix") to a horse not scheduled to receive it and for failing to timely administer Lasix to a horse that was scheduled to receive it. He was fined $1,000 and paid the fine. He did not appeal.

F. On September 15, 2017, Dr. Wilcox was disciplined for failing to keep proper treatment and billing records. A Final Order finding in favor of Commission Staff in Administrative Complaint No. 217004 was issued by the Commission in which Dr. Wilcox was fined $1,000. He paid the fine and did not appeal.

G. Trainer Penny Loudermilk and Roy Moore were clients of Dr. Wilcox during the 2016 racing season and used him to administer Lasix to horses under their care.

H. In 2017, Dr. Wilcox administered a substance he described as "plus" (or "+") in injectable form to horses under his care.

I. A bottle of "P-Bloc," labeled by the compounding pharmacy, Rapid Equine Solutions of Aston, PA, was provided to Commission Staff at the deposition of Dr. Wilcox on September 18, 2018.

J. Dr. Wilcox never sought permission from stewards or Commission Staff prior to administering the "plus" to horses under Commission jurisdiction.

K. Dr. Wilcox withheld the contents of the "plus" formula from Commission Staff during an interview, conducted on April 4, 2018, by former Commission counsel Holly Newell.

L. Dr. Wilcox stated that the formula was proprietary in explaining his decision to withhold its contents from Holly Newell.

M. At his deposition, Dr. Wilcox stated that the proprietary nature of the formula was how it was put together with Vetalog or Predef.

Official notice was taken of certain published Food and Drug Administration ("FDA") materials commonly known as the FDA Green Book and the FDA Orange Book (and related databases).

As set forth above, Summary Judgment was issued in favor of the Commission Staff and against Dr. Wilcox with respect to Paragraph 9. During the Hearing, Commission Staff withdrew Paragraphs 8, 10, 11 and 15. Evidence was not presented with respect to Paragraph 13, and thus it will be treated as having been withdrawn by Commission Staff. In its expanded Finding of Facts in support of the Amended Complaint, Commission Staff identified 75 specific incidents in support of each violation alleged under Paragraphs 16 – 20. In support thereof, Commission Staff presented evidence establishing a pattern of behavior that violates Commission rules under each Paragraph; i.e.; no evidence was presented with respect to each of the 75 alleged occurrences identified in the expanded Findings of Fact. This Recommended Order is issued with respect to Paragraphs, 12, 14 and 16-20 as discussed below and incorporates the Summary Judgment Order with respect to Paragraph 9. During the Hearing, Commission Staff bore the burden of persuasion and the burden of going forward under IC 4-21.5-3-14(c).

EXHIBITS ADMITTED DURING THE HEARING

Commission Staff's Exhibits:

Commission Staff Exhibit A. Dr. Wilcox's 2017 IHRC application for a Practicing Veterinarian License, dated April 7, 2017.

Commission Staff Exhibit B. 2017 Checklist – Practicing Veterinarians IHRC License signed by Dr. Wilcox on April 7, 2017.

Commission Staff Exhibit C. Transcript of Dr. Wilcox deposition taken on September 18, 2018.

Commission Staff Exhibit D. Transcript of Saul Perez deposition taken on September 22, 2018.

Commission Staff Exhibit E. Final Order of the Indiana Horse Racing Commission re: Administrative Complaint No. 217004, dated September 15, 2017.

Commission Staff Exhibit F. Photographs of "P-Bloc" container and substance supplied at Dr. Wilcox deposition.

Commission Staff Exhibit G. Affidavit of Dr. Scot Waterman, DVM, dated October 24, 2018.

Commission Staff Exhibit H. Excerpts of the FDA Green Book.

Commission Staff Exhibit I. Excerpts of the FDA Orange Book.

Commission Staff Exhibit J. Label of "P-Bloc" manufactured and marketed by Creative Science, LLC, of Ballwin Missouri.

Commission Staff Exhibit K. Administrative Complaint No. 218002, issued April 27, 2018, by IHRC against Dr. Duane Wilcox, DVM.

Commission Staff Exhibit L. Amended Administrative Complaint No. 218002, issued September 21, 2018, by IHRC against Dr. Duane Wilcox, DVM.

Commission Staff Exhibit M. Excerpts of Indiana Administrative Code Title 71, showing the rules at issue in this hearing.

Commission Staff Exhibit N. Excerpts of Dr. Wilcox's records dated October, 2017, created following the September 15, 2017, Final Order.

Commission Staff Exhibit O. Transcript of Dr. Michael Ross deposition, taken December 14, 2018.

Commission Staff Exhibit P. Affidavit of Saul Perez, dated October 24, 2018 and all exhibits attached thereto.

Commission Staff Exhibit Q. Excerpt of deposition of Dr. Duane Wilcox on September 18, 2018.

Commission Staff Exhibit T. Summary document labeled "Appendix A" created by Commission Staff showing the specific recordkeeping violations on each page of records supplied by Dr. Wilcox.

Dr. Wilcox's Exhibits:

Dr. Wilcox's Exhibit 1. Transcript of deposition of IHRC Executive Director Michael Smith, taken September 20, 2018.

Dr. Wilcox's Exhibit 2. Curriculum Vitae of Dr. Michael Ross, DVM, Petitioner's expert witness.

RELEVANT REGULATIONS

71 IAC 5.5-1-28 Cooperation with investigations

(a) All licensees shall cooperate fully with all investigations and inquiries made by commission representatives or association security, or both.

(b) All licensees shall obey instructions from commission representatives or association security, or both.

71 IAC 8.5-1-5(7) Furosemide as a permitted foreign substance

Furosemide may be administered intravenously to a horse, which is entered to compete in a race. Except under the instructions of the official veterinarian or the racing veterinarian for the purpose of removing a horse from the veterinarian's list or to facilitate the collection of a post-race urine sample, furosemide shall be permitted only after the official veterinarian has placed the horse on the furosemide list. In order for a horse to be placed on the furosemide list, the following process must be followed:

(1) – (6) ...

(7) Time of treatment. Horses qualified for medication and so indicated on the official bleeder list must be treated at least four (4) hours prior to post time.

(8) – (10) ....

71 IAC 8.5-4-5 Records of treatment

(a) Every veterinarian licensed by the commission who treats any horse or performs other professional services within the enclosure of an organization licensee during a race meeting, or treats horses off the grounds that are actively participating at a race meeting, shall be responsible for maintaining treatment records or a log book on all horses for which they prescribe, administer, or dispense medication or perform other profession services. The treatment records or log book information shall include, but not be limited to, the following:

(1) The date and time of treatment service.
(2) Name of race track.
(3) The veterinarian's printed name and signature.
(4) The registered name of horse.
(5) The trainer's name.
(6) The barn number or location of horse.
(7) The race date and race number, in any.
(8) The medication and dosage.
(9) The reason for treatment or services.

These records shall be current at all times and available to the commission and the stewards upon request. These records shall be retained for at least one (1) year after the conclusion of the race meet and be made available to the commission and stewards upon request. Such records shall be delivered to the commission either upon demand or within twenty-four hours of the request.

(b) – (c) ....

71 IAC 8.5-5-2(c) Prohibited practices

(a) – (b) ...

(c) The possession and/or use of a drug, substance, or medication on the premises of a facility under the jurisdiction of the commission that has not been approved by the United Stated Food and Drug Administration (FDA) for any use (human or animal) is forbidden without prior permission of the commission. For purposes of this rule, the term "drug" is any substance, food of nonfood, that is used to treat, cure, mitigate, or prevent a disease, is any nonfood substance that is intended to affect the structure or function of the animal, and includes any substance administered by injection, other than vaccines licensed by the USDA.

(d) ...

(e) Notwithstanding subsection (c), veterinarians may possess compounded drugs with the restrictions listed below. Compounding includes any manipulation of a drug beyond that stipulated on the drug label, including, but not limited to, mixing, diluting, concentrating, and/or creating oral suspensions or injectable solutions:

(1) ...
(2) compounded drugs may only be made from other FDA-approved drugs;
(3) veterinarians may not possess compounds where there are FDA-approved, commercially available drugs that can appropriately treat the horse; and
(4) compounded drugs must be in containers that meet the prescription labeling requirements in subsections (i) and (j).

Combining two (2) or more substances with pharmacologic effect constitutes the development of a new drug. This may only be done in accordance with state and local laws and must contain FDA approved medications, if available.

(f), (g) ...

(h) A veterinarian shall not possess any drug that is not labeled pursuant to the requirements of subsection (i) or (j).

(i) Drugs possessed by a practicing veterinarians or on the premises of a facility under the jurisdiction of the commission which have not yet been prescribed or dispensed to horses with which the veterinarian has a veterinarian-client-patient relationship must be affixed with the manufacturer's label which must include:

(1) recommended or usual dosage;
(2) route for administration, if it is not for oral use;
(3) quantity or proportion of each active ingredient;
(4) names of inactive ingredients, if for other than oral use
(5) an identifying lot or control number;
(6) manufacturer, packer, or distributor's name and address; and
(7) net quantity contents.

If any information as described herein is not included on the manufacturer's label, but instead is on the manufacturer's package insert, the package insert must be maintained on the veterinarian's truck.

(j) – (k) ....

In rendering findings and conclusions, I am required to weigh the credibility of witnesses about the matters to which they testified including each witness's interest, if any, in the outcome of the matter. Having considered the administrative record, conducted a hearing with evidence and testimony presented by both parties, weighed the credibility of the witnesses and considered the arguments of counsel, I hereby issue the following Findings of Fact, Conclusions of Law and Recommended Order. To the extent that any of the Findings of Fact are more appropriately considered Conclusions of Law, or conversely, they shall be so treated.

FINDINGS OF FACT

1. Horseracing is a highly regulated environment so that it may be conducted at the highest of standards and level of integrity as possible.
2. Substances that are not FDA-approved may not be safe or effective and are among the most difficult to detect. (Transcript, p. 50)
3. Doping substances often originate in compounding laboratories and compounded substances are among the most difficult to detect. (Transcript, p. 53)
4. Often, there is little or no direct evidence of rule violations. Investigations frequently involve piecing together information from various sources, so cooperation of licensees during investigations is crucial to preserve the integrity of horse racing. (Transcript p. 55)

Administration of Lasix:

5. Timely administration of Lasix is important to protect the interests of owners, trainers, and the betting public. Significant repercussion and damage may occur if the services are not performed in accordance with the regulations. (Transcript, p. 154)

6. On June 4, 2016, the horse Dashin' Spirit was scheduled to receive Lasix prior to Race #2 at Indiana Grand.

7. The June 4, 2016 Stewards Daily Report reflects that Dashin' Spirit was scratched from Race #2 because Lasix had not been administered.

8. Dr. Wilcox alleged (for the first time in his Final Prehearing Memorandum on January 15, 2019) that the Lasix administration records ("Lasix Records") for June 4, 2016 reflect that Dr. Jerre Rorick was, in fact, responsible for administering Lasix to Dashin' Spirit but that the Lasix Records had been altered to reflect that Dr. Wilcox was responsible. (Dr. Wilcox's Final Prehearing Memorandum, dated January 15, 2019)

9. At the time of the incident, Dashin' Spirit was owned by Saul Perez and trained by Tony Cunningham. (Perez Dep., p. 14; Transcript, p. 234)

10. Dr. Rorick is a veterinarian licensed by the IHRC who practiced at Indiana Grand during 2016. Mrs. Rorick provided assistance to the veterinarians to coordinate Lasix administration at the track. Both testified that, although Dr. Rorick generally treated horses trained by Mr. Cunningham, Dr. Rorick would not treat horses owned by Saul Perez (Transcript, pp. 188, 196)

11. Dr. Wilcox was generally used by Mr. Perez for Lasix administration during 2016, although he did not specifically testify that Dr. Wilcox was responsible for administering Lasix to Dashin' Spirit on the date in question. (Perez dep., p. 8)

12. Because more than two and one-half years had elapsed since the incident, neither Dr. Rorick, Dr. Mann nor Mrs. Rorick recalled many specifics about the incident nor whether Dr. Wilcox was supposed to administer the Lasix. (Transcript, pp. 192, 199)

13. Dr. Wilcox and his attorney, Mr. Murphy were present at the Perez deposition and had opportunity to consult during the deposition and cross-examine Mr. Perez.

14. Dr. Wilcox claimed, as an affirmative defense, that the Lasix Records were altered without his knowledge.

15. Dr. Wilcox offered as a defense that the Lasix Records for the Race #2 reflected that the initial "R" next to Dashin' Spirit's name (i.e., to signify that Dr. Rorick was responsible for administering Lasix) had been crossed through and replaced with the letter "W" (i.e., to signify that Dr. Wilcox was responsible for administering Lasix). (Transcript, p. 238)

16. Sometime after the horse was scratched, Mr. Perez had a conversation with Dr. Wilcox during which Dr. Wilcox said "I just want to make it right. I know I messed up" and agreed to provide veterinarian services to Mr. Perez without charge for the remainder of the meet (i.e., approximately four months thereafter). (Perez dep., p. 16)

17. Mr. Perez viewed such gestures as a "compromise between [himself] and Dr. Wilcox" and as an incentive for Mr. Perez to forego filing a lawsuit or making a claim against Dr. Wilcox's insurance. (Perez dep., p. 19)

Treatment Records:

18. On October 11, 2017, IHRC Investigator Mike Morris ("Mr. Morris") requested all treatment records for all horses Dr. Wilcox treated that were under IHRC jurisdiction. (Dr. Wilcox Administrative Complaint No. 218002, Exhibit 4A)

19. Mr. Morris requested the records be delivered to him by October 13, 2017. (Dr. Wilcox Administrative Complaint No. 218002, Exhibit 4A).

20. Dr. Wilcox delivered a box of documents to Mr. Morris on November 10, 2017, twenty-eight days after the requested date. (Administrative Complaint No. 218002, Exhibit 4, ¶ 6).

21. Administrative Complaint No. 217004 was issued on April 3, 2017, against Dr. Wilcox, for record keeping violations during 2016, with the recommended penalty that Dr. Wilcox be fined $1,000. (Administrative Complaint No. 217004, page 3); a default order was issued on September 15, 2017 against Dr. Wilcox and he paid the fine.

22. Dr. Wilcox admitted that his treatment records were not maintained in accordance with the regulations "[b]ecause it's more recordkeeping than I can keep and maintain my practice and take care of my horses and my clients, [A]nd I work by myself because I can't afford to hire an assistant"." (Wilcox dep., p. 42, lines 5 – 23)

23. Dr. Wilcox's treatment records (entered into evidence by Commission Staff as Exhibit N) reflected dates of service in October 2017, and contain numerous examples of inadequate recordkeeping.

24. Dr. Wilcox did not sign the treatment records because he (Dr. Wilcox) did not know what else it would add and the signature would not be legible. (Transcript, p. 300, lines 16 – 24).

25. Dr. Wilcox did not put the barn and stall numbers on the treatment sheets because a trainer may move the horse and Dr. Wilcox does not want to record false information on his treatment sheets. (Transcript, pp. 303– 306)

26. Dr. Wilcox did not consistently record drug dosages because the dosages were standardized in many cases and would not vary. (Transcript, pp. 310 – 320)

27. Dr. Wilcox provided several explanations for why he did not include a reason for treatment in his records. (Transcript, pp. 310 – 320)

28. Dr. Wilcox was familiar with recordkeeping rules and did not recall seeing the word "substantial" in the rule when questioned. (Transcript, p. 325, lines 2 – 9)

29. Dr. Wilcox could not explain all of the discrepancies in his records. (Transcript, p. 326, lines 3 – 12)

Plus and FDA Approval:

30. Veterinarians enjoy positions of trust and autonomy at a racetrack because they are among the few individuals who can possess drugs, needles and syringes. A finding or suspicion that a veterinarian may possess a prohibited substance is especially significant because of an ability to repeat, hide and cover-up their actions. (Transcript, p. 163)

31. Dr. Wilcox is responsible for using only FDA-approved drugs. (Transcript, p. 57)

32. Indiana Grand Racing & Casino ("Indiana Grand") is a property under the jurisdiction of the IHRC. (Joint Stipulation D)

33. Dr. Wilcox administered a substance referred to by him as "Plus" to horses more than 100 times, and administered Plus at the racetrack; (i.e., Indiana Grand) during 2016 and 2017. (Transcript, pp. 225, 267)

34. In order to mix the Plus substance at the racetrack, Dr. Wilcox had to have possessed it (and its components) at the racetrack.

35. Plus was administered by Dr. Wilcox as an anti-inflammatory drug although it also may have been administered to alleviate pain. (Transcript, pp. 57, 268, 269, 276, 380)

36. Dr. Wilcox did not know whether the Plus solution was FDA-approved. (Transcript, p. 228; Wilcox dep. p. 58)

37. Dr. Wilcox developed the Plus substance formula over many years of practice as a veterinarian. (Wilcox dep., p. 54)

38. Dr. Wilcox did not seek approval to use Plus from either the racing stewards of Commission Staff. (Transcript, p. 227; Wilcox dep. p. 65)

39. Dr. Wilcox's Plus formula was a combination of two substances that were drawn into a single syringe and administered to a horse. (Transcript, p. 224; Wilcox dep. p. 52).

40. One of the components of Plus was a corticosteroid that was undisputedly FDA-approved (e.g., Vetalog, Predef). (Transcript, p. 243)

41. Dr. Wilcox testified that the other component of Plus was a 20% salt solution derived from the Sarracenia plant. (Wilcox dep., p. 52)

42. Dr. Wilcox administered Sarracenia injections during 2016 and 2017. (Transcript, p. 267)

43. Pursuant to an order issued on September 3, 2018 by ALJ Buker, Dr. Wilcox produced a 100 ml. sample of a product labeled "P-Bloc" manufactured by Rapid Equine Solutions. (Joint Stipulation I)

44. Dr. Wilcox provided sworn testimony that the sample he provided at his deposition was an exact sample of the formula that was used for every Plus injection administered to any IHRC racehorse. (Wilcox dep., p. 55)

45. The only ingredient listed on the Rapid Equine P-Bloc's label is "Ammonium Chloride (20 MG/ML)". The label also provides that the P-Bloc Sample is "Single Use Only" and its contents are a "COMPOUNDED RX". (Exhibit F)

46. Dr. Wilcox testified that sometime after his deposition on September 18, 2018 and early December 2018 he became aware that the Rapid Equine P-Bloc contained only ammonium chloride. (Transcript, pp. 241, 244, 247)

47. Dr. Wilcox did not produce to Commission Staff the correct sample when he produced the Rapid Equine P-Bloc. (Transcript, p. 250)

48. The label of another substance named "P-Bloc", manufactured by Creative Science LLC, provides that it is a "Multiple Dose Vial", "is indicated for the temporary relief of symptoms associated with neurologic pain", "should not be used in areas of local inflammation" and "is contraindicated in areas of local inflammation". (Exhibit J)

49. Creative Science P-Bloc is "An injectable source of the volatile salts of Pitcher Plant (Sarraceniaceae) with 5% w/v as a solution aide and 0.75% w/v Benzyl Alcohol as a preservative". (Exhibit J)

50. Dr. Wilcox previously purchased P-Bloc from a number of places under the assumption that it all contained Sarracenia. (Transcript, p. 245)

51. On at least one occasion Dr. Wilcox mistakenly purchased Rapid Equine P-Bloc when he intended to purchase Creative Science P-Bloc. (Transcript, p. 245)

52. The Green Book is an FDA-maintained database of all animal drug products that are FDA-approved; the Orange Book is an FDA-maintained database of all human drug products that are FDA-approved. (Transcript, p. 70, 71)

53. By FDA definition, compounded drugs are not FDA-approved. (Transcript, pp. 52, 77)

54. The experts provided conflicting testimony regarding FDA approval of Creative Science P-Bloc and Sarracenia.

55. The Commission Staff's expert, Dr. Waterman, testified that FDA-approval is an objective fact, that neither P-Bloc nor Plus were listed in either the Green or Orange Books, and he found no mention of P-Bloc, Sarracenia extracts, Pitcher plant extracts or Sarapin in either the FDA databases or the DESI lists maintained by the FDA. (Transcript, pp. 66, 70, 87).

56. Rapid Equine P-Bloc is frequently used to mask pain and is not FDA-approved. (Transcript, pp. 61, 62, 75)

57. The experts disagreed with respect to whether an ingredient listed in the Green or Orange books meant that other products using the same ingredient would be treated as FDA approved. (Transcript, pp. 73, 77, 348)

58. Shortly before the Hearing, Dr. Wilcox raised as an affirmative defense that Sarracenia, although not an FDA-approved substance *per se*, is "grandfathered" under relevant FDA rules. (Transcript, p. 71)

59. The Creative Science P-Bloc label reflects that it contains Sarracenia. (Exhibit J)

60. The experts provided conflicting testimony regarding whether a grandfathered drug is FDA-approved or merely exempt from being required to obtain FDA approval.

61. On the FDA's website appears a copy of a Warning Letter dated May 23, 2018 issued to Creative Science LLC in which the FDA states that the company's product "P-Bloc "is an unapproved new animal drug and [Creative Science's] marketing of this product violates the FD&C Act [i.e., the Food Drug and Cosmetic Act]". (https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/creative-science-inc-554119-05232018)

Compounded Drugs

62. To prepare the Plus substance, Dr. Wilcox drew contents from a vial of P-Bloc into a syringe and drew contents from a vial of another corticosteroid (e.g., Vetalog) into the same syringe, and then injected the combined substance into the horse. (Transcript, pp. 224, 243)

63. Mixing P-Bloc and another drug creates a compounded drug. (Transcript, p. 364)

64. Neither the Rapid Equine P-Bloc label nor the Creative Science P-Bloc label sanctioned mixing the product in any manner. (Exhibits F, Exhibit J)

65. Multiple FDA-approved substances were available to treat inflammation, including corticosteroids such as isoflupredone (Predef), methylprednisolone (Depo-Medrol) and triamcinolone (Vetalog). (Transcript, p. 104)

66. Multiple FDA-approved substances were available as nerve blocks to treat pain including lidocaine and mepivacaine. (Transcript, p. 107)

67. Ammonium chloride and Sarracenia were less likely to cause adverse reactions and may pose less risk than FDA-approved corticosteroids. (Transcript, pp. 351, 352, 353)

68. FDA approved corticosteroids have been used safely in thousands of horses. (Transcript, p. 353)

69. Treatment of a horse varies from horse to horse and may include both medical and economic considerations. (Transcript, p. 339)

70. There is no legitimate reason to possess non-FDA-approved substances in a regulated area if there are FDA-approved alternatives available and approval of stewards or IHRC is not received. (Transcript, p. 164)

71. The label of Rapid Equine P-Bloc clearly reflects that it is a compounded drug and thus, its label must include each of the items required under 71 IAC 8.5-5-2(e)(4) in order to satisfy the Commission rules. (Exhibit F)

72. The Rapid Equine P-Bloc label does not include certain information required under 71 IAC 8.5-5-2(e)(4). (Transcript, p. 108)

73. Concerns regarding possession of a prohibited substance, poor recordkeeping and inadequate labeling are significantly heightened when cooperation is not forthcoming. (Transcript, p. 163)

ANALYSIS

Paragraph 12

Paragraph 12 of the Amended Complaint alleges that on June 4, 2016, Dr. Wilcox failed to timely administer Lasix to the horse Dashin' Spirit which caused the horse to be scratched from Race #2. Timely administration of Lasix is important to protect the interests of owners, trainers, and the betting public. Significant and widespread repercussion and damage may occur if the services are not performed in accordance with the regulations.

In defense to this charge, Dr. Wilcox alleged (for the first time in his Final Prehearing Memorandum on January 15, 2019) that the Lasix administration records ("Lasix Records") for that day reflect that Dr. Jerre Rorick was, in fact, responsible for administering Lasix to Dashin' Spirit but that the Lasix Records had been altered to reflect that Dr. Wilcox was responsible. In support of his defense, Dr. and Mrs. Rorick and Dr. Mann, another veterinarian practicing at Indiana Grand at the time of the incident, were called by Dr. Wilcox to testify at the Hearing.[5]

At the time of the incident, Dashin' Spirit was owned by Saul Perez and trained by Tony Cunningham. The record is unclear with respect to who, in fact, was responsible for administering Lasix to Dashin' Spirit on the date of the incident. Dr. and Mrs. Rorick both testified that, although

[5] The deposition of Mr. Perez occurred on September 22, 2018, and the defense that the Lasix Records had been altered was not raised until January 15, 2019 (sixteen days before the Hearing) in Dr. Wilcox's Final Prehearing Memorandum, at which time Mr. Murphy also requested to continue the Hearing date and re-open discovery in order to depose witnesses in support of Dr. Wilcox's defense. Dr. Wilcox was granted an opportunity to subpoena witnesses and documents for testimony and production at the Hearing; however, his request to continue the Hearing in order to depose witnesses was denied at least in part because Dr. Wilcox knew or should have known that Commission Staff intended to prosecute the Dashin' Spirit incident no later than November 5, 2018, the date of Commission Staff's Motion for Summary Judgment, and thus, had ample opportunity to request additional discovery and otherwise prepare his defense.

Dr. Rorick generally treated horses trained by Mr. Cunningham, Dr. Rorick would not treat horses owned by Saul Perez. However, because more than two and one-half years had elapsed since the incident, neither Dr. Rorick, Dr. Mann nor Mrs. Rorick recalled many specifics about the incident nor whether Dr. Wilcox was supposed to administer the Lasix. The deposition testimony of Saul Perez[6] suggests he generally used Dr. Wilcox for such purposes during 2016, although he did not specifically testify that Dr. Wilcox was responsible for administering Lasix to Dashin' Spirit on the date in question.

At the Hearing, Dr. Wilcox testified that he recalled seeing the Lasix Records and that the initial "R" next to Dashin' Spirit's name (i.e., signifying that Dr. Rorick was responsible for administering Lasix) had been crossed through and replaced with the letter "W" (i.e., signifying that Dr. Wilcox was responsible for administering Lasix). However, Dr. Wilcox did not produce those records or any other evidence in support of his testimony.[7] Other than Dr. Rorick's specific denial that neither he nor any other veterinarian was involved in altering the Lasix Records, no other witness testified and no evidence was produced with respect to the alteration of the Lasix Records.

Despite conflicting testimony at the Hearing, I find that the conduct of Dr. Wilcox after the incident on June 4, 2016 established that he was responsible for the administration of Lasix to Dashin' Spirit. Specifically, sometime after the horse was scratched, Mr. Perez had a conversation with Dr. Wilcox during which Dr. Wilcox said "I just want to make it right. I know I messed up"

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[6] Mr. Perez did not testify at the Hearing; however, both Dr. Wilcox and Mr. Murphy attended his deposition and had ample opportunity to cross-examine Mr. Perez concerning his testimony.

[7] Mr. Murphy objected to the admission of the affidavit of Mr. Perez at least in part because he was not able to obtain the Lasix Records from Indiana Grand. However, although a subpoena duces tecum was issued to Indiana Grand on January 23, 2019 (providing for a January 28, 2019 deadline to produce the records), service apparently was not attempted until January 25 and was not in accordance with procedures set forth in Ind. Tr. Rule 4.6. Moreover, although admitted, Mr. Perez's affidavit was not used or otherwise relied upon in this Recommended Order.

and agreed to provide veterinarian services to Mr. Perez without charge for the remainder of the meet (i.e., approximately four months thereafter). Mr. Perez clarified during his deposition that he viewed such gestures as a "compromise between [himself] and Dr. Wilcox" and as an incentive for Mr. Perez to forego filing a lawsuit or making a claim against Dr. Wilcox's insurance. Admissions against his own self-interest -- coupled with an unsolicited bestowal of economic incentives – suggests culpability on the part of Dr. Wilcox. Accordingly, I find that sufficient evidence exists to support that Dr. Wilcox did violate 71 IAC 8.5-1-5(7) by failing to timely administer Lasix to Dashin' Spirit on June 4, 2016.

Paragraph 14

Paragraph 14 alleges that Dr. Wilcox failed to maintain treatment records as required under 71 IAC 8.5-4-5. In a letter dated October 11, 2017, Michael Morris, a Commission Staff investigator, requested treatment records for all horses treated by Dr. Wilcox that were under the jurisdiction of the IHRC. Mr. Morris requested that the records be provided by October 13, 2017; i.e., one day after the 24-hour deadline that otherwise would apply under 71 IAC 8.5-4-5. The records were provided to Mr. Morris on November 10, 2017. During his deposition, Dr. Wilcox acknowledged that his treatment records were not maintained as required. Dr. Wilcox responded to the effect that he did not have time to adequately keep his records because of his other responsibilities (e.g., maintaining his practice, taking care of horses and clients) and that he could not afford to hire an assistant. At the Hearing, Dr. Wilcox acknowledged the importance of accurate recordkeeping and agreed that failure to do so was unacceptable. During the Hearing, Dr. Wilcox was questioned about entries from fourteen pages of records dated October 2017 and admitted as Exhibit N.[8] The records contained a number of errors on their face; e.g., entries

[8] The fourteen pages were represented by Commission Staff counsel to be a sample of the records provided by Dr. Wilcox. A summary worksheet of violations was prepared and admitted by Commission Staff at trial that errors that

regarding drug dosage, reason for treatment, barn/stall numbers were not recorded. In addition, the records were not always signed. During cross-examination, Dr. Wilcox explained that he always administered 10 cc doses of Banamine, Ketofen, Bute, ESE (estrogen with Selenium), estrogen (20 cc doses) and Robaxin (15 cc doses) in his practice; he did not include barn/stall information because he was concerned about a "falsified record" if a horse were moved after treatment; a signature would not add anything to the record and may be illegible; and that, in his opinion, he has complied with the regulations if he administers a drug based on a trainer's instructions. Dr. Wilcox had been the subject of a previous disciplinary action[9] in which a Final Order was issued on September 15, 2017 against him for failure to maintain records as required under 71 IAC 8.5-4-5 (Exhibit E).[10]

At the Hearing, Dr. Wilcox acknowledged that the IHRC rules did not require merely "substantial" compliance. Treatment records and labeling regulations are important to create and preserve an accurate, contemporaneous record of what, in fact, was performed or provided to an animal and to assist in the conduct of an investigation. Investigators may need to independently corroborate that treatment is appropriate and in accordance with standards and regulations. Investigations are hampered and gamesmanship may occur if the records only can be interpreted by assistance from the person who created the record. As Mr. Smith testified, proper recordkeeping is of critical importance so that the IHRC can review a treatment record and

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were believed to exist on hundreds of records. The summary worksheet was admitted at the Hearing as Exhibit T and as an attachment to Exhibit N.

[9] At the Hearing, Mr. Murphy objected to the admission of his previously disciplinary action under Rule 404 of the Indiana Rules of Evidence. However, I.C. § 4-31-6-6 grants the IHRC broad authority to revoke, suspend or otherwise penalize a licensee for a number of reasons enumerated in section 6(b) thereof, including that the licensee has previously violated IHRC rules under subsection 6(b)(4)) or engaged in conduct against the best interest of horse racing under subsection 6(b)(10).

[10] Because the Final Order was not clear with respect to the dates of the records to which it pertained, it was agreed by counsel and ordered by ALJ Buker that Commission Staff only could prosecute Dr. Wilcox under Paragraph 14 using treatment records created after September 15, 2017.

determine what has occurred. Independent review of a record is especially important in the event a treating veterinarian is unable (or unwilling) to augment a treatment record with additional information. Dr. Wilcox's contentions that he cannot comply with IHRC rules because he does not have an assistant and the rules are too onerous is unpersuasive – especially in light of the fact that he was disciplined previously for violating the same regulation. Accordingly, I find that Dr. Wilcox failed to maintain treatment records in the manner prescribed under 71 IAC 8.5-4-5.

Paragraph 16

Paragraph 16 of the Amended Complaint charges Dr. Wilcox with injecting horses with a substance that was not FDA-approved in violation of 71 IAC 8.5-5-2(c).

Indiana Grand is a property under the jurisdiction of the IHRC. Dr. Wilcox admitted in his deposition to injecting horses with a substance referred to by him as "Plus" more than 100 times and admitted that Plus was administered at Indiana Grand during 2016 and 2017. According to Dr. Wilcox, Plus was administered as an anti-inflammatory drug, although it also may have been administered to alleviate pain. Dr. Wilcox testified that he did not know whether the Plus substance was FDA-approved, and that he did not seek approval to use Plus from either the racing stewards or Commission Staff. Accordingly, whether Dr. Wilcox violated 71 IAC 8.5-5-2(c) turns on whether the Plus substance is approved for use (human or animal) by the FDA.

Plus

At his deposition, Dr. Wilcox testified that the Plus formula was a combination of two substances that were drawn by him into a single syringe and administered to a horse. One of the components of Plus was a corticosteroid that was undisputedly FDA-approved (e.g., Vetalog, Predef). Dr. Wilcox testified that the other component of Plus was a 20% salt solution derived

from the Sarracenia[11] plant. Dr. Wilcox testified at the Hearing that he administered at Indiana Grand Sarracenia injections during 2016 and 2017. Pursuant to an order issued by ALJ Buker on September 3, 2018 (the "September 3 Discovery Order"),[12] Dr. Wilcox produced a 100 ml. sample of a product labeled "P-Bloc" manufactured by Rapid Equine Solutions (photographs of which were admitted at the Hearing as Exhibit F) (the "Rapid Equine P-Bloc"), and testified that it was an exact sample of the formula that he used for every Plus injection administered to any IHRC racehorse. Based on its label, and despite Dr. Wilcox's earlier testimony that Plus contained Sarracenia, the only ingredient listed on the Rapid Equine P-Bloc's label is "Ammonium Chloride (20 MG/ML)"; i.e., Sarracenia is not listed as an ingredient. The label also provides that the P-Bloc Sample is "Single Use Only" and its contents are a "Compounded RX".

At the Hearing, Dr. Wilcox testified that sometime after his deposition on September 18, 2018 and early December 2018, he became aware that the Rapid Equine P-Bloc contained only ammonium chloride. Dr. Wilcox acknowledged that he did not produce the correct sample of the substance when he produced the Rapid Equine P-Bloc as required under the September 3 Discovery Order. Accordingly, it is unclear what substance was, in fact, administered in the Plus injections.[13]

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[11] Extracts derived from the salt of the Pitcher plant have been generally referred to throughout this matter as Sarracenia, Sarracenia Purpurea, Sarraceniaceae, and Serapin. Unless otherwise noted, the term Sarracenia will be used to generically identify any of these substances for purposes of this Recommended Order.

[12] The September 3 Discovery Order ordered Dr. Wilcox to "Identify the contents of the substance identified as "plus" on your bills. Produce information identifying the contents and formula, along with a sample for testing. Produce an affidavit stating that the supplied formula and sample is the true formula used and identified as "plus" on billing statements."

[13] At his deposition on December 14, 2018, Dr. Wilcox's expert, Dr. Ross, testified that during his research, he had discovered a third substance named "P-Bloc" that contained ammonium sulfate. No testimony or other evidence was produced during the Hearing to suggest this third substance may have been administered in the Plus injections and thus, it was not considered for purposes of this Recommended Order.

At the Hearing, the label of another substance named "P-Bloc", manufactured by Creative Science LLC (Exhibit J), was produced by Commission Staff (the "Creative Science P-Bloc").[14] The label of the Creative Science P-Bloc identifies it as "An injectable source of the volatile salts of Pitcher Plant (Sarraceniaceae) with 5% w/v as a solution aide and 0.75% w/v Benzyl Alcohol as a preservative". Dr. Wilcox acknowledged that he had previously purchased P-Bloc from a number of places under the assumption that it all contained Sarracenia. Dr. Wilcox further testified that on at least one occasion he had mistakenly purchased Rapid Equine P-Bloc when he intended to purchase Creative Science P-Bloc.

In light of the foregoing evidence and Dr. Wilcox's previous and consistent testimony that one of the Plus components was a solution derived from the Sarracenia plant, it may be reasonably inferred that Dr. Wilcox mistakenly produced a sample of Rapid Equine P-Bloc at his deposition when he intended to provide a sample of Creative Science P-Bloc. Moreover, because it was Dr. Wilcox's conduct that created the confusion,[15] he should not now benefit by claiming that the Commission Staff did not fully satisfy its burden to establish that one of the Plus components was non-FDA-approved because it was not accurately identified. Accordingly, I find that Commission Staff can satisfy its burden of persuasion if it can establish that neither the Rapid Equine P-Bloc nor the Creative Science P-Bloc is FDA-approved.

Rapid Equine P-Bloc

FDA-approval status of a drug generally is confirmed by searching either the Green Book (for animal use) or the Orange Book (for human use) to determine whether the drug is listed. The

[14] The label further provides that it is a "Multiple Dose Vial", "is indicated for the temporary relief of symptoms associated with neurologic pain", "should not be used in areas of local inflammation" and "is contraindicated in areas of local inflammation".

[15] Although he testified that he believed in good faith when he produced the Rapid Equine P-Bloc that it contained Sarracenia, Dr. Wilcox never provided the correct sample to Commission Staff in direct violation of the September 3 Discovery Order and his ongoing discovery obligations under the Indiana Trial Rules.

Commission Staff's expert, Dr. Waterman, testified that FDA-approval is an objective fact, that neither P-Bloc nor Plus were listed in either the Green or Orange Books, and that he found no mention of P-Bloc, Sarracenia extracts, Pitcher plant extracts or Sarapin in either the FDA databases or the DESI lists[16] maintained by the FDA[17]. Dr. Wilcox's expert, Dr. Ross, testified that he "could not find reference to Sarracenia purpurea in a[n] FDA-approved drug".[18]

Dr. Waterman testified that, by FDA definition, compounded drugs are not FDA-approved, and explained that although substances may be compounded legally if strict FDA guidelines are followed,[19] doing so does not render the resulting substance FDA-approved. Dr. Wilcox's expert, Dr. Ross, also testified that he did not believe that any compounded product could be FDA-approved.

Dr. Waterman further testified that the Rapid Equine P-Bloc did not meet the FDA requirements to be a legally compounded substance because, for example, the compounded

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[16] According to Dr. Waterman, DESI designated drugs are certain drugs (3,000 – 4,000 drugs) approved from 1938 – 1962 (during which time, efficacy was not a requirement for FDA approval) that were subjected to additional testing post-1962 under the FDA's Drug Efficacy and Safety Implementation (DESI) program to determine whether the drugs were safe and effective under the 1962 guidelines.

[17] The experts disagree with respect to whether the presence of an ingredient in the Green or Orange Books means that other products using the same ingredient would be treated as FDA-approved. For example, Dr. Ross testified that he had identified at least five different preparations of the chemical, ammonium chloride, in the Orange Book that were FDA approved, and concluded, in his opinion, that ammonium chloride was an FDA-approved substance. Dr. Waterman disagreed that use of a particular ingredient supported a conclusion that other products using the same ingredient should be FDA approved because of the FDA's "very grave concerns" about compounded drugs and their usages. Dr. Waterman also explained that although the FDA has strict criteria for when FDA approved substances may be legally compounded (see FN 17) following such criteria does not make the resulting substance, while legal, FDA approved. Independent evidence in support of either expert's position with respect to the treatment of ingredients was not produced. Although not entirely clear, the fact that the FDA approval process is highly rigorous and the FDA Orange and Green books identify thousands of drugs with great specificity (including trade names) suggests that FDA approval of a particular ingredient, by itself, does not support a conclusion that any other substance made from the same ingredient would be FDA approved, and thus, the omission of either P-Bloc, Sarracenia or Plus from the Orange or Green Books is highly persuasive that the drugs are not FDA-approved.

[18] Nonetheless, Dr. Ross later testified that in his opinion, Sarracenia is or should be considered a grandfathered substance and implied that grandfather status would be equivalent to FDA approval. Grandfathered drugs are discussed hereunder.

[19] Dr. Waterman draws a distinction between "legally compounded drugs" (i.e., drugs that may be compounded legally under FDA guidelines) and FDA approval of the compounded drug. As stated above, neither expert believes that any compounded substance can be FDA-approved.

substance must be for treatment of a specific patient under FDA guidelines, and the quantity of the Rapid Equine P-Bloc (i.e., 100 ml) suggests multiple uses. Dr. Waterman also testified that the fact that multiple products using the exact same name but with different ingredients were for sale also supported a conclusion that any such product would be FDA-approved because "the FDA would never allow that level of confusion to exist [with respect to] the safety of the product". Moreover, the Rapid Equine P-Bloc, also is clearly labeled a "COMPOUNDED RX" and, in the opinion of both experts, the FDA does not approved compounded drugs. Based on the foregoing, I find that Rapid Equine P-Bloc is not an FDA-approved substance.

Creative Science P-Bloc

At the Hearing, Dr. Wilcox raised as a defense to the charge that he administered a non-FDA-approved drug, that Sarracenia, although not an FDA-approved substance *per se*, is "grandfathered" under relevant FDA rules. As set forth above, the Creative Science P-Bloc label reflects that it contains Sarracenia.

In 1962, the Federal Food, Drug and Cosmetic Act (the "Act") was amended to require that, in addition to being safe, a drug must also be effective with respect to its intended use. The 1962 Act "grandfather clauses"[20] specifically exempt from the effectiveness requirements some drugs that were on the market in the U.S. if certain conditions were met (see discussion below). As an exemption to the comprehensive regulatory scheme devised by the FDA, courts have concluded that a grandfather clause should be strictly construed and the party claiming such status bears the burden of proof with respect to each of the requirements.[21] As explained by Dr. Waterman, the fact that a drug is exempt from the effectiveness requirement does not mean that a

[20] 21 U.S.C 321 (p) [relating to human drugs] and (v) [relating to animal drugs]. The two provisions are identical with respect to requirements for grandfathered status, as set forth below.

[21] United States v. Articles of Drug, etc., 745 F.2d 105 (1st Cir. 1984); and see United States v. Allan Drug Corp., 357 F.2d 713, 718 (10th Cir.), United States v. An Article of Drug (Bentex Ulcerine), 469 F.2d 875, 878.

drug is approved by the FDA: "It's not grandfathered approval. It's grandfathered from having to go through the approval process"; "if the grandfathering made that substance FDA approved, it would be in the Green Book or the Orange Book." Dr. Ross testified that although he found no evidence and did not have direct knowledge to support that Sarracenia was in an FDA-approved drug, he believed that Sarracenia is or should be treated as a grandfathered substance and that grandfather status would be the equivalent of FDA-approval.

In the present context, it is not necessary to determine whether or not grandfather status is the equivalent of FDA approval under the statutory scheme. Even if FDA-approved status were to apply to grandfathered drugs, Dr. Wilcox has not established that either Creative Science P-Bloc or Sarracenia is a grandfathered drug. As set forth in United States v. Articles of Drug, etc., 745 F.2d 105 (1st Cir. 1984), in order for a drug to be exempt from the Act (i.e., treated as a grandfathered) the drug: (1) must have been commercially used or sold in the U.S. before October 10, 1962, (2) must not have been within the definition of a "new drug" in the 1938 Act, (3) must not have been covered by an effective new drug application, and (4) must currently be intended solely for use under conditions prescribed or recommended in its 1962 labeling. Dr. Ross testified he was aware throughout his career of the existence of Sarracenia, and his general impression was that it had existed in both the veterinary and human medical realm for many years based on references in textbooks dating from the late 1800's and early 1900's. Even if it was assumed that requirement (1) above was satisfied, no evidence was produced at the Hearing to establish that requirements (2) – (4) were satisfied. Specifically, no evidence was provided with respect to whether either Creative Science P-Bloc or Sarracenia falls outside the definition of a new drug under the 1938 Act or is covered by an effective new drug application, and no evidence was produced with respect to whether either Creative Science P-Bloc or Sarracenia was intended solely

for use under conditions prescribed or recommended under its 1962 label (assuming such labels existed). Accordingly, because not all of the requirements to be treated as a grandfathered drug under United States v. Articles of Drug, etc. were satisfied, I find that neither Creative Science P-Bloc nor Sarracenia is a grandfathered drug.

Moreover, on the FDA's website is a copy of a Warning Letter dated May 23, 2018 issued to Creative Science LLC,[22] in which the FDA states that the company's product P-Bloc "is an unapproved new animal drug and [Creative Science's] marketing of this product violates the FD&C Act". The letter further provides that the product constitutes a new animal drug because it is not generally recognized among qualified experts as safe and effective for use under the conditions prescribed, recommended or suggested in its labeling and concluded the product is unsafe under section 512(a) of the FD&C Act. The Warning Letter also provides that because the National Drug Code ("NDC") listing for the product contained inaccurate information, the product's listing data was removed from the FDA's online NDC Directory.[23]

Based on the foregoing,[24] I find for purposes of this Recommended Order that, because neither Creative Science P-Bloc nor Sarracenia are grandfathered drugs, and neither substance was

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[22] See discussion below regarding Post-Hearing Evidentiary Matters

[23] The NDC reference in the Warning Letter, 53413-752 is consistent with the NDC reference on the label of the Creative Science P-Bloc.

[24] The experts disagreed with respect to whether an ingredient listed in the Green or Orange Books meant that other products using the same ingredient would be treated as FDA-approved. For example, Dr. Ross testified that he had identified at least five different preparations of the chemical, ammonium chloride, in the Orange Book that were FDA approved, and concluded, that ammonium chloride was an FDA-approved substance. Dr. Waterman disagreed that use of a particular ingredient supported a conclusion that other products using the same ingredient would be FDA-approved because of the FDA's "very grave concerns" about compounded drugs and their usages. Dr. Waterman also explained that although the FDA has strict criteria for when FDA-approved substances may be compounded, following such criteria does not make the resulting substance FDA-approved. Independent evidence in support of either expert's position with respect to the treatment of ingredients was not produced. Although not entirely clear, the fact that the FDA approval process is highly rigorous and the FDA Orange and Green Books identify thousands of drugs with great specificity (including trade names) suggests that FDA approval of a particular ingredient, by itself, does not support a conclusion that any other substance made from the same ingredient would be FDA-approved. Thus, the omission of either "P-Bloc" or "Plus" from the Orange or Green Books is suggestive that neither drug is FDA-approved. Based on the foregoing testimony, I find that insufficient evidence was presented to establish that an FDA-approved ingredient, by itself, would render other products made from such ingredient FDA-approved.

listed in either the Green Book or Orange Book, neither substance is FDA-approved. Consequently, Plus was not FDA-approved because, in addition to being a compounded drug, one of its components was not FDA-approved (i.e., either Rapid Equine P-Bloc, Creative Science P-Bloc or Sarracenia). Because Dr. Wilcox possessed Plus and its components (i.e., Rapid Equine P-Bloc, Creative Science P-Bloc or Sarracenia) at Indiana Grand and administered Plus without obtaining approval from either the racing stewards or IHRC to do so, I find that sufficient evidence exists to support that Dr. Wilcox violated the provisions of 71 IAC 8.5-5-2(c) as set forth in Paragraph 16.

Paragraphs 17-19

Paragraphs 17-19 generally allege that Dr. Wilcox possessed a compounded substance in violation of the rules applicable to compounded substances set forth in 71 IAC 8.5-5-2(e)(2)-(4), under which a veterinarian only may possess compounded drugs subject to the following restrictions:

(1) ...;

(2) compounded drugs may only be made from other FDA-approved drugs;

(3) veterinarians may not possess compounds where there are FDA-approved, commercially available drugs that can appropriately treat the horse; and

(4) compounded drugs must be in containers that meet the labeling requirements set forth in 71 IAC 8.5-5-2(i) and (j).

As a threshold matter for purposes of 71 IAC 8.5-5-2(e), compounding includes "any manipulation of a drug beyond that stipulated on the drug label, including, but not limited to, mixing, diluting, concentrating, and/or creating oral suspensions or injectable solutions." As set

forth above, Dr. Wilcox testified that to prepare the Plus substance at Indiana Grand, he drew contents from a vial of P-Bloc into a syringe and drew contents from a vial of another corticosteroid (e.g., Vetalog) into the same syringe, and then injected the combined substance into the horse. Dr. Ross testified that mixing P-Bloc and another drug created a compounded drug. Neither the Rapid Equine P-Bloc label nor the Creative Science P-Bloc label sanctions mixing the product in any manner. Accordingly, I find, based on the testimony of both experts and under the plain meaning of the compounding definition in the regulation, that Dr. Wilcox created a compounded substance (i.e., Plus) when he mixed the corticosteroid with either the Rapid Equine P-Bloc or the Creative Science P-Bloc at Indiana Grand.

Paragraph 17

Paragraph 17 charges Wilcox with a violation of 71 IAC 8.5-5-2(e)(2) for possession of a compounded drug that was not made from other FDA-approved drugs. As set forth above, Plus is a compounded substance that included either Rapid Equine P-Bloc or Creative Science P-Bloc, neither of which is FDA-approved. Accordingly, I find that Dr. Wilcox violated 71 IAC 8.5-5-2(e)(2).

Paragraph 18

Paragraph 18 charges Wilcox with a violation of 71 IAC 8.5-5-2(e)(3) for possession of a compounded drug when other FDA-approved drugs are commercially available that can appropriately treat the horse. As set forth above, the Plus injections were intended to treat inflammation[25] and/or pain. Dr. Waterman testified that multiple FDA-approved substances were available to treat inflammation, including corticosteroids such as isoflupredone (Predef),

[25] When asked, Dr. Waterman was unable to explain why the Sarracenia label in Exhibit J provides: "CAUTION: P-Bloc should not be used in area of local inflammation" and "P-Bloc is contraindicated in areas of local inflammation."

methylprednisolone (Depo-Medrol) and triamcinolone (Vetalog)[26]. Dr. Ross concurred that these products are commonly used as preparations to treat inflammation in horses. Dr. Waterman also testified that a number of FDA-approved substances were available as nerve blocks to treat pain, including lidocaine and mepivacaine. Dr. Ross testified that ammonium chloride and Sarracenia were less likely to cause adverse reactions and may pose less risk than FDA-approved corticosteroids.[27] Dr. Ross also testified that treatment of a horse varies from horse to horse and may include both medical and economic considerations.[28]

It is reasonable to interpret the term "appropriately" in 71 IAC 8.5-5-2(e)(3) in the context of the highly regulated environment that exists for horseracing.[29] Thus, despite a veterinarian's belief that a non-FDA-approved substance is more appropriate in a purely clinical sense for treatment of pain or inflammation, under IHRC regulations, she or he is required to use available FDA-approved alternatives when treating horses at the racetrack. As set forth above, Plus is a not

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[26] Dr. Waterman also mentioned dexamethasone although he was not certain whether it was approved for joint inflammation.

[27] Dr. Ross acknowledged that FDA approved corticosteroids had been used safely in thousands of horses.

[28] Other reasons for not using an FDA-approved substances were provided at the hearing (e.g., Depo-Medrol may remain in a horse's system longer than desired, lidocaine and mepivacaine sting when administered, etc., but, as Dr. Waterman explained "just because a horse is not going to like it in the short term, doesn't mean it's not a usable product".

[29] On at least two occasions during the Hearing, Mr. Murphy read into the record in support of Dr. Wilcox's defense a statement from United States of America v. 9/1 KG. Containers, etc., 854 F.2d 173 (7th Cir. 1988) essentially as follows (Transcript, pp. 127, 356): "We must take it as given that for significant diseases, there are no effective FDA-approved drugs. Many veterinarians find this state of affairs deplorable. Because they cannot buy in finished form the drugs they think they should be able to use, they have elected to make their own. They purchase the active ingredient, mix them in proportions they deem best and administer their concoctions as professional judgment dictates. The veterinarians do not sell the drugs so the FDA's usual methods of control do not come into play. The FDA has looked the other way for decades." Dr. Ross testified that the statement accurately reflects what is commonplace in veterinary medicine (although he acknowledged that he testified as a veterinarian under general practice rules, and not as a veterinarian subject to a racing commission's rules).

U.S. v. 9/1 KG. Containers, etc. involved an appeal of a forfeiture action of bulk drugs and is distinguishable from this matter in a number of ways, including that it did not involve horseracing or another highly-regulated industry. In addition to the foregoing, the court further explained that although "reasonable persons could think it appropriate to rely on tort law and professional discipline... to assure the safety of drugs,... Congress and the FDA have reached a different conclusion." In the present context, the statement could suggest that whether or not reasonable minds differ about the use non-FDA-approved drugs to treat horses, the Indiana legislature and IHRC have reached a different conclusion; i.e., that such substances are simply not permitted under the comprehensive framework established for horseracing.

FDA-approved and other FDA-approved substances were available to treat inflammation and/or pain. Accordingly, I find that 71 IAC 8.5-5-2(e)(3) was violated when Dr. Wilcox administered Plus.

Paragraph 19

Paragraph 19 charges Wilcox with a violation of 71 IAC 8.5-5-2(e)(4) for possession of a compounded substance that does not satisfy certain labeling requirements. Under 71 IAC 8.5-5-2(e)(4) and (i), the label of a compounded drug must include seven enumerated items described generally as (1) recommended or usual dosage, (2) route of administration, (3) quantity or proportion of each active ingredient, (4) names of inactive ingredients, (5) an identifying lot or control number, (6) manufacturer or distributor's name and address, and (7) net quantity contents.

The label of Rapid Equine P-Bloc clearly reflects that it is a compounded drug and thus, its label must include each of the foregoing items in order to satisfy the Commission rules. Based on a review of Exhibit F, and as established by Dr. Waterman during his testimony, the Rapid Equine P-Bloc label does not include items (1), (2), (4), (5) and (6) of the foregoing listed requirements. Accordingly, I find that Dr. Wilcox violated 71 IAC 8.5-5-2(e)(4) by possessing Rapid Equine P-Bloc at the racetrack.

Paragraph 20

Paragraph 20 charges Wilcox with a violation of 71 IAC 8.5-5-2(h) for possession of a drug that does not comply with the labeling requirements set forth in 71 IAC 8.5-5-2(i).[30] Under this provision, the label of a drug must include seven enumerated items described generally as (1) recommended or usual dosage, (2) route of administration, (3) quantity or proportion of each active

[30] As set forth in the Summary Judgment Order, Paragraph 20 has been treated as a charge for failing to satisfy the labeling requirements under 71 IAC 8.5-5-2(i) which reflects the substance of the Commission Staff's analysis.

ingredient, (4) names of inactive ingredients, (5) an identifying lot or control number, (6) manufacturer or distributor's name and address, and (7) net quantity contents.

Based on a review of Exhibit J, the Rapid Equine P-Bloc label does not include items (1), (2), (4), (5) and (6) of the foregoing listed requirements. Accordingly, I find that Dr. Wilcox violated 71 IAC 8.5-5-2(e)(4) by possessing Rapid Equine P-Bloc at the racetrack.

CONCLUSIONS OF LAW

1. ALJ Buker has jurisdiction over this matter pursuant to his appointment by the IHRC and the provisions of I.C. § 4-21.5, *et seq.* and 71 IAC 10-3-7.
2. The IHRC has promulgated rules, consistent with its legislative directive, that provide for the assessment of sanctions, including license suspension, revocation and/or fines to those who violate its rules.
3. At all times relevant, Dr. Wilcox was a licensee of the IHRC and subject to all rules and statutes that regulate pari-mutuel horse racing in Indiana.
4. As a licensee of the IHRC, Dr. Wilcox was required to cooperate fully with all investigations and inquiries.
5. The Administrative Complaint and the Amended Complaint were issued in accordance with Indiana statutes and IHRC rules and were supported by substantial, reliable and credible evidence presented to ALJ Buker.
6. Commission Staff had the burden of persuasion and the burden of going forward with proof on the Administrative Complaint and the Amended Complaint by a preponderance of the evidence pursuant to I.C. § 4-21.5-3-14.

7. I.C. § 4-21.5-3-14(c) provides that the party asserting an affirmative defense specified by law has the burden of persuasion and the burden of going forward with the proof of the affirmative defense.

8. Indiana Trial Rule 8(C) provides that a party pleading an affirmative defense shall have the burden of proving such matters.

9. Under the foregoing provisions, Dr. Wilcox had the burden of persuasion with respect to all affirmative defenses raised by him.

10. By a preponderance of the evidence, Commission Staff met its burden of proof as to all violations alleged against Dr. Wilcox with respect to Paragraphs 12, 14 and 16 – 20.

11. As set forth in the Summary Judgment Order, Commission Staff established by a preponderance of the evidence that Dr. Wilcox failed to cooperate fully during an investigation conducted by IHRC personnel regarding his activities at Indiana Grand.

12. 71 IAC 8.5-4-5 (1) neither contemplates nor permits "substantial" performance in record keeping; the provision is specific with respect to what information is required; and (2) does not obligate IHRC investigators to consult with the person making the record in order to determine whether the requirements have been satisfied.

13. By a preponderance of the evidence, Commission Staff met its burden of proof with respect to each of the following:

    a. Dr. Wilcox was responsible for administering Lasix to the horse Dashin' Spirit within the rules of the IHRC;

    b. Dr. Wilcox failed to timely administer Lasix to the horse Dashin' Spirit on June 4, 2016;

    c. Dr. Wilcox failed to maintain treatment records in compliance with IHRC rules;

d. Rapid Equine P-Bloc, Creative Science P-Bloc, Sarracenia and Plus are not FDA-approved drugs;

e. Dr. Wilcox possessed and used a drug, Plus, containing either Rapid Equine P-Bloc, Creative Science P-Bloc or Sarracenia, none of which were FDA-approved, at Indiana Grand;

f. Dr. Wilcox possessed a compounded drug, including Plus and its component (i.e., either Rapid Equine P-Bloc, Creative Science P-Bloc or Sarracenia) at Indiana Grand where (a) the substance itself (or a component thereof) was not an FDA-approved drug, (b) other commercially available FDA-approved drugs could appropriately treat inflammation and/or pain in a horse, and (c) the labeling did not comply with IHRC regulations; and

g. Dr. Wilcox possessed Plus and Rapid Equine P-Bloc at Indiana Grand which were not labeled in accordance with IHRC regulations.

h. Dr. Wilcox did not meet his burden of proof as follows:

i. Dr. Wilcox did not establish by a preponderance of the evidence that the Lasix Records were altered and that he was not responsible for administering Lasix to Dashin' Spirit, and

ii. Dr. Wilcox did not establish by a preponderance of the evidence that either Creative Science P-Bloc or Sarracenia was a grandfathered drug.

ULTIMATE FINDINGS OF FACT AND CONCLUSIONS OF LAW

1. Based on all of the evidence heretofore presented, including the Hearing and by stipulation of the parties, Commission Staff met its burden of proof by a preponderance of the evidence that Dr. Wilcox violated each of the following IHRC rules:

a. 71 IAC 5.5-1-28, by failing to cooperate fully during an investigation conducted by IHRC personnel;

b. 71 IAC 8.5-1-5(7), by failing to timely administer Lasix to the horse Dashin' Spirit on June 4, 2016;

c. 71 IAC 8.5-4-5, by failing to maintain treatment records in compliance with IHRC requirements;

d. 71 IAC 8.5-5-2(c), by possessing and administering Plus and its component substance (i.e., either Rapid Equine P-Bloc, Creative Science P-Bloc or Sarracenia), which were not FDA-approved, on the premises of Indiana Grand;

e. 71 IAC 8.5-5-2(e)(2), by possessing Plus, a compounded drug, at least one of the components of which is not an FDA-approved drug;

f. 71 IAC 8.5-5-2(e)(3), by possessing Plus, a compounded drug, when other commercially available FDA-approved drugs are available to appropriately treat inflammation in a horse;

g. 71 IAC 8.5-5-2(e)(4), by possessing Rapid Equine P-Bloc, a compounded drug that was not labeled in compliance with IHRC regulations; and

h. 71 IAC 8.5-5-2(h), by possessing Rapid Equine P-Bloc, a compounded drug that was not labeled in compliance with IHRC regulations.

2. Dr. Wilcox's violations of each of the foregoing regulations were contrary to the best interests of horseracing in Indiana, especially in light of the following:

a. Veterinarians enjoy positions of trust at a racetrack because they are among few who can possess drugs, needles, syringes, etc.; and thus, a finding that they may

possess a prohibited substance is especially significant because of the ability to repeat, hide and cover-up their actions.

b. Concerns regarding possession of a prohibited substance, poor recordkeeping and inadequate labeling are significantly heightened when cooperation is not forthcoming.

POST-HEARING EVIDENTIARY MATTERS

At the conclusion of the Hearing, both parties were asked to provide research and information with respect to the current state of the law regarding grandfathered drugs (including both the appropriate legal standard and relevant policy rationale) in order to assist me during my deliberations. Following submission thereof by the parties, Dr. Wilcox filed a "Motion to Strike Evidentiary Materials Submitted Post Trial" challenging the submission of certain materials provided by Commission Staff on the basis that they constituted hearsay and were not properly authenticated. Ind. Code § 4-21.5-3-25(a) and (b) provide that a proceeding (including the Hearing) shall be conducted in an informal manner without recourse to the technical, common law rules of evidence and specifically provide the authority to admit hearsay. Moreover, of the three documents objected to by Dr. Wilcox, at least two[31] were independently located by me before the Hearing during my research of these matters. Accordingly, Dr. Wilcox's motion is hereby **DENIED.**

RECOMMENDED ORDER

Commission Staff may recommend penalties and an administrative law judge may accept, reject or modify the recommended penalty. 71 IAC 10-3-12(f). The ten (10) year suspension and fine of Ten Thousand Dollars ($10,000) recommended against Dr. Wilcox in the Amended

[31] Specifically, the CPG Sec. 440.100 Marketed New Drugs, etc. materials, and the FDA Warning Letter

Complaint are each reasonable in light of the substantial, credible and reliable evidence presented during the Hearing. Having considered all of the facts and evidence presented by the parties, including facts in mitigation, I hereby recommend that a Final Order be entered by the Indiana Horse Racing Commission in favor of the Indiana Horse Racing Commission Staff and against Dr. Wilcox affirming Administrative Complaint No. 218002 (as amended) in all material respects with respect to Paragraphs 9 (as set forth in the Summary Judgment Order), 12, 14 and 16-20 and sanctions be adopted recommending that Dr. Wilcox:

(a) Be suspended for a period of ten (10) years, and

(b) Be fined in the amount of Ten Thousand Dollars ($10,000).

Pursuant to I.C. § 4-21.5-3-29(d), Dr. Wilcox has fifteen (15) calendar days following receipt of this Recommended Order to file written exceptions with the Indiana Horse Racing Commission.

RESPECTFULLY SUBMITTED THIS 2nd DAY OF MAY 2019.

Michael Buker

Administrative Law Judge

CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing has been duly served by email on the 2nd day of May 2019 to the following parties of record:

David P. Murphy
David P. Murphy & Associates, P.C.
504 West Main Street
Greenfield, Indiana 46140
Email: DPMurphy504@outlook.com

Dale Lee Pennycuff
Indiana Horse Racing Commission
1302 North Meridian St., Suite 175
Indianapolis, IN 46202
Email: DPennycuff@hrc.in.gov

Noah Jackson
Indiana Horse Racing Commission
1302 North Meridian St., Suite 175
Indianapolis, IN 46202
Email: NJackson1@hrc.in.gov

Michael Buker

Michael Buker
Administrative Law Judge