PUBLIC

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION
OFFICE OF ADMINISTRATIVE LAW JUDGES

In the Matter of	)	
	)	
W. BRET CALHOUN,	)	
Appellant,	)	**Case No. 9430**
vs.	)	
	)	**Hon. Dania L. Ayoubi**
THE HORSERACING INTEGRITY & SAFETY AUTHORITY, a federal administrative agency.	)	**Administrative Law Judge**
Appellee.	)	

APPELLANT'S STATEMENT OF CONTESTED FACTS

Appellant Bret Calhoun, pursuant to the FTC's Order dated May 21, 2024, hereby submits his statement of contested facts.

The Authority's Final Order (hereinafter, the "Order") refused to make express findings to address disputed issues of operative, case-determinative facts. Instead, the Order rejected Appellant's arguments by implication when it found (without explanation) that the post-race samples contained more than 50 ng/mL of diclofenac:

> 10. In both cases, Diclofenac was present above the screening limit was detected by the Kentucky Laboratory and confirmed by the Pennsylvania Equine Toxicology and Research Laboratory (the "PETRL") for both Covered Horse Tatanka and Covered Horse Ain't Broke.

[Order, Section 3(A), ¶ 10.] To reach this result, the Authority necessarily found that (1) the Authority established chain-of-custody, (2) the Kentucky Laboratory tested and reported the samples in accordance with the Rule 6000 Series, and (3) the Kentucky Laboratory's estimation was accurate and reliable (despite the B Laboratory's contrary estimation in the 10-15 ng/mL range). Appellant contested each of these premises and the ultimate conclusion at the IAP hearing (*see* IAP Hearing Demos), and he does so again here.

1. Appellant Contests the Implicit Finding of Custody and Control

Custody and control are material to whether the Authority has established a foundation that the samples (1) belonged to the Covered Horses and (2) maintained their integrity throughout the sampling and testing period. The Authority ignored its evidentiary obligation to prove custody and control during the sampling period, and its belatedly generated document is incompetent proof. Though the rules of evidence do not strictly apply, the "chain-of-custody" document generated five months after the race is hearsay upon hearsay upon hearsay. The Authority made no attempt to authenticate this document or to establish the foundation for its contents.

Further, the Authority never established custody/control of the *urine samples* during testing. The laboratory documentation packages contain only a "summary" document for the *blood* samples. [RX2.7; RX5.9.] No documentation (even in summary form) is provided for the urine samples, which are the samples in question. *See* [RX 11.5 (original documentation required)]; Rule 3070(d) (WADA Technical Documents are authoritative).

2. Appellant Contests the Finding That the Post-Race Urine Samples Contained More Than 50 ng/mL of Diclofenac and the Premises Necessary to Establish that Finding

Whether the post-race samples *in fact* contained more than 50 ng/mL of diclofenac is material to (1) whether the Authority has met its burden of proof and (2) whether the Rules establishing that burden are valid.[1] Rule 3312 *generally* prohibits "any amount" of a controlled medication substance detected in a post-race sample. Rule 3312(c). But "[a]s an exception to the general rule," the Authority "may establish special criteria for the reporting or evaluation of certain Controlled Medication Substances, including a Minimum Reporting Level [or] Screening

[1] The Authority should have to justify to the Commission and to a federal court why it holds a trainer "strictly liable" for the presence of a drug "above the applicable screening limit" even where the B Laboratory clearly shows a concentration *below* the applicable screening limit. A developed and clear factual record on the issue is therefore necessary.

Limit . . . .” Rule 3312(d). As an NSAID, diclofenac is “subject to Screening Limits” of 50 ng/mL in urine. Rule 3312(e). A Rule 3312 violation occurs only if diclofenac is “detected in the Post-Race Sample . . . *above* the applicable Screening Limit.” Rule 3312(e)(1) (emphasis added). The Authority bears the burden to prove this fact to a degree higher than the preponderance of the evidence.

Appellant further contests the implicit findings that the Kentucky Laboratory’s report is reliable, accurate, and compliant with the Authority’s standards, and he contends instead that the report should have been deemed a “negative finding.” Rules 3122(c) & 3342(b). On that point, the Authority is already attempting some misdirection. Appellant never argued that the Rules required the laboratory to use a “quantitative” method as described by Rule 6310(e). *See* Application for Review, p.4. To the contrary, Appellant challenges the Rules as arbitrary-and-capricious precisely *because* quantitative analysis is inapplicable to substances regulated with screening limits.[2] *Id.*

Notwithstanding that “quantification” is not the required testing *procedure*, the Rules are equally clear that a mere *identification* of diclofenac is not enough evidence for the Authority to carry the burden of proof. The Authority’s Standards require an accurate and reliable *estimation* of amount following fit-for-purpose testing. Rules 6306(d)(2) & 6311(d)(2). And to that end:

- The B Laboratory testing for both Covered Horses show that post-race samples contained far less than 50 ng/mL (closer to 10-15 ng/mL) [Demos 8-13];
- The Kentucky Laboratory’s Method was not fit for low-level estimations, nor was its method validated in compliance with the Rule 6000 Series [Demos 14-27];

[2] The laboratory may — in its complete discretion — ignore a screening limit during the Initial Testing phase. Rule 6309(b). The only mandatory aspect of a “screening limit” is that laboratory can report the finding as an “Adverse Analytical Finding” ***only if*** it detects an “estimated concentration greater than the Minimum Reporting Level.” Rule 6311(d)(2).

- Serious defects in testing, including quality-control failures, method design, and demonstrable carryover, render the Kentucky testing unreliable [Demos 14-27];
- These same defects are departures from the Authority's standards for laboratory testing [*see, e.g.*, Demos 15, 24-25, 27];
- The Kentucky Laboratory's departures from the Rule 6000 Series, from the incorporated standards in WADA Technical Documents, and from accepted scientific practice are the most likely explanation for its reported Adverse Analytical Finding and the disparate conclusions between it and the B Laboratory's findings [Demos 28-33; RX 8.2].

Each of these points (which are set forth in Dr. King's report [RX8.2]) were raised at the hearing but never expressly ruled upon.

In sum, the Authority has not produced "sufficient proof" of a Rule 3312 violation. The Authority cannot prove to the ALJ's "comfortable satisfaction" that the samples in fact contained more than 50 ng/mL of diclofenac, and Appellant contests the (implied) findings that the Authority presented competent evidence of a "presence" violation under Rule 3312(e)(1).

Dated: May 24th, 2024.

Respectfully submitted,

/s/ Joseph C. DeAngelis

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CERTIFICATE OF SERVICE

Pursuant to 16 CFR 1.146(a) and 16 CFR 4.4(b), a copy of the foregoing is being served this 24th day of May, 2024, via First Class mail, e-filing, and/or email upon the following:

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