PUBLIC

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION
OFFICE OF ADMINISTRATIVE LAW JUDGES
FTC DOCKET NO. D-9444

ADMINISTRATIVE LAW JUDGE: **HON. JAY L. HIMES**

IN THE MATTER OF:

EUSABIO JUAREZ-RUFINO **APPELLANT**

THE AUTHORITY'S BOOK OF AUTHORITIES

March 25, 2026

Respectfully submitted,

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

In the Matter of	)	
Dr. Scott Shell, DVM	)	Docket No. 9439
Appellant.	)	

ADMINISTRATIVE LAW JUDGE DECISION
ON APPLICATION FOR REVIEW

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TABLE OF ABBREVIATIONS

AB1 – Appeal Book Part 1

AB2 – Appeal Book Part 2

ADMC – Anti-Doping and Medication Control

ADRV – Anti-Doping Rule Violation

AOBr. – Appellant's Opening Brief

ARBr. – Appellant's Reply Brief

ARPFOF – Appellant's Reply to Authority's Proposed Findings of Fact

AuOBr. – Authority's Opening Brief

AuRPCOL – Authority's Reply to Appellant's Proposed Conclusions of Law

AuRPFOF – Authority's Reply to Appellant's Proposed Findings of Fact

HISA – Horseracing Integrity and Safety Act, 15 U.S.C. §§ 3051-60

HIWU – Horseracing Integrity & Welfare Unit

The Authority – Horseracing Integrity and Safety Authority

I. INTRODUCTION

This decision arises under the Horseracing Integrity and Safety Act ("HISA"), 15 U.S.C. §§ 3051 *et seq*., and the Rules implementing the Act. Among other things, HISA created the Horseracing Integrity and Safety Authority (the "Authority"), a private, independent, self-regulatory, nonprofit corporation, to "develop[] and implement[] a horseracing anti-doping and medication control program and a racetrack safety program" throughout the United States.[1]

The Authority promulgated, and the Federal Trade Commission approved, rules that include the statutorily-required Anti-Doping and Medication Control ("ADMC") Program.[2] The HISA and ADMC Program rules address, in summary: (1) the persons and thoroughbred racehorses the Program covers; (2) the substances that are banned outright or subject to threshold presence requirements, or are regulated as controlled medications; (3) the conduct constituting violations and corresponding sanctions; and (4) investigation and enforcement in furtherance of the statute.[3] The Authority has contracted with the Horseracing Integrity & Welfare Unit ("HIWU") to implement and enforce the ADMC Program on behalf of the Authority.[4] HIWU charges of ADMC Program violations are heard by an Internal Adjudication Panel, which, as

[1] 15 U.S.C. § 3052(a).

[2] 15 U.S.C. §§ 3053, 3055, 3057.

[3] *See generally* ADMC Rule 3000 series; 88 Fed. Reg. 5070-5201 (Jan. 26, 2023) (FTC Notice of HISA Proposed Rule and Request for Comment); Order Approving the ADMC Rule Proposed by HISA (Mar. 27, 2023) (https://www.ftc.gov/system/files/ftc_gov/pdf/P222100CommissionOrderAntiDopingMedication.pdf); 88 Fed. Reg. 27894 (May 3, 2023) (FTC Notice of Final Rule, effective May 22, 2023) (available at https://hisaus.org/regulations?modal-shown=true#equine-anti-doping-and-controlled-medication-protocol-rules).

[4] 15 U.S.C. §§ 3054(e)(1)(B) & (E), 3055; Rules 3010(e)(1), 5720(a); HISA Announces Selection of Drug Free Sport International as Partner to Build Independent Anti-Doping and Medication Control Enforcement Agency (May 3, 2022), https://www.hiwu.org/news/hisa-announces-selection-of-drug-free-sport-international-as-partner-to-build-independent-anti-doping-and-medication-control-enforcement-agency.

here, may consist of a single arbitrator.[5] The FTC has authority to review civil sanctions imposed for ADMC Program Rule violations in HIWU-initiated enforcement proceedings.[6]

Under the ADMC Program, the more serious violations are Anti-Doping Rule Violations ("ADRVs"), which include Banned Substances that "should never be in a horse's system."[7] To implement the Program, the Authority issued a Prohibited List of Banned Substances.[8] Rule 3214(a), applicable to Covered Persons, prohibits "Possession of a Banned Substance . . . unless there is a compelling justification for such Possession."

II. THE UNDERLYING FACTS

A. Summary of the Case

As a veterinarian who provides services to Covered Horses, Appellant Dr. Scott Shell is a Covered Person subject to HISA, to the ADMC Program Rules, and to the enforcement system created.[9] HIWU has charged Dr. Shell with Possession of four Banned Substances, discussed more fully below. Possession is undisputed. Therefore, the case turns on whether Dr. Shell had "a compelling justification for such Possession," as well as on other defenses asserted. Rule 3214(a). One additional wrinkle is worthy of mention at this point.

Dr. Shell practices in both Ohio and West Virginia, and services both Covered Horses, subject to HISA, and non-Covered Horses, commonly found on farms. Also, while HISA and the

[5] Rules 3360, 7020.

[6] 15 U.S.C. § 3058; 16 C.F.R. § 1.145 *et seq.*; *see* 87 Fed. Reg. 60077 (Oct. 4, 2022) (Final Rule).

[7] Rule 3010(c). *See also* Rules 1020 (definition of ADRV), 3111(a) (Prohibited Substances). Capitalized terms used, but not defined in this decision, are those defined in HISA Rule 1020 of the General Provisions. Other abbreviations are set forth in the Table of Abbreviations.

[8] Rules 1020 (definition of Prohibited List), 3111(a).

[9] 15 U.S.C. §§ 3051(6), (21); Rule 1020 (definitions of "Attending Veterinarian" and "Covered Person").

Rules apply in Ohio, in 2022 a United States district court issued an order that, in effect, prohibits enforcement by the Authority and HIWU in West Virginia. Although HIWU's charges against Dr. Shell arise from his Possession of four Banned Substances at an Ohio racetrack, he contends that Possession was permitted as part of his providing services to horses on farms and in West Virginia where enforcement is prohibited.

In this review decision, I first set forth the facts forming the basis for HIWU's charges against Dr. Shell and then summarize the Arbitrator's ruling, which found HIWU's charges proven and determined the sanctions to be imposed. After that, I address the issues presented, the scope of the review under HISA, and my analysis of the issues raised and the sanctions ordered.

B. Dr. Shell's Practice and HIWU's Search

Dr. Scott Shell, a licensed Veterinarian in both Ohio and West Virginia, practices in both States under the corporate name, Scott Shell DVM Inc. AB1 at 2012 (¶¶ 1, 3); AB2 at 6672-75, 6680 (Shell). His practice includes two other veterinarians, Dr. Barbara Hippie and Dr. Maggie Smyth, and a head veterinary assistant, Janet Duhon. AB1 at 2012 (¶ 3); AB2 at 6756-57 (Shell). Dr. Shell is a Covered Person under the ADMC Program, administered by the Authority. AB1 at 1784 (¶ 13); ARPFOF at 1 (¶ 2). Besides servicing Covered Horses, Dr. Shell has a farm practice where he provides veterinary services to non-Covered Horses. AB2 at 6675, 6682-83 (Shell).

On September 28, 2023, HIWU investigators conducted searches of: (1) Dr. Shell's office at the JACK Thistledown Racino racetrack in Ohio ("Thistledown"); (2) Dr. Shell's veterinary truck; and (3) a veterinary truck registered to Dr. Shell's practice, operated by Dr. Hippie. AB1 at 622-37. The search uncovered four substances that the ADMC Program prohibits as Banned Substances:

Carolina Gold (sometimes referred to as "GABA")
Sarapin ("Pitcher Plant")

Isoxsuprine, and
Osphos.

AB1 at 507-08, 607-609, 642; AB2 at 6834-35. HIWU charged Dr. Shell with—and he admits—Possession of the four Banned Substances. *See* HISA Rule 3214(a); AB1 at 507, 607 (EAD Charge Letters), 1784-85.[10]

C. The Four Banned Substances Charged As Possession Violations

The four Banned Substances may be summarized as follows:

Carolina Gold (GABA): HIWU's search found two bottles of Carolina Gold, a Category S0 Banned Substance on the ADMC Program's Prohibited List. Carolina Gold is also prohibited at West Virginia racetracks under West Virginia Racing Commission Rules. AB1 at 642 (¶ 6), 1174; AB2 at 6836-37 (Shell), 7209 (Benson).

Carolina Gold contains Gamma Aminobutyric Acid ("GABA"), an endogenous neurotransmitter, which exerts an inhibitory effect on the central nervous system and thus has a calming effect on a horse. AB2 at 6710-11, 6837 (Shell), 7087 (Scollay). If Carolina Gold is given to a racehorse, "it can be performance limiting, if not, potentially fatal, depending on the severity of its effect ['in preventing exercise induced pulmonary hemorrhage']." AB2 at 7090 (Scollay). GABA has a half-life of approximately 22 minutes when given intravenously and ceases to be detected between six and eight hours later. AB2 at 7524 (Benson).

Carolina Gold is not FDA-approved, which means that "[i]t is an illicitly manufactured, illegal, unapproved new animal product." AB2 at 7088 (Scollay), 7209 (Benson). A compounded substance, Carolina Gold does not comply with FDA guidance for compounding. AB2 at 7091

[10] HIWU originally charged Dr. Shell with Possession of three Banned Substances and Dr. Hippie with one, for Possession of Pitcher Plant. After the Provisional Suspension of Dr. Hippie was lifted, HIWU added Possession of Pitcher Plant to the charges against Dr. Shell.

(Scollay), 7491, 7494 (Roberts). As Dr. Scollay explained:

> It has not been examined by the FDA for safety, efficacy, purity, stability, any of that stuff, and so it qualifies essentially as administering an unknown.
>
> . . . .
>
> Has it been contaminated with bacteria, with fungus, with other substances? I mean, you'd have to do a pretty serious risk benefit analysis to put that into a horse when, if you're trying to calm it down . . .

AB2 at 7088, 7089.

Dr. Shell's expert veterinarian witness, Dr. Andrew Roberts, testified similarly: "what is actually in the bottle, it would be of interest to know." AB2 at 7492 (Roberts). Dr. Roberts has never used Carolina Gold in his practice and has never kept it on his truck. AB2 at 7492, 7501 (Roberts).

There is no significant, legitimate use for Carolina Gold on non-Covered Horses. AB2 at 7088-90, 7112 (Scollay). Nor is it life-saving or needed for emergency use. AB2 at 6891 (Shell), 7088-89 (Scollay). FDA-approved substances having a similar calming effect are available. AB2 at 7087, 7089 (Scollay). Indeed, Dr. Roberts "agreed" that there are "no recognized medical uses" for a product, such as Carolina Gold, that contains GABA. AB2 at 7489 (Roberts).

Pitcher Plant: HIWU investigators found a bottle of Sarapin, also known as "Pitcher Plant," during their search of a truck operated by Dr. Hippie, which Dr. Shell owned. AB1 at 643; AB2 at 6704 (Shell). Pitcher Plant is a Category S6 Banned Substance on the Prohibited List and is also prohibited at West Virginia racetracks under the West Virginia Racing Commission Rules. AB1 at 1202, 3396; AB2 7224-25 (Benson), 7505 (Roberts). Pitcher Plant is an herbal analgesic that reduces inflammation and relieves pain. AB1 at 1202; AB2 at 6713 (Shell), 7091-92 (Scollay). Its use is not limited to emergencies. AB2 at 7092-93 (Scollay).

Pitcher Plant was, but no longer is, FDA-approved. AB2 at 7225 (Benson). There are multiple FDA-approved analgesics that can be used instead. AB2 at 7093 (Scollay). There is no

approved analytical method to detect administration of the substance in a horse. AB2 at 7225 (Benson), 7504-05 (Roberts).

Isoxsuprine: During their search of Dr. Shell's truck, HIWU investigators also found a tub of Isoxsuprine powder. AB1 at 642, 654; AB2 at 6703-04 (Shell). Isoxsuprine also is a Category S0 Banned Substance on the Prohibited List, as well as prohibited under the West Virginia Racing Commission Rules. AB1 at 1178; AB2 at 7231 (Benson). Dr. Shell testified he uses Isoxsuprine to vasodilate the feet of older horses and horses that have navicular disease or founder (lameness). AB2 at 6707 (Shell). A chronic condition, navicular disease is "a degenerative disorder of a small bone in the horse's foot and results in foot pain, lameness . . . ." AB2 at 7094 (Scollay), 7223 (Benson). Isoxsuprine's use is not limited to emergencies. AB2 at 7100 (Scollay), 7224 (Benson).

The FDA's previous approval of Isoxsuprine for use in humans has since been withdrawn as lacking a pain-relieving effect. AB2 at 6990 (Shell); 7094 (Scollay). To treat these conditions in horses, there are FDA-approved, HISA-permitted Controlled Medication Substances. AB2 at 7096-97 (Scollay).

Osphos: During their search, HIWU investigators also recovered two boxes of Osphos, a bisphosphonate, from Dr. Shell's office located on the backside of Thistledown. AB1 at 643 (¶ 11); AB2 at 6996 (Shell). Bisphosphonates are a Category S6 Banned Substance on the Prohibited List. AB1 at 1159. Osphos is used to strengthen bones and to treat navicular disease, repairing bone erosion. AB2 at 6709-10 (Shell), 7223 (Benson); *see also* AB2 at 7098-99 (Scollay) (describing the effect of bisphosphonates to clean and rebuild bone). Since the underlying condition is chronic, Osphos has uses in circumstances that are non-urgent and non-emergency. AB2 at 6997 (Shell), 7223-24 (Benson).

Unlike the other three Banned Substances found, Osphos is FDA-approved for treatment of horses that are more than four years old. AB2 at 7099 (Scollay), 7363 (Roberts). However, it should not be administered to young, growing horses or to racehorses because it "makes the bone too brittle" and risks fracture. AB2 at 6710 (Shell), 7099-100 (Scollay). If administered to young horses, Osphos will remain in the body, able to act, for years. AB2 at 7100 (Scollay).

D. The Federal Injunction Covering West Virginia

A specific issue in this case arises from Dr. Shell's practice in West Virginia. In 2022, the United States District Court for the Western District of Louisiana held that the Authority violated the Administrative Procedure Act in the process of promulgating the HISA Rules. The Court thus issued a preliminary injunction against enforcement of the Rules against the plaintiffs, one of whom was the State of West Virginia. *Louisiana v. Horseracing Integrity & Safety Auth. Inc.*, 617 F.Supp.3d 478 (W.D. La. 2022), *remanded*, No. 22-30458, 2022 WL 17074823 (5th Cir. 2022). As a result of the district court's injunction, the Authority and HIWU do not enforce HISA in West Virginia. AuRPCOL ¶ 10; AB2 at 7125-26 (Scollay).

Dr. Shell thus argues that Covered Horses under HISA—those that are authorized to run in races subject to HISA—become "non-Covered Horses" while in West Virginia. Even though three of the four Banned Substances found in Dr. Shell's Possession in Ohio are also prohibited in horseracing in West Virginia (Osphos is the exception), Dr. Shell contends that he may dispense or administer them to otherwise Covered Horses while they are in West Virginia. This outlier circumstance, he further maintains, provides a compelling justification for his Possession of these substances in Ohio.

The Arbitrator rejected this argument, as do I in the analysis that follows.

E. HIWU's Other "Administration" Case

Another matter also gives rise to an issue I must decide. Besides this Possession case, HIWU charged Dr. Shell with administering, by injecting into many racehorses, a Banned Substance that Dr. Shell believed was an unregulated vitamin and thus permissible to use. The arbitrator in that case—referred to as the "Administration Case"—upheld HIWU's charges, and, among other things, determined that Dr. Shell should be subject to a two-year period of Ineligibility, during which he may not offer services to Covered Horses or Covered Persons. On review, I upheld the sanctions imposed.[11] The possible effect of the Ineligibility arising from the Administration Case is an issue in this proceeding.

F. The Arbitration Subject to this Review

Upon service of HIWU's EAD Charge Letter in October 2023, a Provisional Suspension was imposed on Dr. Shell. *See* Rule 3247(a)(3); AB2 at 6593. He sought to lift the Suspension pending the arbitration hearing to resolve the merits of HIWU's charges, but the hearing officer denied his request. AB1 at 1136, 1138-39; AB2 at 6593-94. During the pre-hearing phase of the arbitration, HIWU moved for an order directing Dr. Shell to produce documents relating to his compelling justification defense. *See* AB1 at 2046-59, 2090-107. While the Arbitrator directed limited production, she also wrote:

> Dr. Shell has made the nature of his practice relevant, and has placed at issue whether he had a noncovered horse practice that ***required*** the carrying of the Targeted Banned Substances. . . . Dr. Shell opened the door to this line of inquiry by raising the defense that the Targeted Banned Substances ***were only used in non-covered horses***. Accordingly, Dr. Shell has the burden of supporting that defense with his veterinary records for covered and non-covered horses. As such, ***the complete veterinary medical records*** for all horses in his practice from the implementation of HIWU's regulations until he was charged are ***relevant and material to the defense***.

[11] AB1 at 99-136 (*HIWU v. Shell*, JAMS Case No. 1501000708 (June 11, 2024)), *aff'd*, FTC No. 9435 (ALJ Oct. 31, 2024).

AB1 at 2278 (emphasis added); *see also* AB1 at 2044-128. In response, Dr. Shell produced additional—albeit, still limited—documents. *See* AB1 at 2297.

In April 2024, a multi-day arbitration hearing was held, during which Dr. Shell and other fact and expert witnesses testified, and numerous exhibits were received in evidence. The parties made voluminous post-hearing submissions, and the Arbitrator heard closing arguments in August 2024. AB2 at 3892-6567, 7528-613. After requesting additional papers on an issue regarding sanctions, discussed further below, the Arbitrator issued her decision. *See* AB2 at 6571-82, 6588-622.

1. Compelling Justification

The Arbitrator concluded that Dr. Shell failed to prove a compelling justification to possess any of the Banned Substances, holding that Dr. Shell's records and other evidence were inadequate to justify Possession under Rule 3214(a). Despite the admonition from her discovery order, the Arbitrator noted that Dr. Shell produced only "limited" records, which "showed some dispensation of the Banned Substances to farm horses and Thoroughbreds in West Virginia, but [these were] not complete records sufficient to justify the possession of the Banned Substances at the Ohio racetrack." AB2 at 6613 (¶ 7.18).

The Arbitrator rejected Dr. Shell's "convenience" argument for Possession of Banned Substances. Additional travel time, needed to avoid Banned Substances at an Ohio racetrack, was unpersuasive unless the "medications [were] needed on a regular basis for time-sensitive emergency treatment." AB2 at 6614 (¶ 7.21). The Banned Substances found in Dr. Shell's truck and office at Thistledown, however, "were not emergency medications required for life-threatening injuries . . . ." AB2 at 6614 (¶ 7.22). Analyzing each individual substance, the

Arbitrator held that Dr. Shell failed to show compelling justification. AB2 at 6615-16 (¶¶ 7.28-33).

The Arbitrator recognized that a federal court injunction "suspended HIWU's operations" in West Virginia. AB2 at 6591 (¶ 2.14); *see also* AB2 at 6601, 6603 (¶¶ 6.7, 6.24). Accordingly, she agreed with Dr. Shell that the Authority and HIWU could not legally regulate the dispensation of Banned Substances in West Virginia, or charge a Veterinarian with a HISA Rule violation for treating a Covered Horse in West Virginia. AB2 at 6614 (¶ 7.25). However, that "does not mean that having a clientele of Thoroughbred horse trainers in West Virginia is a compelling justification for possessing Banned Substances at Ohio racetracks." AB2 at 6614 (¶7.25). The Banned Substances in Dr. Shell's Possession were not "emergency medications that Dr. Shell needed to have at the ready to dash to West Virginia." AB2 at 6614 (¶ 7.25). The Arbitrator further found it significant that Dr. Shell testified that he no longer carries the four Banned Substances on his truck and, despite this changed practice, he is able to meet his ethical obligations as a veterinarian. AB2 at 6616 (¶ 7.34).

The Arbitrator also rejected Dr. Shell's argument that, as a result of HISA's non-enforcement in West Virginia, otherwise Covered Horses automatically became non-Covered Horses while in West Virginia. The Arbitrator held that allowing Dr. Shell to possess Banned Substances in Ohio in order to treat Covered Horses located in West Virginia would create a "loophole" that would "undermine[] the integrity of the ADMC Program and is not justified, much less compelling." AB2 at 6614-15 (¶ 7.25).

Finally, Dr. Shell argued that HIWU made various statements regarding compelling justification, as applied to Veterinarians with farm practices, such as Dr. Shell. He argued that he relied on these statements and thus kept the substances on his trucks and at his Thistledown

facility as a result. Therefore, he maintained, HIWU should be precluded ("estopped") from prosecuting him for Possession. Analyzing the facts, the Arbitrator rejected Dr. Shell's argument. AB2 at 6616-17 (¶¶ 7.37-41).

2. Sanctions

Having concluded that Dr. Shell was liable for Possession, the Arbitrator considered the sanctions to be imposed. The HISA Rules set forth detailed, often intricate, provisions regarding sanctions, which include a two-year period of Ineligibility, during which a Covered Person may not participate in HISA-covered activity, as well as fines and costs. Sanctions can, however, be eliminated or reduced if the Covered Person establishes either No Fault or Negligence ("NF") or No Significant Fault or Negligence ("NSF"). Rules 3224 & 3225.

The Arbitrator held that Dr. Shell failed to establish NF. Dr. Shell admitted Possession of the four Banned Substances and displayed a sufficient lack of appropriate care as to preclude an NF finding. AB2 at 6617 (¶¶ 7.44-48). For NSF, the Arbitrator concluded that Dr. Shell should receive a three-month reduction of the maximum two-year Ineligibility period, resulting in one 21-month period of Ineligibility for all four Possession violations, beginning as of the date of his Provisional Suspension in October 2023. AB2 at 6618-20, 6622 (¶¶ 7.49-60, 8.1). The Arbitrator further imposed a total fine of $20,000, less than $25,000 per violation permitted under the Rules, while declining to direct Dr. Shell to bear any costs of the arbitration. AB2 at 6620-21, 6622 (¶¶ 7.65-66, 8.1).

In ruling on sanctions, the Arbitrator rejected two HIWU arguments: (1) that sanctions should be imposed for each of the four Possession charges; and (2) that Dr. Shell's Ineligibility period should run consecutively after the two-year Ineligibility period arising from the

Administration Case ended, and not concurrent with that other sanction. AB2 at 6621-22 (¶¶ 7.67-7.74).

III. ISSUES ON REVIEW

The following issues are presented for review:

(1) Did Dr. Shell show compelling justification for Possession of any of the four Banned Substances?

(2) Is HIWU, and therefore the Authority, estopped from prosecuting the Possession charges against Dr. Shell?

(3) Does the "compelling justification" defense, recognized in Rule 3214(a), violate the Due Process provision of the Fifth Amendment as unconstitutionally vague?

(4) Is HISA unconstitutional under the private non-delegation doctrine?

(5) Is Dr. Shell subject to either (a) individual sanctions for each of the four Possession violations, or (b) consecutive periods of Ineligibility arising from the Administration Case?

(6) Is Dr. Shell entitled, under the No Fault or Negligence or No Significant Fault or Negligence provisions in Rules 3224 or 3225, to elimination or reduction of the two-year Ineligibility period applicable to Possession violations or to any other part of the sanctions?

IV. SCOPE OF REVIEW

HISA civil sanctions, imposed for rule violations, are reviewable by an FTC Administrative Law Judge (ALJ) upon application of the person aggrieved and thereafter by the Commission itself on a discretionary basis.[12] The ALJ reviews:

> "whether—
>
> (i) a person has engaged in such acts or practices, or has omitted such acts or practices, as the Authority has found the person to have engaged in or omitted;

[12] 15 U.S.C. §§ 3058(b) & (c); FTC Rules 1.146 & 1.147.

> (ii) such acts, practices, or omissions are in violation of this chapter or the anti-doping and medication control or racetrack safety rules approved by the Commission; or
>
> (iii) the final civil sanction of the Authority was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law."

15 U.S.C. § 3058(b)(2)(A); *see also* 16 C.F.R. § 1.146(b)(1)-(3).

The ALJ's review is *de novo*, as though the issue had not been heard before, and no decision had previously been rendered. 15 U.S.C. § 3058(b)(1); FTC Rule 1.146(b)(3); *Adirondack Med. Center v. Sebelius*, 740 F.3d 692, 696 (D.C. Cir. 2014), and *Agyeman v. INS*, 296 F.3d 871, 876 (9th Cir. 2002) (both describing scope of *de novo* review of agency's interpretations of statute).[13]

Thus, the ALJ must determine the merits of the ADRV charged, and whether the sanctions the Authority imposed were "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law."[14] "[T]o pass muster under the arbitrary and capricious standard," a court must only find a "rational connection between facts and judgment." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43, 56 (1983). "To make this finding, the court must consider whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment." *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971).

Judicial review under the arbitrary and capricious standard ensures that "the agency has acted within a zone of reasonableness and, in particular, has reasonably considered the relevant

[13] *See also Barrientos v. Wells Fargo Bank, N.A.*, 633 F.3d 1186, 1188 (9th Cir. 2011), and *Aquarius Marine Co. v. Pena*, 64 F.3d 82, 87 (2d Cir. 1995) (both holding that, on *de novo* review by an appellate court, there is no deference to the district court); *Coalition for Competitive Electricity, Dynergy Inc. v. Zibelman*, 906 F.3d 41, 48 (2d Cir. 2018), and *Freeman v. DirecTV, Inc.*, 457 F.3d 1001, 1004 (9th Cir. 2006) (both describing *de novo* review by an appellate court of district court dismissal of complaint under Federal Rule of Civil Procedure 12(b)(6)).

[14] 15 U.S.C. § 3058(b)(2)(A); FTC Rule 1.146(b)(1)-(3).

issues and reasonably explained the decision." *FCC v. Prometheus Radio Project*, 592 U.S. 414, 423 (2021). To find an abuse of discretion, there must be "a plain error, discretion exercised to an end not justified by the evidence, a judgment that is clearly against the logic and effect of the facts as are found." *Nat'l Wildlife Fed'n v. Nat'l Marine Fisheries Serv*., 422 F.3d 782, 798 (9th Cir. 2005).

Finally, whether the sanctions are in accordance with the law is determined with reference to the substantive law embodied in HISA and the implementing regulations, summarized above.

In exercising its review authority, the ALJ may "affirm, reverse, modify, set aside, or remand for further proceedings, in whole or in part" and "make any finding or conclusion that, in [their] judgment . . . is proper and based on the record."[15]

V. ANALYSIS OF THE ISSUES

A. The Possession Violation and Compelling Justification Defense

Rule 3214(a) provides that "Possession of a Banned Substance" is an "Anti-Doping Rule Violation" "unless there is compelling justification for such Possession." The violation imposes strict liability.[16] Both equine sporting association codes and those in sports generally include analogous provisions. *See e.g.,* Federation Equestre Internationale (FEI) Equine Anti-Doping and Controlled Medication Regulations, Article 3.1 (4th ed. 2025); World Anti-Doping Agency (WADA) Code, Article 3.1 (2021).

[15] 15 U.S.C. § 3058(b)(3)(A); FTC Rule 1.146(d)(3).

[16] *See, e.g., USADA v. Drummond*, Case No. AAA 01-14-000-6146, at 19 (Dec. 17, 2014) ("The Panel rejects Drummond's contention that actual possession requires his specific intent to have under his custody and control a particular banned substance whose characteristics were fully known to him."); *Eder v. International Olympic Committee (IOC)*, CAS 2007/A/1286, 1288 & 1289, at ¶¶ 42, 52 (Jan. 4, 2008) (possession does not require proving "subjective intent," or "intent to use"); *Diethart v. IOC*, CAS 2007/A/1290, at ¶ 40 (Jan. 4, 2008) (possession "constitutes in itself an antidoping rules violation").

Dr. Shell has the burden of providing that defense "by a balance of probability (*i.e.*, a preponderance of the evidence) . . . ." Rule 3121(b). Since he does not dispute Possession of the four Banned Substances, his liability turns on the defense of "compelling justification."[17]

1. "Compelling Justification"

While a defense of "compelling justification" to possession is common in sports law anti-doping codes generally, as in the HISA Rules the expression is invariably undefined. Further, decisions considering the defense typically arise under a rule that prohibits a human athlete from failing to provide a test sample "without compelling justification."[18] Thus, these sports world decisions, arising in a different factual context, offer only limited guidance. In any event, "[w]hen interpreting a statute, we begin with the text." *Lackey v. Stinnie*, No. 23-621, slip op. at 5 (U.S. Feb. 25, 2025).

Dictionaries reflecting ordinary word usage can be helpful. An authoritative dictionary's definition of "justification" is:

> 1. A lawful or sufficient reason for one's acts or omissions; any fact that prevents an act from being wrongful.
>
> 2. A showing, in court, of a sufficient reason why a defendant acted in a way that, in the absence of the reason, would constitute the offense with which the defendant is charged.

BLACK'S LAW DICTIONARY (12th ed. 2024). And for that "reason" to be "compelling," it must be "both powerful and convincing. *See* [WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY OF THE ENGLISH LANGUAGE UNABRIDGED 462] (defining 'compelling' as 'forcing, impelling, [or] driving [circumstance]' and as 'tending to convince or convert by or as if by forcefulness of

[17] The arbitrator found that Dr. Shell has failed to prove compelling justification to her "comfortable satisfaction." AB2 at 6616 (¶ 7.35). That was error. On this review, the parties recognize that the preponderance standard applies. AuRPCOL at 13 (¶ 3).

[18] *See, e.g., Klein v. ASADA*, CAS A4/2016 (May 25, 2017), cited by both Shell and the Authority.

evidence') . . . ." *United States v. Canales-Ramos*, 19 F.4th 561, 567 (1st Cir. 2021) (construing the federal "compassionate release" statute, applicable to incarcerated individuals).[19]

Of necessity, this defense is fact-driven and thus case-specific. Moreover, we should not lose sight of the forest. Rule 3214(a)'s Possession violation is part of a regulatory scheme directed to banishing doping from thoroughbred horseracing; compelling justification, excusing Possession, is the exception and should, accordingly "be interpreted restrictively." *WADA v. Contreras*, CAS 2013/A/3341, at 20 (¶ 116) (May 28, 2014).

2. Dr. Shell's "Non-Covered Horses" Practice as a Compelling Justification

As described above, Dr. Shell practices in both Ohio and West Virginia. He provides veterinary services not only to Covered Horses regulated under HISA, but also to farm horses that do not run in Covered Horseraces. Dr. Shell contends that he had the Banned Substances that HIWU seized in Ohio because he needed them in his farm practice to treat these non-Covered Horses in both Ohio and West Virginia.

For his West Virginia practice, Dr. Shell makes still another argument. The federal court's preliminary injunction prevents HIWU and the Authority from enforcing the HISA Rules in West Virginia. Accordingly, Dr. Shell maintains, any otherwise Covered Horse is "non-Covered" while in that State and, therefore, he may dispense or administer Banned Substances to those horses in West Virginia. Since the Banned Substances are part of his practice in West Virginia, according to Dr. Shell, he had a compelling justification to possess them at Ohio's Thistledown racetrack.

I consider this argument, applicable to otherwise Covered Horses in West Virginia, first.

[19] *See also* https://dictionary.cambridge.org/us/dictionary/english/compelling.& /justification. I do not suggest that dictionary definitions are always useful, much less dispositive. However, particularly where other sources of guidance are limited, they can assist the analysis.

Then, I address his other argument that the four Banned Substances are necessary for his farm practice.[20]

a. Otherwise Covered Horses Physically in West Virginia

Rule 1020 defines "Covered Horse" to mean:

> [A]ny Thoroughbred horse, or any other horse made subject to the Act by election of the applicable State Racing Commission or the breed governing organization for such horse under section 3054(l), ***during the period***: (A) beginning on the date of the horse's first Timed and Reported Workout at a Racetrack that participates in Covered Horseraces or at a training facility; and (B) ending on the date on which the horse is deemed retired pursuant to Rule 3050(b).

(Emphasis added). Rule 3050(b)(1) provides that: "If an Owner wishes to retire a Covered Horse such that it is no longer made available for Testing, the Owner must provide ***written notice*** of such retirement to the Agency, in accordance with its procedures." (Emphasis added). Other subsections in Rule 3050(b) establish processes for "unretiring" a Covered Horse, and limitations once unretirement is accomplished. *See* AB2 at 7101-07 (Scollay) (explaining operation of the definition and the retirement process).

No HISA Rule recognizes an automatic change from Covered to non-Covered that occurs if a Covered Horse is moved from a jurisdiction subject to HISA to one that is not. As Dr. Mary Scollay, HIWU's chief scientist since October 2022, explained:

> Q: Can you help us understand exactly what a covered horse is, what the definition is?
> A: Sure, it is a thoroughbred from the time that it has generated its first published work or made its first start until it is either retired or it is deceased.
> . . . .
> Q: And so if someone were to attempt to cover their horse and then uncover the horse and then cover their horse and uncover their horse, that's simply not permissible under the regs., is it?
> A: No.

AB2 at 7101, 7106 (Scollay).

[20] Many records Dr. Shell produced in this case contain hand notations such as "non-covered" or "farm horse." Dr. Shell testified that his secretary made the notations, but did not explain why. AB2 at 6853. I infer these hand notations were made simply for production purposes in this case, not as ordinary course business records.

Although Dr. Shell testified that he met with Dr. Scollay after a presentation she made at Mahoning racetrack in Ohio, it is undisputed that he never asked her whether he could dispense Banned Substances to horses in West Virginia; nor is there any evidence he asked anyone else from HIWU or the Authority. *See* AB2 at 6822-25 (Shell). He similarly offered no evidence that he sought advice concerning the effect of the Western District of Louisiana preliminary injunction. Instead, he testified, without corroboration, that trainers "unregister" and "re-register" Covered Horses when transporting them from a State subject to HISA, such as Ohio, to one not subject to HISA, such as West Virginia. AB2 at 6792-98 (Shell).

The Arbitrator concluded that holding otherwise Covered Horses located in West Virginia as no longer covered would "undermine[] the integrity of the ADMC Program and is not justified, much less compelling." AB2 at 6614-15 (¶ 7.25). I agree.

If accepted, Dr. Shell's position would permit evasion of the ADMC Program. Covered Persons, such as owners or trainers, who may be in West Virginia could receive and use Banned Substances with otherwise Covered Horses, or have them administered in West Virginia. Their racehorses could then be transported to run out of the State in Covered Horseraces. Any such result would fly in the face of a core principle of the ADMC Program: "Covered Horses should compete only when they are free from the influence of medications, other foreign substances, and treatment methods that affect their performance." Rule 3010(d)(1). And, since three of the four Banned Substances here also are prohibited by the West Virginia Racing Commission, permitting their dispensation in West Virginia could impair the integrity of races in that State as well.

This case illustrates the potential for evasion of the ADMC Program. Dr. Shell dispensed Carolina Gold—often identified in his records as for "farm use"—to various West Virginia

trainers, who ran thoroughbred racehorses throughout the country in HISA-covered States. Lack of individual horse identification in the records Shell produced makes it impossible to determine whether—or which of—those horses had received Carolina Gold in West Virginia. *See* AB1 at 3451-98; AB2 at 6868-74, 6920-30 (Shell). Moreover, Dr. Shell dispensed the Carolina Gold in a vial, sometimes with instructions to the trainer for its use, rather than treating the horse himself. *See* AB2 at 6761-62, 6852 (Shell). For example:

- Dr. Shell dispensed Carolina Gold to a Covered Trainer in West Virginia for a thoroughbred racehorse that thereafter raced at Mahoning Valley in Ohio, and previously at Monmouth Park in New Jersey. AB1 at 3451-52; AB2 at 6878-83 (Shell).
- Dr. Shell dispensed Carolina Gold to Covered Trainers for thoroughbred racehorses with the instructions:
  - "Give 5cc IM [in the muscle] before race at Mountaineer [in West Virginia] for calming/relaxation." AB1 at 3426-27; AB2 at 6845-47, 6853-55 (Shell).
  - "Give 5cc IM night before race or work for nerves Give IM." AB1 at 3429-30; AB2 at 7214 (Benson).
  - "Give 5cc IM night before training or race for nerves." AB1 at 3442-43; AB2 at 6872-73 (Shell).
- Dr. Shell dispensed Carolina Gold to a Covered Trainer in Ohio for a thoroughbred racehorse stabled in West Virginia that raced at Mountaineer. AB1 at 3445, 3447; AB2 6874-77 (Shell).

Once the Banned Substance is dispensed in West Virginia to a trainer with administration instructions, the opportunity to inject the Covered Horse for races elsewhere is obvious. I reject

Dr. Shell's loophole argument: that he was entitled to provide Banned Substances to thoroughbred racehorse trainers in West Virginia to use as they pleased. Covered Horses that are not "retired" in accordance with Rule 3050(b)(1) remain Covered Horses while in West Virginia for purposes of Rule 3214(a) charges of Possession of Banned Substances at HISA-covered locations in Ohio.

b. Dr. Shell's Farm Practice Proof

Dr. Shell also argues that his farm practice, often involving non-Covered Horses, required his Possession of the Banned Substances that HIWU seized. The factual backdrop for his defense revolves around remarks by HIWU's Dr. Scollay to educate industry participants on the HISA Rules during the period after the law's enactment, but prior to the ADMC Program taking effect in May 2023. Dr. Scollay's remarks, Dr. Shell argues, informed his view of the proof he would need to demonstrate compelling justification.

i. Dr. Scollay's Mahoning Presentation

Besides serving as HIWU's chief scientist, Dr. Scollay is a regulatory veterinarian with 37 years of industry experience. AB2 at 7056-57 (Scollay). After HISA's enactment, she made public presentations throughout the country to educate horserace industry participants on the new, not yet effective, ADMC Program. AB2 at 7059-60 (Scollay). The presentations were themselves substantially the same, and each afforded those attending an opportunity to ask questions. AB2 at 7060-62, 7065 (Scollay). Discussion of compelling justification as a defense to Banned Substance possession charges under Rule 3214(a) typically arose in response to audience questions:

> I'd had several questions at different presentations about non-covered horses or mixed populations in some race tracks, trainers have populations of thoroughbreds which are covered horses and quarter horses which are not under HISA jurisdiction. And so they asked questions about a trainer possessing a

> banned substance in his barn if it were prescribed for a non-covered horse. And I explained that HISA regulations do not have authority over non covered horses.

AB2 at 7066 (Scollay); *see also* ARPFOF at 9 (¶ 34).

One of Dr. Scollay's presentations took place in March 2023 at the Will Rogers Downs Racetrack in Oklahoma, where an audience member recorded her remarks. AB2 at 7062-63 (Scollay). During discussion of Banned Substances, an audience member asked whether the "banned possession" rule applied to veterinarians.[21] Dr. Scollay replied that veterinarians were covered and "you don't need that on your truck."[22] She continued: the "***caveat*** I will tell you is:

> … [i]f the veterinarians are practicing also on a population of non-Covered horses, they're taking care of quarter horses or they've got a country practice part-time they are able to possess a Banned Substance because we don't have control over those horses, and so to the extent that they want to use bisphosphonates on a Non-Covered horse, we can't ban them from possessing them … we can't penalize people for something that we don't have control over so, you know, let's just say because we have the ability to investigate, if the story starts to get a little weird or a little extreme, you're going to get more than a raised eyebrow. But at the end of the day if someone is practicing out in the country, we don't have the authority to control the medications they administer or carry for Non-Covered Horses … the regulation addresses if there is justification for them to be in Possession of a Banned Substance and certainly a practice that incorporates Non-Covered horses.

AuRPFOF at 3 (¶ 9) (emphasis added); AB1 at 1547-48; AB2 at 7117-18 (Scollay) (the recorded remarks "[s]ound[] exactly like what I said.").[23]

Although Dr. Shell did not attend the Will Rogers Downs presentation, he testified to attending one at Mahoning racetrack in Ohio, where Dr. Scollay spoke. AB2 at 6687, 6789,

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[21] https://www.facebook.com/Traoracing/videos/891125828812595/?extid=CL-UNK-UNK-UNK-AN_GK0T-GK1C&mibextid=2Rb1fB&ref=sharing (Video Mark ≈24:40-50). *See also* AB1 at 2576 (Scollay witness statement).

[22] *Id.*

[23] *See also HIWU v. Perez*, JAMS Case No. 1501000589, *aff'd*, FTC No. 9420 (ALJ Decision on Application for Review, Feb. 7, 2024), https://www.ftc.gov/system/files/ftc_gov/pdf/609612_d09420-administrative_law_judge_decision_on_application_for_review_-_public.pdf, *review denied*, 2024 WL 3824065 (F.T.C. Aug. 8, 2024).

6813-15 (Shell). Dr. Scollay gave substantially the same prepared remarks as at other racetracks, "absent the spontaneous exchanges that occur[red] at each racetrack . . . ." AB2 at 7083 (Scollay). According to Dr. Shell, Dr. Scollay made "it clear that it was prohibited to possess or prescribed [sic] banned substances to a covered horse." AB2 at 6815 (Shell). The subject of compelling justification, as applied to veterinarians, again came up. Dr. Scollay's response echoed those given at Will Rogers Downs. AB2 at 6693-94 (Shell). Dr. Shell further testified:

> [Dr. Scollay] said that we were allowed to carry banned substances on our vehicles. In fact, she said you do not have to unload and reload your truck every time you leave the track to go to a farm.
>
> . . . .
>
> She said, as long as you have a farm practice, that with justification, you are allowed to carry them.

AB2 at 6693, 6816 (Shell).

During her Mahoning presentation or those at other racetracks, Dr. Scollay "did not" say that "veterinarians have carte blanche to carry banned substances on their trucks at racetracks if they claim to have a farm practice." AB2 at 7083, 7144-45 (Scollay). She also made "it clear that HIWU would have the ability to investigate any possession of a banned substance," and said "you have to be able to support why you had medication on your truck." AB2 at 6821 (Shell). Thus, as the parties agree:

> [During her presentations] Dr. Scollay would confirm that the ADMC Program has no authority over non-Covered Horses but explain[ed] that Possession needed to be justified and would be further investigated where suspicions or inconsistencies arose.

ARPFOF at 9 (¶ 34).

ii. Dr. Shell's Follow-up Conversation

Having heard Dr. Scollay's Mahoning remarks, Dr. Shell was, nevertheless, "a little antsy." AB2 at 6694, 6822 (Shell). He testified that, after the presentation had concluded, he

spoke to Dr. Scollay. Dr. Shell sought further information regarding his practice of servicing non-Covered horses. According to Dr. Shell: "She reassured me . . . after the meeting that there were [sic] absolutely no reason that I would have to remove banned substances and put them back on my truck every time I drove off the racetrack." AB2 at 6694 (Shell). Dr. Shell further testified:

> Q: And you never asked her the question of whether or not you could have banned substances on your truck to provide to race horses in West Virginia on a farm or otherwise, you never asked her, right?
>
> A: No, I did not ask her.

AB2 at 6823 (Shell).

Dr. Shell had no other contacts with Dr. Scollay after the Mahoning racetrack presentation and follow-up, nor any further "guidance" on compliance with Rule 3214(a). AB2 at 6695-69 (Shell), 7070 (Scollay). Dr. Scollay, who did not know Dr. Shell, did not recall any conversation with him at Mahoning, although she did not deny it could have occurred; nor did she have any calls or emails with him. AB2 at 7071, 7084-85, 7153-54 (Scollay).

iii. The Randall Equine Email Exchange

After the Mahoning presentation, Dr. Meghan Naylor, who practices with Randall Equine Vet Group, emailed Dr. Scollay "to confirm that banned substances legal in non-covered horses such as thyro l were allowed to be carried by veterinarians that practice off track as well." AB1 at 2601; AB2 at 7070-71 (Scollay). After quoting Rule 3214, Dr. Scollay wrote:

> The regulation above provides for ***the ability*** to justify the possession of Banned Substances. ***To the extent*** that your practice provides veterinary care to non-Covered horses—***and can demonstrate*** (through records, day sheets, etc.) the need to carry those substances you ***can establish*** compelling justification.

AB1 at 2601 (emphasis added); *see also* AB2 at 7072-73 (Scollay). Dr. Shell reviewed this email exchange in June 2023. AB2 at 6804, 6806-07 (Shell). There is no evidence that he thereafter

made any outreach to Dr. Scollay, or anyone. *See* AB2 at 6824-25, 6827-28 (Shell).

Dr. Shell argues that Dr. Scollay's Mahoning remarks and response to Dr. Naylor guided him in accommodating his practice servicing non-Covered Horses to the requirements of the HISA's Rules. More specifically, he came away with the view that "compelling justification" would be met if he "show[ed] through ***any*** records, need to carry the Charged Banned Substances for use or intended in Non-Covered practice." AOBr. at 5 (emphasis added); *see also* ARBr. at 1. That "need," Dr. Shell maintains, "resides in Non-Covered use," without more. ARBr. at 3.

This argument, however, disregards that compelling justification calls for strong proof ***by Dr. Shell***. He must demonstrate, through veterinarian practice records or other evidence, that his non-Covered Horse practice requires him to keep Banned Substances on his truck while at racetracks in Ohio, a HISA-covered jurisdiction.

c. Inadequacy of Dr. Shell's Proof

Whether considered overall or for the four Banned Substances individually, Dr. Shell's proffered proof fails to establish compelling justification.

i. Dr. Shell's Records Overall

In Discovery Order No. 1, the Arbitrator made clear that, by undertaking to prove compelling justification, Dr. Shell "opened the door" to showing Banned Substances were "only used in non-covered horses . . . . [T]he ***complete veterinary medical records*** for all horses in his practice . . . are ***relevant and material*** to the defense." AB2 at 5974 (emphasis added). Dr. Shell read and understood the Order. AB2 at 6831-32. Instead of heeding the Arbitrator's advice, his compelling justification proof consisted of a self-selected slice of documents. *See, e.g.*, AB2 at 6893 (Arbitrator), 6959-62, 6964-65 (Shell). Even then, many documents reflect shoddy

recordkeeping practices, often lacking the information Ohio and West Virginia law require veterinarians to keep, include inaccurate entries, and fail to show diagnosed conditions appropriate for dispensing Banned Substances. *See* pp. 27-33, below.

A veterinary medical record should contain the thoughts and impressions of a veterinarian, including any examination, diagnosis, or treatment administered to a specific horse. AB2 at 7184-85 (Benson). It should have sufficient detail so that "somebody else with appropriate training could pick up that record, read it, review it, understand all that had been done, and whether they agreed with it or not, they could carry on with care for that patient because they had the full history on the animal up to the point where they received it." AB2 at 7076 (Scollay); *see also* AB2 at 7075-81 (Scollay) (describing recordkeeping generally). A properly created and maintained veterinary record is, therefore, distinct from a billing record. AB2 at 7184-85 (Benson).

Yet, the documents Dr. Shell produced to show the medications he prescribed to horses "were mostly billing records . . . they didn't have the detail that would be required of a medical record." AB2 at 7181-82 (Benson). The records typically would not enable continuity of care, indicating only the substance Dr. Shell billed for, often without any medical justification for using the substance. AB2 at 5631, 6096-97, 7181-82, 7188-92, 7205-07, 7212, 7249-50 (Benson).

Licensed in both Ohio and West Virginia, and an Attending Veterinarian under HISA Rules, Dr. Shell is obliged to follow prescribed recordkeeping provisions. AB1 at 2728 (Ohio requirements), 2729-30 (West Virginia requirements); HISA Rules 1020 (definitions), 2251, and 3040(d). Dr. Shell knows these rules. *See* AB2 at 6780-83 (Shell). However, overall, records

relating to the four Banned Substances that he offered pale by comparison to those expected of veterinary professionals.

Dr. Shell's frequent argument—that HIWU has not charged him with a recordkeeping violation—misses the point. Both the absence of complete medical documentation, and the state of many records Dr. Shell did produce, impeach the reliability of the documents he relies on to meet ***his*** burden to demonstrate compelling justification for possessing Banned Substances.

What is more, HIWU's review of medical records required under HISA Rule 3040(d) casts further doubt on the probative value of Dr. Shell's proffered evidence. Rule 3040(d) requires Dr. Shell to input all records of treating Covered Horses into an electronic database designated by the Authority. HIWU's comparison of Dr. Shell's inputted records with his practice records disclosed "[p]retty consistent lack of information being inputted into the HISA portal." AB2 at 7289-90 (Wallace); *see also* AB1 at 2499, 2502, 2537, 2568; AB2 at 7291-03, 7307-12 (Wallace). Compared to the input deficiencies of other Attending Veterinarians, "there were more for Dr. Shell's practice." AB2 at 7303 (Wallace). These missing records, too, confirm that Dr. Shell's lack of attention to recordkeeping render his documentary proof too unreliable to demonstrate compelling justification.

Dr. Shell regularly provided trainers with prescriptions—including those for, Carolina Gold and Pitcher Plant—that lacked specific horse names, and instead listed "Farm Use" as the horse name. AB2 at 5999, 6002, 6013, 6016, 6018, 6023, 6087, 6094. Many of Dr. Shell's documents also fail to indicate whether Dr. Shell examined the horse for which he prescribed medication. AB2 at 7211, 7213-20 (Benson).

ii. The Four Banned Substances

Considered individually for each of the four Banned Substances, Dr. Shell's proof comes

up well short of demonstrating compelling justification.

Carolina Gold: Dr. Shell testified he used Carolina Gold "on farms in both Ohio and West Virginia," largely on young horses. AB2 at 6891 (Shell). Yet, the evidence, including Dr. Shell's own testimony, is much the contrary. Dr. Shell often provided Carolina Gold to thoroughbred racehorse trainers in West Virginia. AB2 at 6856-59, 6862-63 (Shell). Although Dr. Shell maintained he dispensed this Banned Substance for races in West Virginia, many of his records identify the "Patient" as "Farm Use." AB1 at 3426-43, 3460-92; AB2 at 6845-66, 6868, 6874 (Shell). Dr. Shell did not have permission from the West Virginia Racing Commission to possess or dispense Carolina Gold in that State. AB2 at 7209-10 (Benson).

More specifically:

- The prescription labels on the Carolina Gold bottles HIWU seized in September 2023 identified Dr. Shell as the prescribing doctor and the patient as "Snazzy Horse," a "Covered Horse at Thistledown Race Track in Ohio," trained by Michael Rone, a Covered Person. AB1 at 481, 642 (¶ ¶ 4, 7), 647, 652; AB2 at 6005, 6757-58, 6838-39, 6841-42 (Shell). The Snazzy Horse identification is said to illustrate Dr. Shell's office practice when ordering non-FDA approved compounded substances, such as Carolina Gold: "just give [the supplier pharmacy] a name so that we can get the medication ordered, not necessarily the name of that particular horse that is being ordered for." AB2 at 6759-60 (Shell). The Carolina Gold was intended for "[m]ultiple injections." AB2 at 6761 (Shell)
- According to Dr. Shell, the vials of Carolina Gold that HIWU seized were in fact intended for Eddie Clouston, Bill Howard, and John Michael Baird—all thoroughbred

racehorse trainers in West Virginia—based on what Dr. Shell testified were earlier examinations of their horses. AB2 at 6842-45 (Shell). Dr. Shell produced no medical records of the examinations. AB2 at 6844 (Shell).

- The day after HIWU's September 2023 search, Dr. Shell re-stocked his veterinary truck with a vial of Carolina Gold and delivered it to Timothy Collins, a thoroughbred racehorse trainer and Covered Person. AB2 at 5999, 6856-59 (Shell). Dr. Shell dispensed the vial to Collins for use with "two or more thoroughbred racehorses in West Virginia." AB2 at 6862-63 (Shell).
- In August 2023, Dr. Shell dispensed a vial of Carolina Gold to Christopher Logston, a thoroughbred racehorse trainer and Covered Person, in West Virginia for use on "thoroughbred racehorses mares." AB2 at 6853-54 (Shell). There is no prescription; according to Dr. Shell, Logston "had several [horses] that were requiring treatment." AB2 at 6852 (Shell). *See also* AB1 at 3426-27; AB2 at 6002, 6007, 6846-48, 6852-53, 6863 (Shell).
- In December 2023—after HIWU's search—Dr. Shell dispensed Carolina Gold for thoroughbred racehorse Resvalon, which ran in Covered Races, both before and after this date. AB2 at 6032, 6879-83 (Shell); AB1 at 2109, 2300. Dr. Shell offered no medical record for dispensing Carolina Gold to Resvalon, only billing record with the notation "Give 5ccs IM as needed for training to calm nerves, Dispensed." AB2 at 6032, 6880-81 (Shell).
- In 2023, Dr. Shell dispensed Carolina Gold to the following thoroughbred racehorse trainers, all of whom are Covered Persons:
    - Timothy Collins

- Christopher Logston
- Dennis Van Meter
- Shannon Simpson
- Gregory Eidschun
- Annette McCoy

See AB2 at 6845-74 (Shell).

Of the eight records dispensing Carolina Gold that Dr. Shell produced to establish administering the substance to non-Covered Horses, six do not have a particular horse's name, and erroneously list "Farm Use" as the patient name. AB2 at 5521, 5999-6000, 6002-03, 6007, 6013-14, 6016, 6018, 6023-24. Dr. Shell produced no records showing the horses that received Carolina Gold from the vials HIWU seized. AB2 at 6959, 6961-62 (Shell).

Except for two records that postdate HIWU's search, none of the records showing Dr. Shell's dispensation of Carolina Gold contain examination findings or diagnostic assessment of need (in veterinary terms, "differential diagnosis"). *See* AB2 at 5631 (Benson), 6026, 6032. Nor do they include other basic identifying information, such as the patient date of birth, sex, weight, and breed, that a medical record should memorialize. AB2 at 5521, 5999-6000, 6002-03, 6007, 6013-14, 6016, 6018, 6023-24.

To the documents Dr. Shell prepared after HIWU's search, I attach limited weight. Created post-search, this proof is subject to manipulation to bolster his litigation position. Such post-event evidence has been called "all-but-meaningless." *FTC v. Whole Foods Market, Inc.*, 548 F.3d 1028, 1047 (D.C. Cir. 2008) (Tatel, J., concurring).[24]

[24] *See also Chicago Bridge & Iron Co. v. FTC*, 534 F.3d 410, 435 (5th Cir. 2008) ("The probative value of such evidence is deemed limited not just when evidence is actually subject to manipulation, but rather is deemed of limited value whenever such evidence ***could arguably*** be subject to manipulation.") (emphasis in original); *Hosp.*

Pitcher Plant: Dr. Shell contends that he uses Pitcher Plant for his farm practice, and in West Virginia where he regarded all thoroughbred racehorses as non-Covered Horses, regardless of whether they ran at tracks subject to HISA. The records he offered show the following:

- The prescription label on the seized bottle of Pitcher Plant identified Dr. Shell as the prescribing doctor and the patient as "Totally Obsessed." AB1 at 484, 643-44, 650. Totally Obsessed is a Covered Horse "stabled at Thistledown," trained by Gary Johnson, a Covered Person. AB2 at 6953-54 (Shell). The Totally Obsessed identification allegedly is another "administrative error" resulting from Dr. Shell's office practice. AB2 at 6954-55 (Shell).
- In June 2023, Dr. Shell dispensed Pitcher Plant to trainer Mark Tomczak, a Covered Person, using as the patient name "Farm Use." AB1 3590; AB2 6980-84 (Shell). Tomczak has an Ohio billing address and regularly raced horses in Covered Races in 2023, including Laurel Park in Maryland and Colonial Downs in Virginia. AB1 at 3590, 3592; AB2 at 6982-83 (Shell). Dr. Shell offered no records identifying the horses who received the Pitcher Plant dispensed to Tomczak. AB2 at 6981-82, 6984 (Shell).
- In September 2023, Dr. Shell dispensed Pitcher Plant to "Venezuelan Dreamer," a thoroughbred racehorse trained by Juan Gotera, a Covered Person. AB1 at 3587. Venezuelan Dreamer ran in a Covered Race a few days later. AB2 at 6978 (Shell); AB1 at 2491, 3587-88.
- In October 2023, Dr. Shell dispensed Pitcher Plant to trainer Larry Reed, a Covered

Corp. of Am. v. FTC, 807 F.2d 1381, 1384 (7th Cir.1986) ("Post-acquisition evidence that is subject to manipulation by the party seeking to use it is entitled to little or no weight."); *United States v. Bazaarvoice, Inc.*, No. 13-cv-00133, 2014 WL 203966, at *57 (N.D. Cal. Jan. 8, 2014).

Person, for the thoroughbred racehorse "High Rolling Dude." AB1 at 3596; AB2 at 6984-88 (Shell); AB1 at 3596-600. Although Reed has a farm in West Virginia, Dr. Shell billed him at an Ohio address, where Reed lives. AB1 at 3596; AB2 6986 (Shell). Reed raced High Rolling Dude at Mahoning racetrack in Ohio on several occasions. AB1 at 3598-99; AB2 6987 (Shell).

- After the ADMC Program became effective in May 2023, Dr. Shell dispensed Pitcher Plant repeatedly in 2023 to the following additional thoroughbred racehorse trainers, all Covered Persons, in West Virginia, using the Patient Name "Farm Use":
  - Eddie Clouston
  - Greg Eidschun
  - Dennis Van Meter

AB1 at 3578-85; AB2 6977-79 (Shell).

Three of the seven records produced for Pitcher Plant erroneously list "Farm Use" as the patient name. AB2 at 6087-89, 6094, 6099. All seven records, including the four with a specific horse name, lack key identifying information; one postdates the search and thus has limited probative value. AB1 at 2389; AB2 at 6092, 6096, 6105. *See* pp. 29-30 & n.24. Moreover, none of the Pitcher Plant records Dr. Shell offered contain any examination findings or differential diagnoses, making them deficient as medical records, and akin to billing records.

Isoxsuprine: The tub of Isoxsuprine found in Dr. Shell's truck had his prescription label, but no horse listed as a patient. AB1 at 430, AB2 at 6992 (Shell). The records Dr. Shell offered for this Banned Substance are limited.

For Isoxsuprine, Dr. Shell produced only four records memorializing his dispensation. One record, covering an older horse named "Cat," is largely a billing record covering many unexplained dispensations of the substance, most of which took place before the ADMC program

took effect in May 2023. AB1 at 3797. For one post-effective date entry, there are notes of a physical examination by Dr. Hippie, which state that Cat is "acutely lame," and which include additional medical information. The Hippie notes do not include Isoxsuprine as recommended treatment; nor are they a fulsome medical record. *See generally* AB2 at 7232-36 (Benson). The same billing record further shows Dr. Shell prescribed Isoxsuprine the next day, as well as a month later, with no explanation.

A second record, from October 2023, shows dispensation to Cool Stance, along with a brief diagnosis ("laminitis both front feet") and administration instructions by Dr. Shell. AB2 at 6081. But the record does not disclose he contemporaneously examined Cool Stance. Dr. Shell testified that Cool Stance's founder (lameness) prevented his racing. AB2 at 6750 (Shell). As a post-search record, it is, again, of minimal probative value.

A billing record produced by Dr. Shell shows that Isoxsuprine was dispensed to Michael J. Baird, a West Virginia trainer who raced Covered Horses in Covered Races. AB1 at 3799-800; *see also* AB1 at 2478 (HIWU schedule), 2720 (Benson reply report). Another billing record, apparently for a quarter horse, also was produced. AB1 at 3798. However, Dr. Shell offered no corresponding medical records.

There are FDA-approved, HISA-permitted substances to treat lameness, and the condition, although discomforting, does not require urgent treatment. AB2 at 7096-97, 7100 (Scollay), 7223-24 (Benson). Dr. Shell's proof regarding Isoxsuprine is insufficient to establish compelling justification for carrying this Banned Substance at a covered racetrack in Ohio.

Osphos: The boxes of Osphos recovered from Dr. Shell's office did not contain prescription information. AB1 at 662. The only documentary record of Dr. Shell directly dispensing Osphos, is to a quarter horse named "Hornet." AB2 at 6083. Dr. Shell billed Mike

Roberts, a blacksmith. AB2 at 6742 (Shell). This record, too, postdated the HIWU search, and is thus lacking probative value. AB2 at 6083. Perhaps unsurprisingly, the contents of this post-search billing record improves on those from the pre-search period, where comparable information is absent. AB2 at 6083 ("Navicular disease short striding, both front, uncomfortable on turns, preparing for barrel race in two weeks"), 7222 (Benson). Dr. Shell has also treated the horse Cat with Osphos, as has Dr. Hippie, for several years. AB1 at 528-37; AB2 at 7043, 7045-46 (Schulman).

This minimal proof is insufficient to demonstrate a compelling need for Dr. Shell to carry Osphos on an Ohio covered racetrack. Osphos simply is not needed on an emergency basis. AB1 at 528; AB2 at 6997 (Shell), 7100 (Scollay), 7223-24 (Benson).

d. Overall Assessment of Dr. Shell's Compelling Justification Proof

Dr. Shell attempted to minimize incorrect document entries, such as "farm use," as "ministerial" errors made by Janet Duhon, his head veterinary technician. *See, e.g.*, AB1 at 647, 686; AB2 at 6932-33 (Shell). However, Dr. Shell admitted that he knew Ms. Duhon "pulled" the horse's name "out of her hat" when restocking substances in bulk, and that he was ultimately responsible for his employees' conduct. AB2 at 6956 (Shell); *see also* AB2 at 6759-61, 6933-38 (Shell). Worse still, he admitted often failing to provide her with specific horse information for the reorders. AB2 at 6937-38. Dr. Shell's own expert witness, Dr. Roberts, conceded that these types of error should not regularly occur. AB2 at 7510-11, 7515 (Roberts).

The frequency of the claimed errors is too great to accept Dr. Shell's clerical or scrivener's miscue explanation. And, to reiterate, the practice records Dr. Shell offered, some of which he referred to as "cliff notes," are not comprehensive to begin with. AB2 at 6748, 6750 (Shell). The errors are all the more unacceptable in view of both State regulatory and HISA Rule

obligations. A veterinarian may be able to prove compelling justification despite imperfect recordkeeping, of course. But wherever the line may be drawn in an individual case, the records Dr. Shell offered were insufficient to establish that he had a compelling justification to possess the Banned Substances seized in Ohio only, or even primarily, for use in his Ohio or West Virginia farm practice or to supply trainers in West Virginia. Besides lacking medical records that Dr. Shell is required to keep, the mostly billing records offered are too incomplete and too riddled with claimed errors to find Dr. Shell to have discharged his burden of proof. *See generally* AB2 at 7181-83, 7187-96, 7205-07, 7250 (Benson); AB1 at 2722 (Benson Expert Report ¶¶ 51-52).

Adopting the standard of proof for compelling justification that Dr. Shell advocates and attempted—showing need "through any records"—would so dilute Rule 3214(a)'s compelling justification requirement as to render Possession charges against a veterinarian with a non-Covered Horse practice effectively illusory.

Dr. Shell also sought support for his compelling justification defense from Christine Schulman, the owner of Cat, one of the Ohio farm horses he serviced. Cat received two of the four Banned Substances, Isoxsuprine and Osphos. AB2 at 7036-54 (Schulman). Both can be used to treat lameness, but neither is required on an urgent basis. Although Ms. Schulman was complimentary of Dr. Shell's care generally, she had no experience with Dr. Shell's use of Carolina Gold or Pitcher Plant and lacked any knowledge of his conduct with racehorses or their trainers. AB2 at 7052 (Schulman).

To be sure, the testimony of fact witnesses can be probative of compelling justification. But here, the incremental support from this single witness is minimal, especially when evaluated in relation to the evidence at large. It is insufficient to show compelling justification for

Dr. Shell's Possession in Ohio of Isoxsuprine and Osphos, much less for that of Carolina Gold and Pitcher Plant.

Dr. Shell has not met his burden of proving compelling justification.

B. Dr. Shell's Estoppel Argument

Dr. Shell contends that estoppel precludes HIWU from prosecuting him for possessing the four Banned Substances in Ohio. He bases his argument on the same conduct by HIWU's Dr. Scollay that informed Dr. Shell's views on proving his farm practice defense.[25]

The elements of estoppel are not controversial: "the party claiming the estoppel must have relied on its adversary's conduct in such a manner as to change his position for the worse, and that reliance must have been reasonable in that the party claiming the estoppel did not know nor should it have known that its adversary's conduct was misleading." *Heckler v. Community Health Services of Crawford Cty., Inc.*, 467 U.S. 51, 59 (1984) (internal quotation marks omitted). *See also*, e.g., *Ohio State Bd. of Pharmacy v. Frantz*, 555 N.E.2d 630, 633 (Ohio 1990).

In sports law specifically, "the doctrine of estoppel, which primarily prevents sports federations from taking explicit contradictory positions, . . . has a very limited scope in disciplinary proceedings." *Sport Lisboa e Benfica SAD v. FIFA*, CAS 2021/A/8076, at ¶ 58 (Oct. 10, 2002) (citing authorities). Broader application, leading to "the (temporary) non-enforcement of legitimate and binding provisions[,]" could mean that "many sports and state provisions would run the risk of no longer achieving their goals due to previous unpunished violations. . . ." *Id.* ¶ 58. *See also New Zealand Olympic Committee (NZOC) v. The Salt Lake Organizing Committee*

[25] The Authority, the opposing party here, is, of course, bound by Dr. Scollay's acts. HIWU implements and enforces the ADMC Program on behalf of the Authority. Rule 3010(e) ("The Protocol will be implemented and enforced on behalf of the Authority by: (1) an anti-doping and controlled medication enforcement agency known as the Horseracing Integrity and Welfare Unit"); *see also* 15 U.S.C. § 3054(e)(1)(E)(i) (directing the Authority to enter an agreement to "implement[] the anti-doping and medication control program on behalf of the Authority"); AB1 at 313, 315-16 (HIWU response), 324, 326-27, 329 (Authority response).

for the Olympic Winter Games of 2002 (SLOC), CAS OG/02/006, at ¶ 18 (Feb. 20, 2002) (recognizing "[a]n estoppel that arises when one makes a statement or admission that induces another person to believe something and that results in that person's reasonable and detrimental reliance on the belief" (quoting BLACKS LAW DICTIONARY, 7th ed. 1999)).

Dr. Shell bases his estoppel argument on his reliance on the farm practice statements detailed above, which arise from: (1) Dr. Scollay's substantially similar industry presentations, given at the Will Rogers Downs and Mahoning racetracks; (2) the follow-up conversation Dr. Shell testified he had with Dr. Scollay that same day; and (3) the subsequent email exchange between Dr. Scollay and the Randall Equine veterinarian group. These facts are simply insufficient to demonstrate estoppel.

Dr. Shell admits there was no other "guidance" forthcoming from either Dr. Scollay, the Authority, or HIWU. AB2 at 6695-96 (Shell). The information that Dr. Scollay did impart would not reasonably be understood to suggest that possession of a Banned Substance would be excused whenever a veterinarian had a non-Covered Horse practice for which the Banned Substance might be useful, so long as there were some supporting records or other evidence, however incomplete or unreliable.

During her racetrack presentations, Dr. Scollay noted that the HISA Rule on Possession of Banned Substance applied to Veterinarians, who should not have the substances on their trucks. As "a caveat"—that is, as a caution or exception—she explained during her Will Rogers Downs presentation that, if a veterinarian's practice included non-Covered Horses, the Authority and HIWU could not sanction the veterinarian for possession "because we don't have control over those horses . . . [. W]e can't penalize people for something that we don't have control over," AuRPFOF at 3 (¶ 9); *see also* AB1 at 1114; AB2 at 7117-18 (Scollay). However, she

expressly qualified these remarks, stating that Possession would not be excused based on the mere assertion that a veterinarian's practice included "non-Covered Horses . . . or . . . a country practice." Rather, HIWU had "the ability to investigate, [and] if the story starts to get a little weird or a little extreme, you're going to get more than a raised eyebrow." AuRPFOF at 3 (¶ 9).

Dr. Shell also testified that, during Dr. Scollay's follow-up remarks to him at Mahoning, she said, in substance, that Dr. Shell did not have to reload his truck "every time [he] drove off the racetrack." This essentially impromptu comment neither detracts from nor materially enhances the thrust of her "caveated" public guidance. Dr. Shell could not reasonably have understood Dr. Scollay's comment to mean he could possess Banned Substances whenever he drove his truck to an Ohio racetrack. He similarly could not reasonably have thought his West Virginia practice would excuse possession in Ohio. Indeed, in talking with Dr. Scollay, Dr. Shell knew his practice extended to West Virginia. But he admittedly did not raise the topic with Dr. Scollay, who did not even know him. AB2 at 6727-28 (Shell), 7084, 7085-86 (Scollay). And Dr. Shell offered no proof that the Authority or anyone else at HIWU knew anything about his West Virginia activity.

Dr. Scollay's response to the Randall Equine email from Ms. Naylor similarly reiterated that merely having a practice that included "non-Covered horses" did not provide a defense to possession. Instead, "to the extent" that a veterinarian "can demonstrate"—"through records, day sheets, etc."—a need "to carry" Banned Substances, the veterinarian "can establish compelling justification." AB1 at 2601.

Fairly considered overall, Dr. Scollay's guidance acknowledged that, if a veterinarian's practice included non-Covered Horses, to meet the burden of showing compelling justification, the veterinarian had to offer reliable proof. Further, with Dr. Scollay's response to the Randall

Equine email exchange, if not earlier, Dr. Shell should reasonably have understood that simply having a non-Covered Horse practice did not entitle him to keep Banned Substances in his truck; he had to have adequate practice records as proof of need. AB2 at 6807-08, 6812 (Shell).

One other estoppel consideration should be discussed. It is undisputed that Dr. Scollay's remarks at both the Will Rogers Downs and Mahoning presentations concerning the Possession ADRV, its applicability to Veterinarians, and the compelling justification defense were substantially the same. And thus far throughout this decision, I have assumed Dr. Shell's best version of the facts relating to Dr. Scollay's presentation remarks and to her follow-up conversation with him. However, I have serious reservations concerning at least parts of Dr. Shell's testimony on these matters.

In pre-arbitration hearing filings—including Dr. Shell's two pre-hearing briefs, his witness statement, and the synopsis of his testimony—he referred—repeatedly and consistently—***only*** to Dr. Scollay's remarks ***at Will Rogers Downs*** in Oklahoma and to her response to the Randall Equine email, both of which he quoted and otherwise cited. For example, his pre-hearing brief stated:

> It cannot be disputed that on March 24, 2023, Dr. Mary Scollay gave a presentation at Will Rogers Downs in Oklahoma, about the HISA program . . . .
> . . . .
> Dr. Scollay confirmed her position in an email dated June 16, 2023, at 10:46:24 a.m., EDT, ***to Randall Equine Vet group*** . . . .
> . . . .
> Dr. Shell objectively, and reasonably ***relied on an objective statement*** of HIWU's Chief of Science, made . . . ***at an Oklahoma presentation*** . . . .
> . . . .
> Dr. Scollay elaborated in an email . . . ***to Randall Equine Vet Group*** . . . .
> . . . .
> [H]e ***relied on*** an objective statement from Dr. Scollay.[26]

[26] AB1 at 1513 (¶¶ 27, 28), 1520 (¶¶ 49, 50), 1527 (¶ 75), (emphasis added). *See also* AB1 at 1522-23 (¶¶ 55, 57-58), 1523-24 (¶ 61), 1534-35 (¶¶ 108-10, 114), 1537-38 (¶ 123).

Dr. Shell made similar representations in his other pre-hearing filings.[27]

In these filings, Dr. Shell ***never*** said he attended the Mahoning presentation and heard Dr. Scollay say substantially the same thing there as she had at Will Rogers Downs. Dr. Shell similarly ***never*** mentioned a follow-up conversation with Dr. Scollay at Mahoning. Moreover, at the arbitration hearing, although Dr. Shell testified he "took notes" of Dr. Scollay's Mahoning remarks, he offered no notes to corroborate his Mahoning testimony. AB2 at 6689 (Shell). Further, while Dr. Shell testified that Randall Equine's Ms. Naylor participated in the follow-up conversation, he never called Dr. Naylor to testify.

The absence of both Dr. Shell's own notes or testimony from Dr. Naylor to corroborate the public and follow-up remarks attributed to Dr. Scollay cast significant doubt on Dr. Shell's own testimony. I attach limited weight to it in evaluating his asserted estoppel argument.[28] In all events, however, Dr. Shell was admittedly on notice that, if he sought to rely on a compelling justification defense, he would have to prove it with fulsome evidence. There is no basis for estopping the Authority from imposing sanctions for his violations of Rule 3214(a).

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[27] *See* AB1 at:

1. Amended pre-hearing brief: 1779-81 (¶¶ 2-4), 1785-86 (¶¶ 21-22), 1788 (¶ 27), 1791-92 (¶¶ 37-38), 1793-94 (¶¶ 41-42), 1795 (¶ 45), 1798 (¶ 56), 1805 (¶ 79), 1806 (¶ 82), 1808 (¶ 88);

2. Witness statement: 2014-15 (¶¶ 15-16, 18-20), 2016 (¶ 22), 2019 (¶ 38), 2021-23 (¶¶ 49-52, 54); and

3. Synopsis of testimony: 2040-41.

[28] *See, e.g., Interstate Circuit, Inc. v. United States*, 306 U.S. 208, 226 (1939) ("The production of weak evidence when strong is available can lead only to the conclusion that the strong would have been adverse"); *Graves v. United States*, 150 U.S. 118, 121 (1893) ("[I]f a party has it peculiarly within his power to produce witnesses whose testimony would elucidate the transaction, the fact that he does not do it creates the presumption that the testimony, if produced, would be unfavorable."); *Gass v. United States*, 416 F.2d 767, 775 (D.C. Cir. 1969) ("An adverse inference is permitted from the failure of the accused to call witnesses peculiarly within his power to produce when their testimony would elucidate the transaction.") (cleaned up); *Gumbs v. Int'l Harvester, Inc*., 718 F.2d 88, 96 (3d Cir. 1983) ("The unexplained failure or refusal of a party to judicial proceedings to produce evidence that would tend to throw light on the issues authorizes, under certain circumstances, an inference or presumption unfavorable to such party.").

C. Dr. Shell's Constitutional Arguments

1. Rule 3214 Is Not Unconstitutionally Vague

Dr. Shell contends that Rule 3214(a) violates due process, as overly vague. He argues that, "no Covered Person of reasonable intelligence could know what facts must be proved to demonstrate 'compelling justification,' or how to comport their behavior." AOBr. at 11. According to Dr. Shell, without more content, "compelling justification is always/was subject to the adjudicator's arbitrary and capricious whim." AOBr. at 11 (internal quotation marks deleted). As applied to him specifically, Dr. Shell maintains that he "reasonably relied on Dr. Scollay's guidance," but that the Arbitrator arbitrarily and capriciously "credited post-hoc requirements to show Compelling Justification . . . ." AOBr. at 11.

Dr. Shell's argument is unpersuasive.

To satisfy the Constitution's Due Process requirement of fair notice, a regulation must be "reasonably comprehensible to people acting in good faith." *MobileTel, Inc. v. FCC*, 107 F.3d 888, 896 (D.C. Cir. 1997) (cleaned up); *see also, e.g., United States v. Ancient Coin Collectors Guild*, 899 F.3d 295, 321-22 (4th Cir. 2018). This inquiry includes examining "the particular situation of the defendant," and whether, as one to whom the regulation is directed, "it lacked reasonable notice." *Gen. Elec. Co. v. EPA*, 53 F.3d 1324, 1330 (D.C. Cir. 1995). "Words or phrases having a technical or other special meaning" may be "well enough known to enable those within its reach to correctly apply them." *United States v. Weitzenhoff*, 35 F.3d 1275, 1289 (9th Cir. 1993) (cleaned up). Thus, the understanding and practice among those subject to regulation are relevant considerations. *See, e.g., Ohio Cast Prods., Inc. v. Occupational Safety & Health Review Comn'n*, 246 F.3d 791, 799 (6th Cir. 2001).

Moreover, the Supreme Court has "expressed greater tolerance of enactments with civil rather than criminal penalties because the consequences of imprecision are qualitatively less severe." *Village of Hoffman Estates v. Flipside, Hoffman Estates, Inc.*, 455 U.S. 489, 498-99 (1982) (footnote omitted). Finally, vagueness challenges to laws "which do not involve First Amendment freedoms must be examined in the light of the facts of the case at hand." *United States v. Mazurie*, 419 U.S. 544, 550 (1975).

As discussed above, Dr. Shell's contacts with Dr. Scollay at the Mahoning racetrack presentation and via her email exchange with Randall Equine put Dr. Shell on notice that a "compelling justification" could arise from a veterinarian practice that HISA did not reach, such as "if veterinarians are practicing also on a population of non-Covered Horses, . . . or they've got a country practice . . . ." AuRPFOF at 2-3 (¶¶ 8, 9); AB2 at 7117-18 (Scollay). At the same time, Dr. Scollay cautioned that HIWU had "the ability to investigate," and that if a veterinarian's "story starts to get a little weird or a little extreme, you're going to get more than a raised eyebrow." AuRPFOF at 2-3 (¶¶ 8, 9); AB2 at 7117-18 (Scollay).

A veterinarian subject to HISA, such as Dr. Shell, would reasonably understand that a practice that included non-Covered horses could provide a "justification" for a defense to a charge of possessing a Banned Substance. Dr. Shell himself clearly had this understanding, as this is, itself, the basis for his defense. But as Rule 3214(a) expressly states, Dr. Shell's proof had to be "compelling"—strongly persuasive—and on this score, he failed. *See Village of Hoffman Estates*, 455 U.S. at 489 (rejecting a vagueness challenge to the constitutionality of a local ordinance that prescribed civil penalties and including licensing guidelines).

Because Dr. Shell was on notice that a non-Covered horse practice could, depending on the proof offered, satisfy Rule 3124(a)'s "compelling justification" element, the Rule is not

unconstitutional as applied to him. And since a litigant "who engages in some conduct that is clearly proscribed cannot complain of the vagueness of the law as applied to the conduct of others," I need not reach Dr. Shell's facial challenge to Rule 3124. *Village of Hoffman Estates*, 455 U.S. at 495 & n.7; *Broadrick v. Oklahoma*, 413 U.S. 601, 610 (1973) ("Embedded in the traditional rules governing constitutional adjudication is the principle that a person to whom a statute may constitutionally be applied will not be heard to challenge that statute on the ground that it may conceivably be applied unconstitutionally to others, in other situations not before the Court.") (citing authorities); *United States v. Nassif*, 97 F.4th 968, 981-82 (D.C. Cir. 2024) (rejecting defendant's vagueness challenge where the law "clearly proscribed his own conduct").

My determination regarding Dr. Shell's Due Process argument is fully consistent with my also rejecting Dr. Shell's estoppel argument. Dr. Scollay's guidance was sufficient to provide reasonable notice to Dr. Shell that his practice, which included non-Covered horses, ***could—if*** adequately proven—be a "justification" that Rule 3214(a) recognizes. That disposes of Dr. Shell's argument that the Rule is unconstitutionally vague. The reasonable import of Dr. Scollay's guidance does not, however, enable Dr. Shell to satisfy the elements of an estoppel sufficient to defeat HIWU's Possession charges.

2. Prosecution of this Case by the Authority and HIWU is Not Unconstitutional

Relying on the Fifth Circuit's decision in *National Horsemen's Benevolent and Protective Ass'n v. Black*, 107 F.4th 415 (5th Cir.), *cert. pet's filed*, Nos. 24-429, 24-433 & 24-472 (Oct. 15, 16, and 22, 2024), Dr. Shell argues that HIWU's enforcement proceeding here violates the private nondelegation doctrine and thus is unconstitutional. AOBr. at 14. The Sixth Circuit, however, rejected this same argument and upheld HISA's constitutionality, as did an Eighth Circuit majority in a recent decision affirming denial of a preliminary injunction.

Oklahoma v. United States, 62 F.4th 221 (6th Cir. 2023), *cert. denied*, 144 S.Ct. 2679 (2024); *Walmsley v. FTC*, 117 F.4th 1032 (8th Cir.), *cert. pet. filed*, No. 24-420 (Oct. 15, 2024). In the prior Administration Case involving Dr. Shell, I also rejected this constitutional argument, and the Authority's opposition in this case is based substantially on my earlier ruling. *In re Shell*, Docket No. 9345 (Oct. 31, 2024); AuOBr. at 11. Although I again reject Dr. Shell's argument, I believe further discussion is warranted.

As my prior decision noted, the Sixth Circuit's geographic scope includes Ohio, and Dr. Shell is himself an Ohio-based and licensed veterinarian. He also is licensed in West Virginia, and he practices in both States. AB1 at 2012 (¶ 1); AB2 at 6672, 6677 (Shell). The HIWU search giving rise to this case involved his two trucks and storage facility at Thistledown, located near Cleveland, Ohio. AB1 at 168-69, 452 (¶ 4), 2012 (¶ 8), 2018 (¶ 34), 3612; AB2 at 6996 (Shell). Both trucks, registered to Dr. Shell, bore an Ohio tag number. AB1 at 168-69, 2018 (¶ 35). Dr. Scollay's remarks, which form a substantial part of Dr. Shell's defense in this case, took place during a presentation, which Dr. Shell testified he attended, at Mahoning racetrack in Ohio. AB2 at 6687-89, 6693-94, 6813-16, 6822-23 (Shell). Thus, the contacts with the Sixth Circuit predominate. By contrast, this case has no connection whatsoever to horseracing within the States covered by the Fifth Circuit.

Although not located within the Fifth Circuit, West Virginia's connection to this case should be addressed—a consideration that did not arise in Dr. Shell's earlier case. As described above, in 2022 the District Court for the Western District of Louisiana issued a preliminary injunction that enjoins HISA's operation in the State of West Virginia. *Louisiana v. Horseracing Integrity & Safety Auth. Inc.*, 617 F.Supp.3d 478 (W.D. La. 2022). The Western District based its ruling on the Authority's non-compliance with the Administrative Procedure Act during

adoption of various HISA rules, and "not [on] the constitutionality of the Act." *Id.* at 501. However, in another case, begun in federal district court in Texas, the Fifth Circuit issued its *National Horsemen's* decision. The Fifth Circuit thereafter remanded an appeal from the Western District's preliminary injunction, and the Western District has since stayed proceedings. *Louisiana v. Horseracing Integrity & Safety Auth. Inc.*, No. 22-30458, 2022 WL 17074823 (5th Cir. Nov. 18, 2022); Order, 6:22-CV-01934 (W.D. La. Sept. 14, 2023).

As a result of the Western District's injunction, the Authority and HIWU do not enforce HISA in West Virginia. AuRPCOL ¶ 10; AB2 at 7125-26 (Scollay). This position, however, is not based on the Fifth Circuit's later constitutional ruling, which does not apply outside the States covered by the Fifth Circuit. Therefore, the Western District's injunction, issued for APA non-compliance, does not factor into my deciding whether the overall case contacts warrant reaching the same conclusion as the Fifth Circuit on HISA's constitutionality.

The "presumption of constitutionality" instructs that a federal law may be invalidated "only upon a plain showing that Congress has exceeded its constitutional bounds." *United States v. Morrison*, 529 U.S. 598, 607 (2000); *see also Turner Broadcasting System, Inc. v. FCC*, 507 U.S. 1301, 1301 (1993) (A federal statute "is presumptively constitutional.") (Rehnquist, C.J., in chambers). Bearing in mind both the presumption and the particular facts here, I follow the Sixth and Eighth Circuit's rulings upholding the Authority and HIWU's authority. Thus, Dr. Shell's argument fails.

VI. SANCTIONS

A. Single or Separate Violations Under Rule 3228(d)

HIWU charged Dr. Shell with Possession of each of the four Banned Substances as separate Rule 3214 violations. AB1 at 439 (EAD Charge Letter, covering Isoxsuprine, Carolina

Gold (GABA), and Osphos (Bisphosphonate)), 607 (EAD Notice Letter, covering Sarapin (Pitcher Plant)). In doing so, it relied on Rule 3228(d):

> (d) Violations involving both a Banned Substance or Method and a Controlled Medication Substance or Method.
>
> Where a Covered Person is found, based on a common set of facts, to have committed a (1) violation involving one or more Banned Substance(s) or Banned Method(s), ***and*** (2) a violation involving one or more Controlled Medication Substance(s) or Controlled Medication Method(s), they shall be treated as separate violations, but shall be adjudicated together in consolidated proceedings pursuant to the procedure that applies to Anti-Doping Rule Violations under the Arbitration Procedures.

(Emphasis added).

Dr. Shell challenged HIWU's resort to Rule 3228(d), arguing that, to assert "separate violations," HIWU had to allege violations involving:

> "(1) . . . one or more Banned Substance(s) . . . , ***and***
>
> (2) . . . one or more Controlled Medication Substance(s) . . . ."

Since HIWU alleged four Banned Substance violations, but ***no*** Controlled Medication violations, Rule 3328(d), Dr. Shell argued, did not apply. *See, e.g.*, AB1 at 1510 (Shell Pre-Hearing Brief).

The Arbitrator agreed with Dr. Shell. By virtue of the "and" conjunction, the Arbitrator concluded that, to trigger Rule 3328(d), there needed to be at least one Controlled Medication violation charged along with at least one Banned Substance violation. And here there was no Controlled Medication charge. AB2 at 6612 (¶¶ 7.7-7.9). Accordingly, the Arbitrator rejected HIWU's use of Rule 3228(d).

On this review, the Authority maintains that the Arbitrator misconstrued Rule 3228(d). AuOBr. at 7, 14-16. Dr. Shell contends that the Arbitrator's ruling was correct. AOBr. at 14-15; ARBr. at 6. Resolution of this issue can affect the sanctions potentially imposed, including the calculation of the length of any period of Ineligibility. I can review the construction of Rule

3228(d) de novo. I conclude that the Arbitrator erred as a matter of law.

The alternative construction here is that, where HIWU asserts (a) one or more Banned Substances violations, ***or*** (b) one or more Controlled Medications violations, ***or*** (c) one or more of both, then Rule 3228(d) authorizes separate charges, which are consolidated for arbitration. In effect, this alternative requires construing "and" as though it were "or." If perhaps counter-textual, this result is, indeed, judicially-recognized in appropriate circumstances: "In the construction of statutes, it is the duty of the court to ascertain the clear intention of the legislature. In order to do this, courts are often compelled to construe 'or' as meaning 'and,' and again 'and' as meaning 'or.'" *United States v. Fisk*, 70 U.S. 445, 447 (1865).

Pulsifer v. United States, 601 U.S. 124 (2024) is a much more recent example. There, the Supreme Court construed a "safety valve" provision of federal sentencing law, which exempted a defendant from mandatory minimum penalties. To qualify, the defendant had to meet specified criteria. One was that the defendant did not have what the Court summarized as "A, B, and C," which "refer[red] to three ways in which past criminality may suggest future dangerousness . . . ." *Id.* at 127. The defendant argued that safety valve relief was available unless all three criteria were met (here, "A, B, and C"). The government argued that if any one of the three applied, safety valve relief was unavailable. The Court agreed with the government.

Writing for the majority, Justice Kagan explained:

> There are two grammatically permissible ways to read Paragraph (f)(1). Yes, one is Pulsifer's [the defendant's]. But the other is the Government's—that a defendant is ineligible for relief unless he can satisfy each of the paragraph's three conditions. The choice between the two . . . is not a matter of grammatical rules. It can sensibly be made only by examining . . . the paragraph's content, as read in conjunction with the Guidelines. Or, as we usually say in statutory construction cases, by reviewing text in context.

Id. at 132-33.

In a lengthy discussion, Justice Kagan provided numerous examples of the need to consider the conjunctions "and" and "or" in context. To illustrate:

> Article III provides that "[t]he judicial Power shall extend to all Cases ... arising under this Constitution, the Laws of the United States, and Treaties." § 2. That statement means—but says more concisely—that the judicial power extends to cases arising under the Constitution; extends to cases arising under federal law; and extends to cases arising under treaties. The provision does not (as Pulsifer's view might suggest) limit judges to hearing the few cases arising simultaneously under all three kinds of law.

Id. at 134-35.

Here, specifically, the alternative is more consistent with the overall structure and intent of the Rules, which treat Banned Substances and Controlled Medications separately. "Banned Substances" are those identified on the "Prohibited List," and "are . . . (1) prohibited at all times . . . ." Rule 3110(a)(1); 88 Fed. Reg. 5085 (definition in Rule 1020). A "Controlled Medication Substance" is one "so described on the Prohibited List or the Technical Document—Prohibited Substances." 88 Fed. Reg. 5086 (definition in Rule 1020), 5124 (Appendix 1 to Rule Series 4000). The "Prohibited List" is set forth in the Rule 4000 Series, which distinguishes, in separate Rules, between: (a) "Banned Substances" "that are prohibited at all times" (Rules 4010, 4100-17); and (b) "Controlled Medication Substances" that are prohibited "during the Race Period and . . . in a Post-Race Sample or Post-Work Sample, except as otherwise specified . . . ." (Rules 4200-25). 88 Fed. Reg.5086 (definition in Rule 1020).

In short, Banned Substance violations are more serious, and thus carry more severe sanctions, than Controlled Medication violations. *See* Rules 3221-23, 3228-33 (Anti-Doping violations), 3321-23, 3327-31 (Controlled Medications), 4310 and 4330 (Covered Horses). Therefore, a Covered Person charged with possessing, for example, ***two*** Banned Substance violations ought to be exposed to ***more*** severe sanctions than one charged with possession of one Banned Substance and one Controlled Medication violation. Yet, under the Arbitrator's

construction, HIWU could charge the latter with two violations, but the former with only one.

That is plainly illogical; it cannot be the likely intent of Rule 3228(d). *Cf. Holy Trinity Church v. United States*, 143 U.S. 457, 460 (1892) ("If a literal construction of the words of a statute be absurd, the act must be so construed as to avoid the absurdity. . . . The object designed to be reached by the act must limit and control the literal import of the terms and phrases employed."); *Dupuch-Carron v. Secretary of HHS*, 969 F.3d 1318, 1330-31 (Fed. Cir. 2020) (citing authorities).

The very structure of the HISA Rules demonstrates that the Arbitrator's ruling on Rule 3228(d) was erroneous:

> The Protocol has intentionally divided the regulation of Anti-Doping Rule Violations [§§ 3210-60] and Controlled Medication Rule Violations [§§ 3310-3360] into separate chapters to reflect the Authority's view that the treatment of such violations should be separate and distinct from each other. Anti-Doping Rule Violations involve ***Banned Substances*** or Banned Methods, which are substances/methods that ***should never be in a horse's system or used on a horse as they serve no legitimate treatment purpose***. Conversely, ***Controlled Medication*** Rule Violations involve Controlled Medication Substances or Controlled Medication Methods, which are substances/methods that ***have been determined to have appropriate and therapeutic purposes***, and so may be used outside the Race Period, except if specified otherwise.
>
> . . .
>
> [T]his is a ***vital*** distinction, and the Protocol recognizes the distinction in ***the penalty structure*** and other provisions throughout the Protocol.

88 Fed. Reg. 5071, 5082 (emphasis added); *see also id*. at 5073.

In consequence, after finding four Banned Substances in Dr. Shell's possession, HIWU had the authority to charge separate violations under Rule 3228(d). As discussed further below, HIWU prosecuted the case on this basis. Contrary to Dr. Shell's argument, this is not a "new" argument or theory, raised by the Authority only "after the close of the record." AOBr. at 15. *See* pp. 53-55 below; AB2 at 5961, 5962, 5963-66 (HIWU's Closing Written Submissions), 6611-12 (¶ 7.6).

Despite Rule 3228(d)'s charging authority, however, an over-arching consideration is inescapable. HIWU's September 2023 search, identifying four Banned Substances in Dr. Shell's possession, arises from a single course of conduct; it does not reflect multiple violations carried out at different times. On these facts, whether each of the four alleged ADRVs can properly be charged and proven individually needs to be assessed.

HIWU v. Puype, JAMS Case No. 1501000973 (Dec. 12, 2024), is instructive. As here, a single HIWU search at a Santa Anita Park barn disclosed two Banned Substances in the possession of Puype, a trainer and Covered Person. HIWU charged Puype with two ADRVs, which it proved at the arbitration hearing. *Id*. ¶ 8.9. The arbitrator, however, declined to sanction Puype for "two violations that arose from the same investigation . . . ." *Id*. ¶ 8.36. Although the arbitrator reached this conclusion in rejecting HIWU's request to impose consecutive periods of ineligibility under Rule 3223(2)(c), the arbitrator applied it generally, imposing only one set of sanctions. *Id.* ¶ 9.1(a). I consider the matter of consecutive sanctions, which the Authority seeks against Dr. Shell, below. Suffice it here to say that *Puype's* ruling accords with many decisions in the sports world globally.

"[I]t is a widely accepted general principle of sports law that the severity of a penalty must be in proportion with the seriousness of the infringement." *W. v. FEI*, CAS 99/A/246, at ¶ 31 (May 11, 2000). Thus, "the substance and the possible application of the [proportionality] principle are not in doubt." *Klein v. ASADA*, CAS A4/2016, at ¶ 232 (May 25, 2017).[29] Accordingly, multiple ADRVs, based on a common set of facts, are often treated as a single

[29] *See also Sport Lisboa e Benfica SAD v. FIFA*, CAS 2021/A/8076, at ¶ 131 (Oct. 10, 2022) (reducing a "manifestly disproportionate" sanction)*; I. v. FIA*, CAS 2010/A/2268, at ¶¶ 133-43 (Sept. 15, 2011) (discussing arbitration proportionality rulings); *Puerta v. ITF*, CAS 2006/A/1025, at ¶ 88 (July 12, 2006) ("[T]he war against doping . . . is a hard war, and to fight it requires eternal vigilance, but no matter how hard the war, it is incumbent on those who wage it to avoid, so far as is possible, exacting unjust and disproportionate retribution.").

violation for sanctions purposes. *See, e.g., World Athletics v. Oduduru*, SR/171/2023, ¶ 117 (Sept. 18, 2023) (possession, and use or attempted use, of multiple prohibited substances found during an apartment search); *Decision of The Athletics Integrity Unit in the Case of Khamidova* ¶ 24 (Mar. 6, 2024) (multiple violations involving different drugs "were committed simultaneous").[30]

Dr. Shell has practiced veterinary medicine for more than 37 years. When HIWU discovered Banned Substances in his Possession, it charged him as a "first-time" offender. AB1 at 440. There is no dispute that, until these proceedings, he had never been sanctioned by a veterinary board or racing authority in either Ohio or West Virginia. AB2 at 6677-68 (Shell). The four ADRVs here arise from his professed, but mistaken, belief concerning his ability to possess Banned Substances for his farm practice or use in West Virginia. Imposing consecutive Ineligibility periods and cumulative fines on him for each of the four Possession violations would be grossly disproportionate to the misconduct underlying this case. For Dr. Shell, a longtime veterinarian nearing retirement, cumulative Ineligibility of eight years would be tantamount to permanent expulsion from practicing in the HISA-covered racing industry. A $100,000 fine, for possessing four Banned Substances discovered during a single search, would similarly inflict undue financial burden.

The Arbitrator rejected HIWU's effort to impose individual sanctions for each ADRV, and so do I.

[30] *See also Salazar and Brown v. USADA*, CAS 2019/A/6530 & 6531, at ¶¶ 444, 466 (Sept. 15, 2021) (multiple tampering violations); *IWF v. Beytula*, 2022/ADD/49, at ¶¶ 115 & 117 (Nov. 7, 2023) (tampering and failure to submit to sample collection were "considered together as one single violation"); *Matter of Vogg*, FEI 2022/HD02, at ¶ xxvi, n.16 (Dec. 20, 2022) (presence and use of single substance "considered together as one single first violation") (heavily redacted); *FINA Proceedings against Villanueva*, ¶¶ 5.11-.13 (Aug. 19, 2020) (six presence violations involving the same substance, collection on different days, were treated as a single violation).

B. Consecutive Ineligibility Based on the Administration Case Sanction

The Arbitrator ruled that Dr. Shell's 21-month Ineligibility period should begin on October 3, 2023, the date his Provisional Suspension began. AB2 at 6621 (¶ 7.64). This determination means, in effect, that Dr. Shell's Ineligibility period runs concurrently with—not consecutive to—the Ineligibility period imposed in the Administration Case. The Authority asserts this was "a clear error of judgment," as it did not account for the fact that, as a result of the Administration Case, Dr. Shell "is already serving a period of ineligibility that ends on January 7, 2026 . . . ." AuOBr. at 13; *see* AB1 at 138. Dr. Shell contends that HIWU raised this argument ***after*** the arbitration hearing had closed, and that it may not properly be raised in this review proceeding. AOBr. at 15. I agree with Dr. Shell.

As support for its "consecutive Ineligibility" argument, the Authority cites Rule 3223(c)(2), which provides: "Where a Covered Person is already serving a period of Ineligibility for another violation of the Protocol, any new period of Ineligibility shall start to run the day after the original period of Ineligibility ends." In resolving whether the Authority's argument is reviewable, additional discussion of HIWU's position in the arbitration proceedings is appropriate.

HIWU's EAD Charge Letter, issued in October 2023, stated its position on sanctions:

> Our records indicate that you have no prior Anti-Doping Rule Violations. Therefore, HIWU is seeking imposition of the following proposed Consequences for three first-time Violations of ADMC Program Rule 3214(a):
>
> - A period of Ineligibility of six years (two years ***per violation***), for you as a Covered Person, beginning on October 5, 2023, the date you received notice of your Provisional Suspension (ADMC Program Rule 3223) (Protocol);
>
> - A fine of USD $75,000 ($25,000 ***per violation***) and payment of some or all of the adjudication costs and HIWU's legal costs (ADMC Program Rule 3223) (Protocol) . . . .

AB1 at 439, 440 (emphasis added). Thus, HIWU sought sanctions for each individual charge, including consecutive Ineligibility periods and cumulative fines. HIWU's position was based on Rule 3228(d), discussed above. *See* AB1 at 453 (¶ 7). The Charge Letter referred only to three ADRVs, although later HIWU charged and consolidated for hearing the fourth violation for Possession of Pitcher Plant. *See* AB1 at 607, 6497 (¶ 3.3).

HIWU's position did not change. In its pre-hearing brief to the arbitrator, HIWU sought:

> a. A period of Ineligibility of six (6) years for Dr. Shell as a Covered Person, beginning on October 5, 2023, the date the Provisional Suspension was imposed;
>
> b. A fine of USD $75,000.00 and payment of some or all of the adjudication costs . . . ."

AB1 at 449, 469 (¶ 54). HIWU's pre-hearing reply brief (after the Pitcher Plant consolidation) was similar, seeking:

> a. A period of Ineligibility of ten (10) years for Dr. Shell as a Covered Person (two (2) years for each violation and two (2) years for Aggravating Circumstances), ***beginning on the date a decision is rendered in this case***;
>
> b. A Fine of USD $110,000.00 ($25,000.00 for each violation and $10,000 for Aggravating Circumstances) and payment of some or all of the adjudication costs . . . .

AB1 at 2453, 2474.

The arbitration hearing was held during April 2024. AB2 at 5922 (¶ 12), 6636, 7035, 7338. HIWU's closing submissions were filed with the Arbitrator in late June 2024. AB2 at 5916.

Meanwhile, weeks earlier in June, the arbitrator in the Administration Case against Dr. Shell issued his decision, which resulted in a single two-year Ineligibility period, despite Dr. Shell's multiple injections of the same substance. AB2 at 6494, 6530. HIWU's subsequent closing submissions made no explicit mention of consecutive periods of Ineligibility, although HIWU did write that the sanctions "for a first ADRV of ADMC Program Rule 3214(a) (Possession) for the Banned Substances ***each*** include: (i) a period of Ineligibility of two (2) years

for the Covered Person, [and] (ii) a fine of up to $25,000, ...” AB2 at 5958 (emphasis added).

In its closing submissions, HIWU discussed the Administration Case decision for purposes unrelated to whether the Ineligibility period in that case triggered operation of Rule 3223(c)(2)’s consecutive sanctions provision—the very point the Authority now seeks to argue in this review proceeding. *See* AB2 at 5958-62 (¶¶ 85, 87, 93, 94 & nn.77-79, 84). HIWU also submitted the full decision in the Administration Case in its closing book of evidence and authorities. AB2 at 6494.

Following the parties’ post-hearing submissions, in August 2024 the Arbitrator heard the parties’ closing statements. HIWU did not raise consecutive sanctions at all; nor was the decision in the Administration Case—***issued two months earlier***—mentioned. AB2 at 7603-12. A few days later, the Arbitrator issued a Request for Additional Authority:

> HIWU asserts that under ADMC Program Rule 3228(d), possession of ***each*** of the Banned Substances at issue in this proceeding constitutes a separate ADRV and, therefore, seeks the imposition of the Consequences [i.e., sanctions] as set out in ADMC Program Rule 3223, for ***each*** separate ADRV, i.e., ***four times*** the period of ineligibility and financial penalty.”

AB2 at 6571 (emphasis added). That was, to reiterate, HIWU’s consistent argument in the arbitration.

The Arbitrator sought further guidance on Rule 3228(d) applicability. She:

> (a) emphasized Dr. Shell’s argument that “Rule 3228(d) does not permit HIWU to charge several counts, for several substances recovered at the same time, as part of one incident”;
>
> (b) noted HIWU’s post-hearing discussion of the decision in the Administration Case, which, HIWU “cite[d] . . . for a different proposition, namely a situation in which the multiple administrations were all with regard to the same substance”; and
>
> (c) questioned whether “that decision appl[ies] to this case . . . .”

AB2 at 6571-72. The Arbitrator’s Request did not mention Rule 3223(c)(2) or any issue of

consecutive Ineligibility periods arising from the Ineligibility sanction in the Administration Case. HIWU still hadn't raised the issue.

HIWU responded to the Arbitrator's Request, arguing that "each Banned Substance constitutes a separate ADRV . . . ." AB2 at 6577. Again, HIWU said nothing about consecutive Ineligibility periods, based on the Administration Case decision. AB2 at 6577.

During the closing statements and throughout the post-hearing briefing and Request for Additional Authorities, Dr. Shell did not address whether Rule 3223(c)(2) permitted imposing a consecutive Ineligibility period resulting from the decision in the Administration Case. HIWU simply ***had not raised any such issue***.

The Arbitrator then issued her final decision. AB2 at 6588. Referring to HIWU's contentions, the Arbitrator quoted from HIWU's pre-hearing reply brief:

> HIWU now seeks the imposition of the following Consequences:
>
> a. A period of Ineligibility of ten (10) years for Dr. Shell as a Covered Person (two (2) years for each violation and two (2) years for Aggravating Circumstances), ***beginning on the date a decision is rendered in this case***;
>
> b. A Fine of USD $110,000.00 ($25,000.00 for each violation and $10,000 for Aggravating Circumstances) and payment of some or all of the adjudication costs . . . .

AB2 at 6611 (¶ 6.81). The Arbitrator reiterated the point in her analysis:

> HIWU relied upon Rule 3228(d) in prosecuting this case, treating the charged Banned Substances as separate violations, and seeking separate the imposition of the Consequences, as set out in ADMC Program Rule 3223, for each separate ADRV, i.e., four times the period of ineligibility and financial penalty, to run sequentially.

AB2 at 6621 (¶ 7.67).

The Arbitrator rejected HIWU's argument that each Banned Substance ADRV gave rise to a consecutive period of Ineligibility:

> 7.72 HIWU also relies upon Rule 3223(c)(2) to support ***consecutive punishments*** for ***the four violations***. Rule 3223(c)(2) provides: "Ineligibility and Financial Penalties for

> Covered Persons . . . (c) Commencement of the period of Ineligibility for a Covered Person. . . . (2) Where a Covered Person is ***already serving a period of Ineligibility for another violation*** of the Protocol, any new period of Ineligibility shall start to run the day after the original period of Ineligibility ends."
>
> 7.73 The Arbitrator is not convinced by HIWU's argument that Rule 3223(c)(2) supports ***consecutive punishments*** based on its language. HIWU did not introduce evidence that Dr. Shell was "already" serving a period of Ineligibility that pre-dated the imposition of the subsequent period of Ineligibility to which it refers. The date of the Provisional Suspension in this case was October 5, 2023, and HIWU identified these charges as first-time antidoping violations.
>
> 7.74 Accordingly, these are charged and ruled upon as first-time anti-doping violations for Dr. Shell that will issue simultaneously when this Final Decision issues.

AB2 at 6621-22 (ellipses in original). Not surprisingly, the Arbitrator's ruling did not mention consecutive Ineligibility based on the sanction in the Administration Case. HIWU ***had never raised the issue***.

After the Arbitrator's decision, HIWU made a written request, citing Rule 7380, "to address a computational error . . . with respect to the period of Ineligibility to be imposed on Dr. Shell." AB2 at 6624.[31] The "computational error," HIWU argued, was the Arbitrator's determination to impose a concurrent, rather than consecutive, Ineligibility period on Dr. Shell. HIWU based its request to modify on the decision in the Administration Case, which "declared Dr. Shell Ineligible from January 8, 2024 through January 7, 2026. The award in the Administration Case was issued after the evidentiary hearing in this matter closed, but before closing submissions." AB2 at 6624. HIWU therefore argued—***for the very first time***—that:

> The start date for Dr. Shell's period of Ineligibility in the present matter should be January 8, 2026, and he should receive credit for the two-day and three-month Provisional Suspension ("Credit Period") he has served against the 21-month period of Ineligibility, such that his period of Ineligibility expires on July 5, 2027.

AB2 at 6625. In other words, HIWU sought—and in this review proceeding the Authority

[31] In pertinent part, Rule 7380 provides that, within seven days, "any party . . . may request the [arbitrator] to correct any clerical, typographical, or computational errors in the final decision."

seeks—to add another roughly 18 months to Dr. Shell's period of Ineligibility—the so-called "computational error."

Dr. Shell opposed HIWU's proposed lengthening of the Ineligibility period, and the Arbitrator rejected HIWU's modification request as untimely:

> HIWU raises this Rule [3323(c)(2)] for the first time in this arbitration, in this Request, submitted after the Final Decision, notwithstanding that HIWU was aware of the potential applicability of the Rule prior to submitting its post-Hearing briefing (June 28, 2024) and closing argument (August 7, 2024).

AB2 at 6631. The Arbitrator also noted that, while HIWU's post-closing submissions referred to the Administration Case decision:

> HIWU did not cite the *Shell Administration Case* for the position that Dr. Shell was already serving a period of Ineligibility. Had that issue been timely raised, the Parties could have briefed it.
> …
>
> HIWU had not raised the fact that it had imposed a period of Ineligibility, and the
>
> Arbitrator has no way of knowing whether the period of Ineligibility had actually begun, or had been appealed, or otherwise was or was not in effect.

AB2 at 6631, 6632.

The Arbitrator's decision to decline to modify the sanctions imposed so as to permit a consecutive, instead of concurrent, period of Ineligibility on Dr. Shell does not bind me on this de novo review. An ALJ is authorized to "affirm, reverse, modify, set aside, or remand for further proceedings, in whole or in part" and "make any finding or conclusion that, in [its] judgement [sic] . . . is proper and based on the record." 15 U.S.C. § 3058(b)(3)(A); FTC Rule 1.146(d)(3). However, ALJ de novo review authority should also be considered in reference to FTC Rule 1.146(a)(1), which provides that, "[e]xcept for good cause shown, no assignment of error . . . may rely on any question of fact or law not presented to the Authority [in the arbitration]."

Certainly, once the arbitrator in the Administration Case issued his June 2024 decision, HIWU was well-aware that Dr. Shell was subject to a period of Ineligibility, and that Rule 3223(c)(2) could be applicable (or perhaps not) to any sanction of Ineligibility imposed in this case. Yet, while calling attention to the Administration Case decision in its post-closing submissions, and arguing that decision on other points, HIWU did not raise its applicability under Rule 3223(c)(2). Thereafter, it closed to the Arbitrator, again without arguing the decision in the Administration Case, issued months earlier, as a basis for consecutive periods of Ineligibility. In sum, HIWU did not raise the consecutive Ineligibility issue until after the Arbitrator had issued her decision. And, indeed, it then did so "based upon a Rule not previously cited or briefed or argued," and despite the Arbitrator's decision "in reliance upon HIWU's positions taken throughout th[e] arbitration . . . ." AB2 at 6632.

HIWU's omissions are inexcusable. Throughout the arbitration, HIWU repeatedly took the position that consecutive sanctions for each of the four charges of Possession it had asserted were appropriate under Rule 3228(d). Then, ***after*** the arbitration decision issued, HIWU changed course, asserting that the Administration Case decision required consecutive sanctions in this case under Rule 3223(c)(2). Fundamental fairness to Dr. Shell—as well as to the arbitration process itself—dictates that HIWU should have presented this changed position promptly to the Arbitrator ***before*** her decision issued.

Again, HIWU's conduct binds the Authority on this review, as "both HIWU and the Authority are bound by [the arbitrator's decision] . . . . Both entities are . . . legally bound to impose the resulting sanctions and have no discretion otherwise." AB1 at 318. *See also* AB1 at 331 ("The Authority is legally bound to impose civil sanctions determined through arbitration."). The Authority has failed to show "good cause," required under Rule 1.146(d)(3), to secure

review of the applicability of the Administration Case decision to the Ineligibility period imposed on Dr. Shell. Equally and independently important, estoppel against the Authority is properly applied here. HIWU repeatedly took a consistent position in the arbitration, on which Dr. Shell and the Arbitrator both relied—only to belatedly change it. *See* pp. 53-54.

Therefore, in my discretion, I decline the Authority's invitation to revisit the Arbitrator's ruling imposing a concurrent period of Ineligibility.

C. Applying the No Fault or Negligence (NF) and No Significant Fault or Negligence (NSF) Analyses to the Sanctions

1. Overview

To eliminate entirely the sanctions that may be imposed for an ADRV, Dr. Shell has the burden of proving "no fault or negligence" ("NF") on his part. Rule 3224(a). Failing proof of NF, Dr. Shell may reduce the sanctions by proving "no significant fault or negligence" ("NSF"). Rule 3225(a); *See In re Poole*, FTC No. 9417 at 10-11 (ALJ Decision on Application for Review, Nov. 13, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/d09417-administrative_law_judge_decision_on_application_for_review_-_public.pdf); *In re Lewis*, FTC No. 9434 at 12-13 (https://www.ftc.gov/system/files/ftc_gov/pdf/611976.2024.10.17_administrative_law_judge_decision_on_application_for_review.pdf).

2. NF: Applying Rule 3324

To establish no fault or negligence for a Possession ADRV, the ADMC Rules require that the Covered Person establish "that he or she did not know or suspect, and could not reasonably have known or suspected, even with the exercise of utmost caution," that he or she had committed the violation. Rule 1020 (definitions). Under Rule 3224(b), an NF finding "only applies in exceptional circumstances."

It is undisputed that Dr. Shell knew each of the substances that HIWU's search found

were Banned Substances under the ADMC Program. Dr. Shell was also aware, in contrast to HIWU, that besides practicing in Ohio, he also practiced in West Virginia, and that his practice in both States included non-Covered Horses on farms. He also testified that, after hearing Dr. Scollay's Mahoning presentation, he understood that:

(1) He "was prohibited to possess or prescribed [sic] banned substances to a covered horse." AB2 at 6815 (Shell).

(2) The prohibition on Possession "was a really important rule because it was new and it was a change to the way things had been done." AB2 at 6815.

(3) Even though he had a farm practice, "HIWU would have the ability to investigate any possession of a banned substance," and that he would "have to be able to support why [he] had medication on [his] truck," which mean relying on records from his practice. AB2 at 6821, 6825-26.

Dr. Shell also knew of the federal court order barring enforcement of HISA in West Virginia, but never sought advice on whether it might be problematic for him to possess Banned Substances in his trucks, or at HISA-covered facilities, in Ohio to treat thoroughbred racehorses located in West Virgina. AB2 at 6697-98, 6820-21, 6823, 6824-25, 6827-28 (Shell).

Nonetheless, Dr. Shell had Possession of three Banned Substances—Carolina Gold, Pitcher Plant, and Isoxsuprine—on his trucks and in his storage facility at Thistledown even though each of them:

(1) was not needed for urgent or emergency use;

(2) was not FDA-approved;

(3) was not essential to treat even non-Covered Horses, inasmuch as FDA-approved substitutes were available; and

(4) was prohibited at locations regulated by the West Virginia Racing Rules, as well as by the HISA Rules.

On these facts alone, Dr. Shell has failed to meet his burden of showing he exercised the "utmost caution" that a finding of NF requires. This is not a "truly exceptional" case. *See, e.g.*, *FIS v. Johaug*, CAS 2017/A/5015 & 5110, ¶ 190 (Aug. 21, 2017) ("[A]thletes have a duty to cross-check assurances given by a doctor even where such a doctor is a sports specialist."); *D. v. FINA*, CAS 2002/A/432, at ¶ 43 (May 27, 2003) (athlete "clearly acted with negligence" by failing to "quer[y] both his physician and his coach" regarding an injected food supplement).[32]

Rule 3224 does not apply. Elimination of any sanction is unwarranted.

3. NSF: Applying Rule 3225

The stringent "utmost caution" standard that Dr. Shell must meet to show NF is relaxed when the focus shifts to NSF. To demonstrate NSF, the Covered Person must establish that "his or her fault or negligence, when viewed in ***the totality of the circumstances*** and taking into account the criteria for No Fault or Negligence, was not significant in relationship to the [ADRV] . . . in question." HISA Rule 1020 (Definitions) (emphasis added). If a Covered Person establishes NSF for the ADRV charged, "then . . . the period of Ineligibility shall be fixed between 3 months and 2 years, depending on the Covered Person's degree of Fault." HISA Rule 3225(a).[33]

[32] *See also Stroman v. FEI*, CAS 2013/A/3318, at ¶¶ 70-74 (Mar. 14, 2014) (Equestrian competitor who permitted an unknown substance, provided by a veterinarian, to be injected without further inquiry, failed to exercise utmost caution.); *Carriere Zwei, FEI Tribunal Decision*, Case No. 2007/08, at ¶ 4.1x (Aug. 10, 2007) (despite assurances of a stable veterinarian that a supplement with a "suspicious name" would not increase testosterone level, an equestrian rider "acted with gross negligence and disregard to the risks" by not "receiving written advices [sic] from renowned veterinarians").

[33] *See also Al Nahyan v. FEI, 2014/A/3591*, at ¶ 237 (8 June 2015) ("the exercise [in analyzing NSF] is essentially one of considering the possible application of the defence in the circumstances that led to the violation."); *Ali Alabbar v. FEI*, CAS 2013/A/3124, at ¶ 12.17(1) ("Significant fault or negligence must mean something different from (mere) fault of negligence. Otherwise one or other of the concepts would be redundant.").

No similar HISA Rule provision applies fault principles to determine the appropriate financial penalties under HISA Rule 3223(b). The amount of the fine is discretionary, allowing for a first offense an amount "up to" $25,000 or twenty-five percent of the purse, whichever is greater, and payment of "some or all" of adjudication and legal costs. HISA Rule 3223(b). However, the degree of fault, among other facts and circumstances, may be considered in exercising discretion to determine an appropriate fine. *See In re Poole*, FTC No. 9417 at 10-11*; In re Lewis*, FTC No. 9434 at 8-9.

Analysis of NSF in HISA cases takes account of the three-tiered approach applied in *Cilic v. ITF*, CAS 2013/A/3327 (Apr. 11, 2014), which adjusts the maximum period of ineligibility and appropriate fines where NSF was shown. *See, e.g.*, *HIWU v. Poole*, JAMS Case No. 1501000576, at ¶¶ 7.16-.20 (Aug. 8, 2023), *aff'd*, No. 9417, at 6-8, 11 (ALJ Nov. 13, 2023) (discussing the arbitrator's three-tiered analysis, and holding de novo that the sanctions imposed were "reasonable, and rationally related to Appellant's degree of fault"); AOBr. at 13; AuOBr. at 12-13. Under the *Cilic* framework, the NSF analysis requires consideration of both "objective" and "subjective" elements of fault:

> The objective element describes what standard of care could have been expected from a reasonable person in the athlete's situation. The subjective element describes what could have been expected from that athlete, in light of his personal capacities.

Cilic, CAS 2013/A/3327, at ¶ 71. The conclusion of the analysis places the offender in one of three ineligibility ranges, depending on degree of fault. As adapted for HISA cases under Rule 3225(a), the tiers are:

a. Slight or Insignificant Fault – three (3) to ten (10) months;

b. Moderate Fault – ten (10) to seventeen (17) months; and

c. Significant Fault – seventeen (17) to twenty-four (24) months.

Poole, JAMS Case No. 1501000576, at ¶ 7.17, *aff'd*, FTC No. 9417, at 7; *see also Cilic*, CAS 2013/A/3327, at ¶ 69.

a. Objective Considerations

HISA's ADMC Program represented a change in the horseracing industry nationwide. Various ADRVs and defenses were defined, and a Prohibited List was created for designated substances. Stringent sanctions for Possession of Banned Substances, among other ADRVs, were adopted. Accordingly, prior to the ADMC Program's effective date in May 2023, Dr. Scollay made presentations at more than 30 racetracks throughout the country to educate industry participants, including veterinarians such as Dr. Shell, on the new regulatory regime. AB2 at 7059-62 (Scollay).

Dr. Scollay's presentations included discussion not only of Banned Substances, but also of the Possession ADRV's application to Veterinarians. *See, e.g.*, AB1 at 2589-90 (Banned Substances slides); AB2 at 7063-68 (Scollay). As discussed earlier, Dr. Scollay noted that while a veterinarian with a farm practice could use Banned Substances in that practice, there were limits: "we have the ability to investigate, if the story gets a little weird or a little extreme, you're going to get more than a raised eyebrow." AB2 at 7117-18 (Scollay); *see also* AB2 at 7067 (Scollay). The defense of compelling justification where industry participants, such as veterinarians, handled Covered and non-Covered Horses was discussed. Dr. Scollay explained that the HISA Rules did not apply to non-Covered horses. However, Veterinarians would have to show a justification, including using proper labeling and documentation. AB2 at 7065-67, 7069-70, 7073-74, 7081-82, 7118, 7133-35, 7152 (Scollay).

The advent of the ADMC Program marked a time for a reasonable Veterinarian to take stock of their practices and existing routines to assure ADMC Program compliance—particularly where the Veterinarian treated both thoroughbred racehorse and farm horses. Although Banned

Substances were subject to the ADMC Program, a reasonable Veterinarian with a farm practice would recognize the possible need to accommodate use of Banned Substances to the HISA Rules—and to be able to show compliance if HIWU questioned possession or use. The existence of the Authority's Prohibited Substances List would have been of particular interest. A reasonable Veterinarian would have determined whether substances in use were on that List, and whether switching to an available permissible substance might be prudent.

Simply put, an ounce of prevention is worth a pound of cure.

Dr. Scollay's presentations offered no guidance on the special circumstance of West Virginia—where HISA could not be legally enforced. Therefore, a reasonable Ohio Veterinarian with a West Virginia practice involving thoroughbred racehorses would have an even greater incentive to take precautions. Besides assessing existing office practice for potential adjustments, a reasonable Veterinarian with a West Virginia practice could be expected to inquire further for guidance from the Authority or HIWU, the West Virginia Racing Commission, or perhaps an attorney.

Knowing a change was coming, Dr. Shell took some action to educate himself. AB2 at 6687-68, 6789-90 (Shell). But there is no evidence that Dr. Shell undertook any sort of practice assessment or sought guidance regarding his practice in West Virginia. There is no evidence that Dr. Shell looked, for example, at his ordering and recordkeeping practices to make sure he could justify his possession and use of Banned Substances in circumstances not subject to HISA Rules. Similarly, despite his active West Virginia practice, he did not ask anyone specifically on the effect, if any, of the federal court order on his dealings with thoroughbred racehorses or their trainers in West Virginia. Nor is there any evidence that he considered FDA-approved alternatives to substances he used that were to become Banned Substances.

Although his typical practice was to service Thistledown from Monday through Thursday, and West Virginia on Fridays, there is no evidence he adjusted the contents of his trucks or his Ohio storage facility at Thistledown to avoid Possession of Banned Substances. *See* AB2 at 6675, 6908 (Shell). Similarly, there is no evidence that any comparable adjustments took place for Dr. Hippie, who handled a majority of the Ohio farm practice, while also servicing Thistledown. AB2 at 6680 (Shell).

Perhaps temporarily inconvenient, adjustments like this were feasible for a reasonable Veterinarian. Since being charged in this case, Dr. Shell has improved his ordering and recordkeeping practices. AB2 at 6864, 6933-34 (Shell). There was, Dr. Shell testified, "a record keeping issue that I needed to correct? Absolutely. Have we corrected it? Absolutely." AB2 at 6931 (Shell); *see also* AB2 at 7026-29 (Duhon). His two trucks now have "two sets of different drugs so that we can not only care properly for our clients at the racetrack . . . as well as our clients on the farm." AB2 at 6771-72; *see also* AB2 at 6999-7001 (Shell). Despite the changes, Dr. Shell is able to discharge his ethical obligations as a veterinarian. AB2 at 7001-03 (Shell).

Prior to the ADMC Program taking effect, a reasonable Veterinarian comparable to Dr. Shell had both the incentive and ability to take action such as this. Objective considerations do not support a sanctions reduction under Rule 3225.

b. Subjective Considerations

The facts discussed in the NF analysis above are relevant to Dr. Shell's individual circumstances—the subjective part of the NSF inquiry—and I incorporate them here. Additional facts bear mention.

Dr. Shell testified that after attending Dr. Scollay's Mahoning presentation, he was "antsy" nonetheless. He sought further guidance regarding his farm practice. AB2 at 6693-94,

6822-23 (Shell). In the ensuing follow-up conversation, according to Dr. Shell, Dr. Scollay told him "if we had a large farm practice and had non-covered horses, that we were allowed to carry the banned substance." AB2 at 6695; *see also* AB2 at 6816, 6823, 6828 (Shell). Dr. Scollay added: "[Y]ou must have records indicating that you are using the banned medication." AB2 at 6825 (Shell). Dr. Shell "assume[d] every record I have would be sufficient," and therefore did not ask what type of record would be needed. AB2 at 6826 (Shell).

Thereafter, Ms. Naylor, a Randall Equine veterinarian, asked Dr. Scollay "to confirm that banned substances legal in non-covered horses . . . were allowed to be carried by veterinarians that practice off track as well." AB2 at 6118. After quoting Rule 3214(a)'s prohibition of Banned Substances "unless there is compelling justification," Dr. Scollay wrote:

> The regulation above provides for the ability to justify the possession of Banned Substances. To the extent that your practice provides veterinary care to non-Covered horses—and can demonstrate (through records, day sheets, etc.) the need to carry those substances you can establish compelling justification.

AB2 at 6118. Dr. Shell received and read a copy of the email "around the time it was sent in June." AB2 at 6804, 6807 (Shell). He understood that to justify Possession, he would need records such as "day sheets" and "veterinarian patient records." AB2 at 6807-08, 6812 (Shell).[34]

Despite what he learned at Mahoning and from the Randall Equine email exchange, there is no evidence Dr. Shell took any steps to assess his ability to demonstrate compelling justification using the documents prepared and maintained in his practice. There is no evidence

[34] A "day sheet" is:

> [A] record of the interactions that the veterinarian has with respective horses, either scheduled or added on the 'while you're here, doc', kind of situation. That day sheet can also record specific treatments or diagnostics for the purpose of the office administrator setting up the billing, and perhaps can also be sort of a cue for the veterinarian who then enters the information into the . . . patient's medical record.

AB2 at 7074 (Scollay).

that Dr. Shell changed his substance ordering or recordkeeping practices in any way. Dr. Shell may be presumed to know the state of his practice routines and recordkeeping. Once the ADMC Program took effect, he could not reasonably have thought, for example, that listing an arbitrary horse's name on a bulk order would, without more, amount to a sufficiently reliable record to defend against Possession of a Banned Substance charge, such as that brought here.

Likewise, as noted above, there is no evidence Dr. Shell considered whether to adjust his practice to take account of the special circumstances of West Virginia. He simply "made the assumption that a racehorse in West Virginia was not covered." AB2 at 6821 (Shell). Therefore, Dr. Shell incorrectly believed—but took no steps to confirm—that he could possess Banned Substances in Ohio to use in his West Virginia practice, so long as he administered or dispensed the Banned Substance in West Virginia, outside of HISA jurisdiction. *See* AB2 at 6823-25, 6827-28 (Shell).

Dr. Shell knew that if he was found in possession of Banned Substances in Ohio, at the very least he could be required to explain their use in West Virginia. He therefore should have been particularly careful about his recordkeeping involving his practice in that State, but was not. Dr. Scollay's remarks simply do not absolve Dr. Shell of responsibility to both act and inquire further to assure that his practice complied with his ADMC Program obligations. By way of analogy, numerous sports law panels have rejected an NSF argument where the athlete used a drug prescribed by their doctor, even when "a specialist," and relied on the doctor's advice, but "did not conduct a thorough investigation" into the prescribed substance or further query her doctor. *P. v. ITF*, CAS 2008/A/1488, at ¶¶ 14, 17 (Aug. 22, 2008). On this subjective analysis, there is no basis for finding that Dr. Shell has met his burden of showing NSF sufficient to

reduce available sanctions.[35]

The subjective NSF analysis should also consider Dr. Shell's dealings with the Banned Substances individually.

First, Carolina Gold, which has a calming influence, is an illicitly manufactured substance—not FDA-approved. There are FDA-approved substances having a comparable effect. AB2 at 6710-11, 6837-38 (Shell), 7087-90 (Scollay). Carolina Gold is not needed for life-saving or emergency use. AB2 at 6891, 6909 (Shell), 7088-89 (Scollay).

Carolina Gold is not only a Banned Substance under the HISA Rules, its use also is prohibited by the West Virginia Racing Commission. AB2 at 6836-37, 6914-17 (Shell), 7209-10 (Benson). The substance thus lacks any legitimate use on Covered Horses. AB2 at 7088-90, 7112 (Scollay). Dr. Roberts, Dr. Shell's veterinary expert, has never used it. AB2 at 7429, 7501 (Roberts). Dr. Shell, however, uses Carolina Gold regularly in his farm practice in both Ohio and West Virginia, as well as in treating thoroughbred racehorses located in West Virginia. AB2 at 6732-34, 6739-42, 6744-46, 6752-54, 6842-48, 6851-84, 6890-91, 6909-10, 6962 (Shell).

Accordingly, Dr. Shell has failed to show NSF for possessing Carolina Gold at Thistledown in Ohio.

Second, Pitcher Plant, which reduces inflammation, is not needed to treat emergencies. AB2 at 6713, 6976 (Shell), 7091-93 (Scollay). Pitcher Plant is also banned at West Virginia racetracks. AB2 at 7224 (Benson). It is not FDA-approved, and there are multiple FDA-approved alternatives. AB2 at 7092-93 (Scollay), 7224-25 (Benson). Again, Dr. Shell used it in his farm

[35] *See also WADA v. Nilforushan*, CAS 2012/A/2959, at ¶¶ 8.17, 8.19 (Apr. 30, 2013) (rejecting NSF where "an extremely experienced" equestrian rider took medicine prescribed by his doctor without a "cross check"); *Radojevic v. FINA*, CAS 2018/A/5581, at ¶¶ 54-56, 60-63, 81 (July 10, 2018) (rejecting NSF where the athlete failed to inquire further regarding a substance prescribed by his doctor); *WADA v. CISM*, 2008/A/1565, at ¶¶ 41-42 (Nov. 4, 2008) (rejecting NSF where the athlete relied on the advice of his personal physician, but took no further steps to determine the ingredients in a medication prescribed for a serious eye condition).

practice, and also administered it to, or dispensed it to trainers for use with, thoroughbred racehorses in West Virginia. AB2 at 6723-27, 6730-31, 6736-37, 6746-47, 6976-88 (Shell).

Dr. Shell has failed to show NSF for possessing Pitcher Plant at Thistledown in Ohio.

Third, Isoxsuprine is used to treat navicular disease or founder—neither a condition requiring urgent treatment. AB2 at 7100 (Scollay), 7224 (Benson). Isoxsuprine is also prohibited at West Virginia racetracks, and there are FDA-approved alternatives available. AB2 at 7094, 7096-97 (Scollay). Dr. Shell used Isoxsuprine in his farm practice and with thoroughbred racehorses in West Virginia. AB2 at 6718-21, 6738-39, 6750-51, 6990-94 (Shell).

Dr. Shell similarly has failed to show NSF for his Possession at Thistledown in Ohio.

Finally, Osphos is used to strengthen bones and treat navicular disease. Unlike the others, although a Banned Substance, Osphos is FDA-approved for horses older than four years. AB2 at 7099 (Scollay), 7363 (Roberts). However, it is not needed on an emergency basis. AB2 at 6997 (Shell), 7223-24 (Benson). While Dr. Shell uses Osphos in his practice, none of the limited documentation he offered shows that he prescribed or dispensed it to thoroughbred racehorses. AB2 at 6721-22, 6742-43 (Shell). On the other hand, Dr. Shell offered witness testimony showing he treated a non-Covered Horse (Cat) with Osphos to the satisfaction of Cat's owner.

Thus, Dr. Shell has shown—albeit, barely—NSF with regard to his Possession of Osphos at Thistledown in Ohio.

Taking account of these facts, Dr. Shell has failed to demonstrate NSF for his Possession on his trucks and in his storage facility at Thistledown in Ohio either for Carolina Gold, Pitcher Plant, or Isoxsuprine. Reduction in the available sanctions is unwarranted under Rule 3225. Reduction under the Rule is, however, appropriate for Dr. Shell's Possession of Osphos.

4. Sanctions Summary

As charged, I have reviewed the sanctions imposed by the Authority de novo. I have ruled that Dr. Shell has not demonstrated NF, but that he has shown a basis for a reduction based on NSF with respect to Possession of Osphos. The Arbitrator similarly held that Dr. Shell failed to show NF. Applying the three-tiered *Cilic* NSF structure, the Arbitrator concluded that Dr. Shell's "objective level of fault falls in the significant fault range," covering 17 to 24 months, resulting in a three-month reduction in Ineligibility. AB2 at 6620 (¶ 7.60). The Arbitrator further ruled that the resulting 21-month Ineligibility period would commence on October 5, 2023, the effective date of Dr. Shell's Provisional Suspension, and would run concurrently with the period of Ineligibility imposed in the Administration Case. AB2 at 6620 (¶ 7.64), 6221-22 (¶¶ 7.72-.73). In addition, the Arbitrator reduced the fine imposed from the maximum of $25,000 to $20,000 and declined to award any costs against Dr. Shell. AB2 at 6620-61 (¶¶ 7.63-66).

I agree with the Arbitrator's *Cilic* tier placement. But if I were the decisionmaker in the first instance, under the totality of the circumstances I would modify the Ineligibility reduction to 1.5 months, beginning as the Arbitrator did as of the date of Dr. Shell's Provisional Suspension. I also would modify the fine reduction by the same percentage, resulting in an Ineligibility period of 22.5 months and a fine of $22,500. I would not modify the zero cost determination. However, my review authority is cabined, requiring that I determine whether the Arbitrator's sanctions rulings were "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 15 U.S.C. § 3058(b)(2)(A)(iii). I do not believe the Arbitrator's rulings on sanctions meet any of the required standards.

In sum, although I have upheld HIWU's authority to charge four individual Possession violations under Rule 3228(d), I have rejected, under the recognized sports law proportionality

principle, per charge sanctions on the facts of this case. I also have held untimely the Authority's argument that the Ineligibility period here should run consecutively with that arising from the Administration Case. Since the Ineligibility period here will run concurrently, any modified length of the Ineligibility period would in all events be academic.

VII. CONCLUSION

Accordingly, the sanctions awarded by the Arbitrator, and imposed by the Authority, are **AFFIRMED**.

ORDERED:

Jay L. Himes

Jay L. Himes
Administrative Law Judge

Date: March 6, 2025

TAB 2

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW MEXICO

JASON SCOTT,

Plaintiff,

v. No. 2:25-cv-632-SMD-GJF

HORSERACING INTEGRITY
& SAFETY AUTHORITY, et al.,

Defendants.

MEMORANDUM ORDER DENYING PLAINTIFF'S MOTION FOR A PRELIMINARY INJUNCTION

THIS MATTER comes before the Court on Plaintiff Jason Scott's ("Dr. Scott's" or "Plaintiff's") motion for a preliminary injunction, Doc. 8 ("Mot. for Prelim. Inj."). In the spring of 2025, the Horseracing Integrity and Welfare Unit ("HIWU"), a private non-profit organization housed within the Horseracing Integrity and Safety Authority (the "Authority") and overseen by the Federal Trade Commission ("FTC"), charged Plaintiff with possessing two "banned substances" which federal regulations prohibit for use in thoroughbred horses. *See* 15 U.S.C. § 3053; HISA Rule 3214(a). Plaintiff denied the allegations. HIWU and Plaintiff are set to arbitrate these charges on November 19, 2025. Plaintiff now moves to enjoin those proceedings, arguing that the Authority and Rule 3214 violate the non-delegation doctrine, Fifth and Seventh Amendments, and the Administrative Procedure Act. Defendants HIWU and the Authority filed a response on behalf of themselves and the FTC (collectively "Defendants") on August 8, 2025. *See* Doc. 37 ("Defs.' Resp."). The FTC also filed a notice of joinder and supplemental arguments opposing Plaintiff's motion, Doc. 38 ("FTC's Resp."). Upon review of the relevant law, record, and oral statements, the Court will **DENY** Plaintiff's request for a preliminary injunction.

BACKGROUND

I. History of the Horseracing Integrity and Safety Authority

In 2020, Congress passed the Horseracing Integrity and Safety Act ("the Act") to standardize horseracing regulations and reduce equine deaths on the track. *See* 15 U.S.C. § 3051 et seq.; 166 Cong. Rec. H4981 (statement of Rep. Tonko). The Act established the Horseracing Integrity and Safety Authority, which is a private, nonprofit organization supervised by the FTC, to advise the agency on and develop horseracing standards. 15 U.S.C. § 3052(a). This allocation of regulatory power to a private entity is notable, though not entirely novel—the Maloney Act, passed 87 years ago, instituted a parallel relationship between the Securities and Exchange Commission ("SEC") and the Financial Industry Regulation Authority ("FINRA").[1] 15 U.S.C. § 78(c); *see also* Doc. 46 at 4 (explaining that the HISA Rules and the Act are "modeled" on the FINRA scheme).

The Authority's board of directors is comprised of nine members, five of whom "shall be independent members selected from outside the equine industry." 15 U.S.C. § 3052(b)(1). The selection of board members is left up to a nominating committee. *Id.* § 3052(d). The Act tasks the Authority with "developing and implementing a horseracing anti-doping and medication control program and a racetrack safety program for covered horses, covered persons, and covered horseraces." *Id.* § 3052(a). These regulations only apply to thoroughbred horses ("covered horses"); they do not concern quarter horses or other breeds. *Id.* §§ 3051(4)-(6), 3054(a)(2). Veterinarians engaged in the care, training, or racing of covered horses are "covered persons." *Id.* § 3051(4). Congress amended the Act in 2022 to increase the FTC's oversight of the Authority and specified that the FTC may "abrogate, add to, or modify" rules the Authority promulgates as

[1] The Maloney Act initially created the National Association of Securities Dealers. FINRA, its successor, was formed in 2007. *See Fiero v. Fin. Indus. Regul. Auth.*, 660 F.3d 569, 571–72 (2d Cir. 2011)

"necessary and appropriate." *Id.* § 3053(c). Any standard drafted by the Authority must be approved by the FTC and deemed as "consistent with" the statute and the FTC's rules. *Id.* The Authority is empowered to investigate and discipline violations of the Act and participate in private arbitration proceedings with alleged violators. *Id.* §§ 3054(c), 3057. The FTC can conduct de novo review over the Authority's factual findings and conclusions of law and may "affirm, reverse, modify, or set aside, or remand" the Authority's decisions. *Id.* § 3058(c). The FTC's decisions are subject to Article III judicial review. 5 U.S.C. § 704; *see* 15 U.S.C. § 3058(b)(3)(B).

In early 2023, the Authority proposed anti-doping and medication control ("ADMC") standards to the FTC. *See* Fed. Trade Comm'n, Notice, HISA Anti-Doping and Medication Control Rule, 88 Fed. Reg. 5070–5201 (Jan. 26, 2023). The FTC approved the ADMC rules following public notice and comment. Fed. Trade Comm'n, *Order Approving the Anti-Doping and Medication Control Rule Proposed by the Horseracing Integrity and Safety Authority* (Mar. 27, 2023). Among other things, the ADMC banned the possession of certain substances "at all times" by "covered persons" "unless there is a compelling justification for such possession." HISA Rule 3214.[2] As with the rest of the Act, the ban is solely applicable to covered horses. HISA created the Horseracing Integrity & Welfare Unit ("HIWU") to enforce the ADMC Program,. HISA Rule 3010(e)(1); *see* § 3054(e). HIWU charges are adjudicated before the Internal Adjudication Panel, which may be a single arbitrator. *Id.*; HISA Rules 3360, 7020. If the arbitrator finds a covered person to have violated the HISA, they may impose sanctions, such as monetary fines or suspension from covered events. 16 C.F.R. § 1.148(b). Any civil sanction the arbitrator imposes is subject to de novo review by an administrative law judge ("ALJ"). 15 U.S.C.

[2] The full set of HISA rules are published in the federal register, *see* 88 Fed. Reg. 5084 (2023). For purposes of this order, the Court will cite the HISA rules in the format HISA uses, e.g. HISA Rule 1010. All of HISA's rule series are available here: https://hisaus.org/regulations.

§ 3058(b)(1). The ALJ's decision is reviewable by the FTC, which is in turn reviewable in an Article III court. *Id.* § 3058; 5 U.S.C. § 704.

II. Factual Background

The Court recounts the facts leading to these charges as expressed in Plaintiff's complaint, Doc. 1 ("Pl.'s Compl."), present motion, Pl.'s Mot. for Prelim. Inj. at 5–7,[3] and attached exhibits. Plaintiff is an equine veterinarian who resides and works in New Mexico. Pl.'s Compl. ¶ 17. Plaintiff's practice encompasses multiple breeds of horses, including thoroughbreds. *Id.* ¶¶ 25, 46. To serve his clients, Plaintiff operates a mobile veterinary clinic that enables him to travel to racetracks, training facilities, and farms across the state. *Id.* ¶ 25. Within his medication stock, Plaintiff carries Pitcher's Plant extract (also known as Sarapin) and Adenosine Monophosphate ("AMP"). *Id.* ¶ 27. Plaintiff exclusively administers Sarapin and AMP to quarter horses, *id.* ¶ 41; he does not use them for the treatment of thoroughbreds. *Id.* Under HISA Rule 4117, Sarapin is "prohibited at all times." AMP, though not specifically named in the ADMC, falls under the Rules' catch-all provision, which bans "[a]ny pharmacological substance that is (i) not addressed by Rules 4112 through 4117 (ii) has no current approval by any governmental regulatory health authority for veterinary or human use, and (iii) is not universally recognized as a valid veterinary use." *See* HISA Rule 4111.

On February 13, 2025, Plaintiff was working a "Mixed Meet," i.e. a meet with quarter horse and thoroughbred events, at the Sunland Park Racetrack in New Mexico. *Id.* ¶¶ 42, 46. HIWU searched Plaintiff's vehicle, found two bottles of Sarapin and two bottles of AMP, and seized them. *Id.* ¶ 42. HISA Rule 3214(a) bans possession of both substances absent a "compelling justification." *See* 88 Fed. Reg. at 5100. On April 30, 2025, HIWU served Plaintiff

[3] The page numbers referenced in this order correlate with the page numbers assigned through the ECF system, rather than those assigned by the parties.

with an Equine Anti-Doping ("EAD") notice, requesting that he "provide a 'compelling justification' for his possession of the two substances. Mot. for Prelim. Inj., Ex. 2. Dr. Scott responded shortly thereafter and explained that "he had medications intended for Quarter Horses on his truck during a Mixed Meet and that Quarter Horses he treats were stabled at the racetrack where medications were seized." Mot. for Prelim. Inj. at 14; Mot. for Prelim. Inj., Ex. 3. On June 5, 2025, HIWU replied and informed Plaintiff that his justification was insufficient. *See* Mot. for Prelim. Inj., Ex. 4 at 1. HIWU further explained that Plaintiff could admit to the allegations and pay the associated fines or deny them and appear before an arbitrator. *Id.* Plaintiff opted to proceed to a hearing. That hearing is now scheduled for November 19, 2025. Doc. 51 at 1.

III. Procedural History

Plaintiff brings three facial challenges to the HISA and Rule 3214: (1) that Congress's creation of the Authority violates separation of powers principles and the non-delegation doctrine; (2) that Rule 3214, the possession rule, was promulgated in violation of FTC regulations and the Administrative Procedure Act ("APA") and is void for vagueness under the Fifth Amendment; and (3) that "the Act and the FTC Order unconstitutionally assign private causes of action tried to a jury at common law to an administrative tribunal, in violation of the Seventh Amendment right to a jury trial." Mot. for Preliminary Inj. at 9. Although Plaintiff styles his motion as a facial challenge, his requested relief at this stage is far narrower. Plaintiff seeks "first and foremost, a stay of administrative proceedings pending a determination of the merits of his claims." Pl.'s Reply at 2; *see also* Mot. for Prelim. Inj. at 1. Plaintiff "has not asked the Court to enjoin any rule that specifically relates to Covered Horses," nor for the Court "to enjoin post-race testing on Covered Horses," nor "to enjoin the racetrack safety program." Pl.'s Reply at 2.

The Court held a hearing on Plaintiff's motion on August 13, 2025. Doc. 44. Following

oral argument, the Court requested supplemental briefing on the issue of jurisdiction—specifically, whether jurisdiction is precluded under *Thunder Basin Coal Co. v. Reich*, 510 U.S. 200 (1994). Plaintiff, the FTC, and the HISA all filed briefing on this issue. *See* Doc. 43; Doc. 45; Doc. 46.

LEGAL STANDARD

A preliminary injunction is an "extraordinary remedy," warranted only where the movant evinces a "clear and unequivocal" right to relief. *Schrier v. Univ. of Colo.*, 427 F.3d 1253, 1258 (10th Cir. 2005). "To obtain a preliminary injunction, the movant must show: (1) a substantial likelihood of success on the merits; (2) irreparable harm to the movant if the injunction is denied; (3) that the threatened injury outweighs the harm that the preliminary injunction may cause the opposing party; and (4) that the injunction, if issued, will not adversely affect the public interest." *Gen. Motors Corp. v. Urb. Gorilla, LLC*, 500 F.3d 1222, 1226 (10th Cir. 2007) (citation omitted). In the Tenth Circuit, the potential for irreparable harm "is the single most important prerequisite for the issuance of a preliminary injunction, [and] the moving party must first demonstrate that such injury is likely before the other requirements for the issuance of an injunction will be considered." *Dominion Video Satellite, Inc. v. Echostar Satellite Corp.*, 356 F.3d 1256, 1260 (10th Cir. 2004). The court "need not consider the other factors" if a movant fails to meet their burden as to any element. *State v. U.S. Env'tl Prot. Agency*, 989 F.3d 874, 890 (10th Cir. 2021).

DISCUSSION

I. Plaintiff Has Failed to Demonstrate a Likelihood of Irreparable Harm.

The Court's analysis begins and ends with the most critical factor—irreparable harm. "To constitute irreparable harm, an injury must be certain, great, actual and not theoretical." *Heideman v. S. Salt Lake City*, 348 F.3d 1182, 1189 (10th Cir. 2003) (internal quotation mark and citation omitted). "[T]he party seeking injunctive relief must show that the injury complained of is of such

imminence that there is a clear and present need for equitable relief to prevent irreparable harm." *Id.* Economic harm typically does not warrant a preliminary injunction, since a party can almost always be made whole again through damages. *Sampson v. Murray*, 415 U.S. 61, 90 (1974); *Heideman*, 348 F.3d at 1189. In suits against the federal government, however, financial injury becomes irreparable because sovereign immunity results in "nonrecoverable compliance costs." *Chamber of Com. of U.S. v. Edmondson*, 594 F.3d 742, 770–71 (10th Cir. 2010) ("Imposition of monetary damages that cannot later be recovered for reasons such as sovereign immunity constitutes irreparable injury."); *see, e.g.*, *Ryan LLC v. Fed. Trade Comm'n*, 739 F. Supp. 3d 496, 518 (N.D. Tex. 2024). A plaintiff may also obtain a preliminary injunction if the economic harm is of such magnitude that delaying relief would threaten their "very existence." *Mountain Valley Pipeline, LLC v. 6.56 Acres of Land*, 915 F.3d 197, 218 (4th Cir. 2019); *Vacquería Tres Monjitas, Inc. v. Irizarry*, 587 F.3d 464, 484 (1st Cir. 2009). A plaintiff who demonstrates that their business will close without judicial intervention can thus fulfill the irreparable harm prong, even if their financial injury could later be calculated. *Mountain Valley*, 915 F.3d at 218 ("Only when a temporary delay in recovery somehow translates to permanent injury—threatening a party's very existence by, for instance, driving it out of business before litigation concludes—could it qualify as irreparable."); *see, e.g.*, *Alpine Secs. Corp. v. Fin. Indus. Regul. Auth.*, 121 F.4th 1314, 1329 (D.C. Cir. 2024) ("Alpine faces irreparable harm because it faces a grave risk of being forced out of business before full SEC review, rendering any opportunity for later review at best inadequate and, at worst, moot.").

Plaintiff initially identified three harms. Mot. for Prelim. Inj. at 48. First, violation of the Seventh Amendment right to a jury trial. Second, the denial of a due process right to fair notice. Third, irreparable financial harm from countering the HIWU's enforcement action and complying

with Rule 3214 because he "cannot recover damages simply by showing that a regulation was arbitrary, capricious, or promulgated in a manner contrary to law." *Id.* at 48, 49. As to the jury trial and due process harms, Plaintiff avers that "the denial of these rights, without more, are irreparable harms" and "[s]uccess on any of these points voids the challenged actions here ab initio." *Id.* at 48.

None of the harms named in Plaintiff's motion relate to his separation-of-powers argument. Spurred by Defendants' argument that a separation-of-powers violation does not in and of itself work an irreparable harm, *see* Defs.' Resp. at 23, Plaintiff's reply located a new harm—a due process violation from being forced to proceed before an unconstitutional agency. Pl.'s Reply at 12–13 (citing *Panama Ref. Co. v. Ryan*, 293 U.S. 388, 433 (1935)). This argument comes too late. All of Plaintiff's alleged harms should have been stated in his initial motion, rather than raised for the first time in reply. *Griffin v. Bell*, 694 F.3d 817, 822 (7th Cir. 2012); *ClearOne Communs., Inc. v. Bowers*, 643 F.3d 735, 782 (10th Cir. 2011). Nevertheless, the Court will discuss the purported due process violation flowing from Plaintiff's separation-of-powers argument insofar as it pertains to the contentions made in Defendants' response.

A. Requiring Plaintiff to proceed before the Authority does not constitute *per se* irreparable harm, even if the Authority's power is unconstitutional under separation-of-powers principles.

Plaintiff challenges Congress's creation of the Authority as an unconstitutional delegation of legislative and executive power. Mot. for Prelim. Inj. at 15. Defendants counter that *Leachco* forecloses this claim as a viable route to injunctive relief. Defs.' Resp. at 23–24 (citing *Leachco, Inc. v. Consumer Prod. Safety Comm'n*, 103 F.4th 748 (10th Cir. 2024), *cert. denied*, 145 S. Ct. 1047 (2025)). There, the Tenth Circuit held that "a mere generalized separation of powers violation, by itself, does not establish irreparable harm." *Leachco*, 103 F.4th at 753. Plaintiff

rebuts that "a successful non-delegation [claim] necessarily entitles the party to retrospective relief[.]" Pl.'s Reply at 7. He then cites *Panama Refining* for the proposition that "if a statute conferring jurisdiction is void on non-delegation grounds," a preliminary injunction is necessary to protect the "right to be free from the unlawful exercise of jurisdiction." *Id.* at 12. In essence, Plaintiff views *Panama Refining* as empowering him to collapse the merits prong with the irreparable harm prong and fast-track his request for a preliminary injunction.

The Court finds Defendants' position to be persuasive. The maneuver Plaintiff attempts—to meet his irreparable harm burden through a separation-of-powers claim—has no feasibility in this Circuit. "Indeed, two United States Courts of Appeals have considered whether Appointments Clause or Separation of Powers violations necessarily establish irreparable harm and have concluded that they do not." *Does 1-26 v. Musk*, 771 F. Supp. 3d 637, 679 (D. Md. 2025) (first citing *Alpine*, 121 F.4th at 1333–34; and then citing *Leachco*, 103 F.4th at 753)). To try and circumvent *Leachco*'s reach, Plaintiff attempts to cabin *Leachco* to Appointments Clause cases. Pl.'s Reply at 9. This reading has no merit in the face of *Leachco*'s plain text. While it is true that *Leachco* addressed a challenge to federal officers' removal protections, its holding went beyond those facts; *Leachco* unequivocally stated that "merely being subjected to an agency *constructed in violation of the separation of powers* does not, by itself constitute irreparable harm." 103 F.4th at 753 (emphasis added).

The Tenth Circuit has made clear that per se irreparable harm is only assumed when the constitutional violation concerns "individual constitutional rights, such as the rights guaranteed by the First and Fourteenth Amendments." *Id.* at 753; *see also Aposhian v. Barr*, 958 F.3d 969, 990 (10th Cir. 2020) ("[O]ur cases finding that a violation of a constitutional right alone constitutes irreparable harm are limited to cases involving individual rights, not the allocation of powers

among the branches of government"). Limiting per se irreparable harm to individual rights preserves the extraordinary nature of preliminary injunctions. "One can only imagine the deluge of preliminary injunction litigation the courts would face if every action allegedly taken in excess of the agency's authority (whether couched in constitutional terms or not) was deemed irreparable, simply because the participants should not be compelled to participate in a proceeding that the agency arguably lacks authority to bring." *Meta Platforms, Inc. v. Fed. Trade Comm'n*, 723 F. Supp. 3d 64, 81 (D.D.C. 2024); *Imp. Motors II, Inc. v. Cowen*, No. 25-CV-07284-RFL, 2025 WL 2589046, at *3 (N.D. Cal. Sept. 8, 2025) ("This Court declines to extend *Axon* to conclude that it overruled *Collins* and created a sweeping new 'entitlement on the merits to a preliminary injunction in every case where [collateral] constitutional challenges [to administrative proceedings] are raised.'" (quoting *Leachco*, 103 F.4th at 759)).

Plaintiff's belief that *Panama Refining* "proves the point" that "[i]f the statute conferring jurisdiction is void on non-delegation grounds, it follows that the Constitution automatically displaced the agency's jurisdiction the moment the statute was enacted" has no force. Pl.'s Reply at 6. *Panama Refining* is one of two anomalous Supreme Court decisions that struck down laws under the non-delegation doctrine. *See Pan. Ref.*, 293 U.S. at 433; *A.L.A. Schechter Poultry Corp. v. United States*, 295 U.S. 495 (1935). In *Panama Refining*, Congress had enacted the Petroleum Act, 15 U.S.C. § 709 and granted the President authority, pursuant to Section 9(c) of the Act, to prohibit the interstate transport of petroleum "withdrawn from storage in excess of the amount permitted" by state law or regulation. 293 U.S. at 405–06. President Roosevelt issued an executive order proscribing just that. Then, in a subsequent executive order, the President authorized the Secretary of the Interior to "exercise all powers vested in the president for the purpose of enforcing Section 9(c) of said act and said order." *Id.* at 406–07 (internal quotation marks omitted).

Petroleum companies challenged Section 9(c) as "an unconstitutional delegation to the President of legislative power and as transcending the authority of the Congress under the commerce clause." *Id.* at 410. The Supreme Court agreed and enjoined Section 9(c) for violating the non-delegation doctrine. "As to the transportation of oil production in excess of state permission, the Congress has declared no policy, has established no standard, has laid down no rule. There is no requirement, no definition of circumstances and conditions in which the transportation is to be allowed or prohibited." *Id.* at 430. The Court then reversed and remanded the cases to district court, instructing the lower court to "modify its decrees in conformity with this opinion so as to grant permanent injunctions[.]" *Id.*

Panama Refining is unusable for determining whether Plaintiff has asserted an irreparable harm. It did not involve administrative proceedings, nor did it discuss irreparable harm, and it has never been expanded to permit pre-enforcement challenges of agency actions under separation-of-powers principles. Plaintiff does not offer any authority to the contrary. He instead ventures that that because *Panama Refining* involved a permanent injunction it "necessarily involv[ed] irreparable harm." Pl.'s Reply at 12. He then appears to subsume a finding of per se irreparable harm into the Supreme Court's decision on the merits of the non-delegation claim. *Id.* In doing so, Plaintiff conjures a holding that simply does not exist. *Panama Refining* did not explicitly discuss irreparable harm, but it is obvious that the litigants did not rest their right to equitable relief on a constitutional violation alone. The *Panama Refining* plaintiffs sought to enjoin specific harms prompted by Section 9(c)—the government's invasion of their property and the risk of criminal penalties, as well as fines.[4] It was on these grounds that the Supreme Court held that they "were

[4] Part of the harm the plaintiffs in *Panama Refining* sought to prohibit, the government's repeated intrusion onto their private property, has long been recognized as a prototypical form of irreparable harm. Samuel L. Bray, *Multiple Chancellors: Reforming the National Injunction*, 131 HARV. L. REV. 417, 433 (2017) (explaining that the plaintiffs in *Panama Refining* "sought an injunction that would keep the defendants from coming upon the refining plant of the

entitled to invoke equitable jurisdiction to restrain enforcement." 293 U.S. at 246. The Court did not presume that the non-delegation claim would result in irreparable harm. Indeed, the Supreme Court has only extended that privilege to the infringement of First Amendment rights. *See Elrod v. Burns*, 427 U.S. 347, 373 (1976) ("The loss of First Amendment freedoms, for even minimal periods of time, unquestionably constitutes irreparable injury."); *Nat'l Ass'n for Gun Rights v. Lamont*, ___ F.4th ___, 2025 WL 2423599, at *23 (2d Cir. 2025) ("[T]he Supreme Court has never applied [the presumption of irreparable harm] outside the First Amendment context.").[5]

Ultimately, *Panama Refining* does not relieve Plaintiff of his duty to demonstrate irreparable harm. He must face certain and great harm in the absence of judicial intervention to justify a preliminary injunction—a burden he has not and cannot meet through an alleged separation-of-powers violation alone. *Leacho* has already been applied to proceedings before the HIWU; the Western District of Oklahoma denied a temporary restraining order, seeking to prevent the Authority from enforcing HISA regulations, on the grounds that "being subjected to an unconstitutional exercise of authority or an illegitimate decisionmaker" does not amount to irreparable harm. *Offolter v. Horseracing Integrity & Safety Auth.*, Case No. CIV-24-749-D, 2024

plaintiff")."[L]egal remedies are presumptively inadequate in cases of continuing injury, whether that injury is to intellectual property rights or to other legally protected interests . . .This principle was well established by the early nineteenth century, when Joseph Story observed that "Courts of Equity" would enjoin "repeated trespasses" and "upon similar principles . . . interfere in cases of Patents for Inventions, and in cases of Copy-rights." Mark P. Gergen et. al., *The Supreme Court's Accidental Revolution? The Test for Permanent Injunctions*, 112 COLUM. L. REV. 203, 212–13 (2012).

[5] Though not decisive in the present case, it is worth noting that whether a constitutional violation presumptively causes irreparable harm is an unsettled question and one on which the circuits have drastically split. *Compare Hanson v. District of Columbia*, 120 F.4th 223, 244 (D.C. Cir. 2024); *Del. State Sportsmen's Ass'n v. Del. Dep't of Safety & Homeland Sec.*, 108 F.4th 194, 204 (3d Cir. 2024) (limiting the presumption of irreparable harm to First Amendment violations), *with Lamont*, 2025 WL 2423599, at *23; *Siegel v. LePore*, 234 F.3d 1163, 1178 (11th Cir. 2000) (applying the presumption of irreparable harm to a select few constitutional amendments, such as the Fourth and Eighth), *and Leaders of a Beautiful Struggle v. Baltimore Police Dep't*, 2 F.4th 330, 346 (4th Cir. 2021); *Patel v. Glenn*, 2022 WL 16647974, (6th Cir. Nov. 3, 2022); *Morehouse Enters. v. Bureau of Alcohol, Tobacco, Firearms & Explosives*, 78 F.4th 1011 (8th Cir. 2023); *Baird v. Bonta*, 81 F.4th 1036, 1046 (9th Cir. 2023) (finding that nearly all constitutional violations presumptively cause irreparable harm).

WL 3732056, at *3 (W.D. Okla. Aug. 8, 2024). Plaintiff's claim is no different. Because he has not stated a harm beyond subjection to the jurisdiction of an allegedly unconstitutional agency, his separation-of-powers claim does not warrant a preliminary injunction. *Leachco*, 103 F.4th at 753.

B. Any costs Plaintiff incurs from defending against arbitration and the imposition of civil fines do not result in irreparable harm because Plaintiff can recover monetary damages from HIWU and HISA.

The Court now turns to Plaintiff's assertion that complying with a rule promulgated in violation of the APA and FTC regulations causes irreparable harm because he will be unable to obtain monetary damages after the arbitration. Mot. for Prelim. Inj. at 48. That concern has no bearing here. HIWU and HISA are private entities and do not enjoy the protection of sovereign immunity. *See* 15 U.S.C. §§ 3052(a), 3053 (stating that the Authority is a "private, independent, self-regulatory, non-profit corporation"); *Walmsley v. Fed. Trade Comm'n*, 117 F.4th 1032, 1037 (8th Cir. 2024) ("The Authority is a private, nonprofit corporation."), *cert. granted, judgment vacated*, 145 S. Ct. 2870 (2025); *Tuma v. Hawthorne Race Course, Inc.*, No. 24-CV-8307, 2025 WL 2098700, at *7 (N.D. Ill. July 25, 2025) ("HISA and HIWU (operating under HISA), are not government bodies but rather private organizations operating under the FTC."). And worries about recovery from the FTC following appeal are premature. Plaintiff may prevail at arbitration or HIWU may decline to impose fines. Thus, at this stage in the litigation, all monetary harm is recoverable. *See Kim v. Fin. Indus. Regul. Auth.*, 698 F. Supp. 3d 147, 169–70 (D.D.C. 2023); *cf. Env'tl Prot. Agency*, 989 F.3d at 886 (irreparable injury must be "imminent").

Delaying relief does not pose any threat to the "very existence" of Plaintiff's veterinary practice. *Mountain Valley*, 915 F.3d at 218. Plaintiff has not demonstrated that Rule 3214's terms nor the enforcement proceeding itself threaten his practice's financial viability. Defendants underscore that Plaintiff "remains fully free to continue treating covered horses and otherwise

engage in horseracing-related activities covered under HISA, not to mention activities that are not covered under HISA." Defs.' Resp. at 23. Plaintiff agrees that he is "permitted to continue his practice" during the pendency of the administrative proceedings. Pl.'s Reply at 7 (arguing that staying the arbitration would not cause Defendants harm because Plaintiff's "alleged conduct is so un-threatening that [the Authority] has permitted him to continue his practice during its pendency"); *cf. Dominion Video*, 356 F.3d at 1261 (reversing district court's finding of irreparable harm where plaintiff had not established "any threat to its existence, damage to its goodwill, loss of customers, or loss of its competitive position in the market"). Plaintiff also does not seek to enjoin the enforcement of Rule 3214 in general. Pl.'s Reply at 2. Thus, the "compliance costs" of adhering to Rule 3214 (assuming they exist, seeing as the cost of not possessing a drug is likely less than the cost of possessing it) would be unaffected by his requested relief. *See United States v. St. Bernard Par.*, 756 F.2d 1116, 1123 (5th Cir. 1985) ("It is black letter law that an injunction will not issue when it would be ineffectual."); *Second Amend. Found., Inc. v. Bureau of Alcohol, Tobacco, Firearms & Explosives*, 702 F. Supp. 3d 513, 540 (N.D. Tex. 2023). The Court finds Plaintiff has not shown any manifest harm caused by the presumed APA and FTC violations.

C. Plaintiff's Fifth Amendment due process claim fails on the merits and therefore does not result in irreparable harm.

Plaintiff contends that Rule 3214(a) provides insufficient notice of the conduct it prohibits and is therefore void-for-vagueness under the Fifth Amendment. Mot. for Prelim. Inj. at 38. In parallel fashion to his non-delegation claim, Plaintiff maintains that proving a due process violation proves irreparable harm. *Id.* at 48. The Tenth Circuit has not addressed whether a Fifth Amendment violation suffices for irreparable harm, but this Court will assume it does under the Tenth Circuit's holding that individual constitutional harms need "no further showing of irreparable injury." *Planned Parenthood Ass'n v. Herbert*, 828 F.3d 1245, 1263 (10th Cir. 2016);

Aposhian, 958 F.3d at 990. However, because the Court finds Plaintiff's due process claim unconvincing, it in turn finds a lack of irreparable harm.

Agency regulations are subject to constitutional challenge under the Fifth Amendment's Due Process clause for being impermissibly vague. *Brennan v. Occupational Safety & Health Rev. Comm'n*, 505 F.2d 869, 872 (10th Cir. 1974). Prohibiting vague statutes and regulations serves twin aims: (1) it ensures that regulated parties are informed of what is required of them to conform their conduct with the law and (2) it provides "precision and guidance" to those enforcing the law so that they "do not act in an arbitrary or discriminatory way." *FCC v. Fox Television Stations, Inc.*, 567 U.S. 239, 253 (2012). Plaintiff brings a facial challenge to Rule 3214. To succeed in that posture, Plaintiff must show that "no set of circumstances exists under which the [Rule] would be valid." *Wash. State Grange v. Wash. State Republican Party*, 552 U.S. 442, 449 (2008). Rules which are "so vague that men of common intelligence must necessarily guess at its meaning and differ as to its application violates due process." *Id.* A regulation is not void for vagueness if it "has a 'plainly legitimate sweep.'" *Fabrizius v. Dep't of Agric.*, 129 F.4th 1226, 1238 (10th Cir. 2025) (quoting *Wash. State Grange*, 552 U.S. at 449). Where, as here, the regulation is "promulgated pursuant to remedial civil legislation," it is interpreted "in the light of the conduct to which it is applied." *Id.*

Plaintiff accuses the Authority of not "provid[ing] a single word of guidance as to how Covered Veterinarians must alter their practice to comply with Rule 3214(a)." Mot. for Prelim. Inj. at 29; *see also id.* at 38 ("The possession rule provides no reasonably discernable range of conduct that it prohibits."). The Court disagrees; the way veterinarians "must alter their practice" to comport with Rule 3214(a) is by refraining from the conduct it proscribes, i.e. possessing banned substances or banned methods. Those substances are enumerated in the Authority's "Prohibited

List," leaving scant room for confusion over what can and cannot be possessed. *See* HISA Rule Series 4000. Further, Plaintiff's statement that "possession is not the fact on which liability depends" is simply untrue. Mot. for Prelim. Inj. at 37. Possession is the exact fact on which liability depends and "delineates [the Rule's] reach in words of common understanding." *Brennan*, 505 F.2d at 872; *United States v. Woods*, 684 F.3d 1045, 1059 (11th Cir. 2012) ("[T]he ordinary meaning of the terms in the statute show it is not unconstitutionally vague. 'Possession' is the act or condition of having in or taking into one's control or holding at one's disposal." (citation omitted)). The Rules also include thorough enforcement guidance, specifying what classes banned substances fall into, the penalty points associated with each class, and the fines/suspension periods applicable to subsequent violations. *See* HISA Rules 3323–33.

The Authority's decision not to define "compelling justification" does not alter the Court's conclusion. Permitting possession when there is a compelling justification for doing so is an exception to the rule. Veterinarians can always comply with Rule 3214 by not possessing the substances it prohibits. Because Rule 3214 imposes strict liability for possession, the scenarios where the "compelling justification" exemption applies will be a small minority. Again, Plaintiff's burden is to show that "there is no set of circumstances where the rule would be valid." *Wash. State Grange*, 552 U.S. at 449. Focusing on the possible ambiguity in granting exceptions ignores the Rule's "plainly legitimate sweep." *Fabrizius*, 129 F.4th at 1238. Moreover, the definition of "compelling" excludes a vast array of justifications, such as a covered person merely wanting to possess the substance, thinking they should be able to, or forgetting that they have it on hand. What Plaintiff's critique amounts to is a question about edge cases. But a regulation "need not spell out all situations" where an activity is prohibited, *Jake's Fireworks Inc. v. Acosta*, 893 F.3d 1248, 1258 (10th Cir. 2018), nor speak with mathematical precision, *Fabrizius*, 129 F.4th at 1239,

to be constitutional. It is enough that those enforcing the law can look to dictionary definitions and the term's use in comparable anti-doping schemes to discern its meaning. *Id.* at 1238–39 (finding dictionary definitions to provide sufficient guidance on the meaning of the term "responsible"). In sum, "[t]here are at least some instances in which a reasonable person can infer meaning from the Final Rule . . . Therefore, the Court concludes that Plaintiffs are not likely to succeed on the merits of their vagueness claim." *Second Amend. Found.*, 702 F. Supp. 3d at 533.

D. Plaintiff has not identified an irreparable harm resulting from the alleged Seventh Amendment violation.

The Court now addresses the question of jurisdiction under *Thunder Basin* and Plaintiff's related Seventh Amendment claim. "Within constitutional bounds, Congress decides what cases the federal courts have jurisdiction to consider" including "when, and under what conditions, federal courts can hear them." *Bowles v. Russell*, 551 U.S. 205, 212–13 (2007). There is a "strong presumption favoring judicial review of administrative action." *Mach Mining, LLC. v. EEOC*, 575 U.S. 480, 486 (2015) (quoting *Bowen v. Mich. Acad. of Fam. Physicians*, 476 U.S. 667, 670 (1986)). "That presumption is rebuttable: It fails when a statute's language or structure demonstrates that Congress wanted an agency to police its own conduct." *Id.* A district court may only intervene in administrative proceedings if it concludes that a plaintiff's claims are not "of the type Congress intended to be reviewed within [the] statutory structure." *Thunder Basin*, 510 U.S. at 212. The court first considers whether Congress intended to preclude judicial review either implicitly or explicitly. *Id.* at 207. If the statute does oust federal courts of jurisdiction, a plaintiff can still obtain review by demonstrating that (1) precluding district court jurisdiction would foreclose all meaningful judicial review; (2) their claims are wholly collateral to the statutory review scheme; and (3) the claims are outside the agency's expertise. *Id.*

The prototypical statute eliminating federal court jurisdiction under *Thunder Basin* is one

which directs review of agency determinations to a U.S. Court of Appeals, instead of to a district court. *Bank of Louisiana v. Fed. Deposit Ins. Corp.*, 919 F.3d 916, 922 (5th Cir. 2019). The Act is not a statute of this ilk. Rather than vest review in a federal appellate court, the statute permits a final FTC decision to be challenged in a district court through the APA. 5 U.S.C. § 704; 15 U.S.C § 3058(b)(3)(B); *cf. Elgin v. Dep't of Treasury*, 567 U.S. 200, 206 (1994).

During Plaintiff's requested hearing in support of his preliminary injunction, the Court asked the parties to share their view as to whether *Thunder Basin* divests the Court of jurisdiction over Plaintiff's Seventh Amendment claim. Numerous other courts have found that *Thunder Basin* counsels against judicial interference in administrative proceedings, including those before FINRA, when the party alleges a Seventh Amendment violation, and the parent statute vests review in the courts of appeals. Although the Act does not mirror that appellate review structure, the Court ordered supplemental briefing as to whether district court review is implicitly displaced by the Act's "text, structure, and purpose." *Bank of Louisiana*, 919 F.3d at 923 (noting that implicit preclusion requires a "more complex analysis"); *see, e.g.*, *Connecticut v. Spellings*, 453 F. Supp. 2d 459, 486 (D. Conn. 2006) (finding that statute's administrative review scheme "reflect[e]d an intent to preclude the type of pre-enforcement action brought by the state" under *Thunder Basin* even though final agency decisions "could be reviewed by a district court under the APA"). However, because Plaintiff has not shown any irreparable harm resulting from the purported constitutional violations, there will be no judicial interference in his administrative proceeding. The Court therefore does not reach the *Thunder Basin* question.

i. Plaintiff's facial challenge under the Seventh Amendment fails because there is no per se irreparable harm.

Plaintiff challenges the HISA's "mandate to use binding arbitration" as a facial violation of the Seventh Amendment right to a jury trial. Mot. for Prelim. Inj. at 10. Facial challenges "are

the most difficult to mount successfully," but may be "brought under any otherwise enforceable provision of the constitution." *City of Los Angeles v. Patel*, 576 U.S. 409, 415 (2015). Plaintiff must demonstrate that the use of arbitration is "unconstitutional in all applications." *Id.* at 418. "[W]hen assessing whether a statute meets this standard" the Court considers "only applications of the statute in which it actually authorizes or prohibits conduct." *Id.*

Plaintiff's Seventh Amendment argument confuses the difference between a facial and an as-applied challenge. He alternates between discussing why the specific claims brought against him and the actions HIWU is generally authorized to initiate warrant a jury trial. *See id.* at 41–47. For instance, he contends that a jury is necessary because "the claims against Dr. Scott have close analogues at common law," *id.* at 45, and predicts that Defendants will "attempt to distinguish the scope of common law fraud or breach-of-contract claims from the charges brought here," *id.* Yet later, Plaintiff compares the Act's goal of accurately reflecting a horse's condition by preventing doping to "a quintessential form of fraud," *id.* at 43. The "'anti-doping' violations defined in HISA's Rules therefore confront a question tried to a jury at common law as a breach of agreement among competitors to run a fair race." *Id.* at 45. These statements reveal a significant discrepancy between the claim Plaintiff purports to bring—a facial challenge—and the one he actually argues—an as-applied challenge. This conflict becomes even more perplexing when evaluating irreparable harm. Plaintiff at once assails HIWU's actions as "void ab initio" under the Seventh Amendment, *id.* at 48, and protests that arbitration violates his "individual right" to a jury trial. *Id.* at 48; Pl.'s Reply at 11. In the end, both theories fail. Plaintiff has not mounted a viable facial challenge, nor has he articulated an irreparable harm flowing from his Seventh Amendment claim.

The right to a jury trial attaches when the suit is one which would have arisen "at common law." *Tull v. United States*, 481 U.S. 412, 417 (1982). The Supreme Court has held that, in the

context of agency proceedings, Congress cannot "eliminate a party's Seventh Amendment right to a jury trial merely by relabeling the cause of action to which it attaches and placing exclusive jurisdiction in an administrative agency or a specialized court of equity." *Granfinanciera, S.A. v. Nordberg*, 492 U.S. 33, 61 (1989). Courts use a two-step analysis to evaluate whether an agency adjudication is proper. First, the court determines if the agency's claim against the individual is "legal in nature." *Id.* at 53. Whether a claim is legal in nature depends on both (1) the cause of action and (2) the remedy it provides, *id.* at 60, but the remedy is the "more important consideration," *id.* (internal quotations omitted). If it is a legal claim, the court then considers whether the right the agency seeks to enforce is subject to the "public-rights exception." *Atlas Roofing Co. v. Occupational Safety & Health Rev. Comm'n*, 430 U.S. 442, 455 (1977). "Under this exception, Congress may assign the matter for decision to an agency without a jury, consistent with the Seventh Amendment." *Secs. & Exchange Comm'n v. Jarkesy*, 603 U.S. 109, 127 (2024).

Plaintiff's primary case for his Seventh Amendment claim is *Jarkesy*. Mot. for Prelim. Inj. at 41–43. In *Jarkesy*, the Securities and Exchange Commission ("SEC") had initiated an enforcement action against two individuals, alleging securities fraud and seeking up to $300,000 in civil penalties. *See Jarkesy*, 603 U.S. at 123. Beginning with the remedy, the Court concluded that the SEC's imposition of civil penalties was "all but dispositive." *Id.* "What determines whether a monetary remedy is legal is if it is designed to punish or deter the wrongdoer, or, on the other hand, solely to restore the status quo.'" *Id.* (quoting *Tull*, 481 U.S. at 422). Because the relevant penalties would not be used to "return any money to victims," but were "designed to punish and deter," they were a prototypical common law remedy. *Id.* at 130. The Court then moved to the cause of action and found that the "close relationship between the causes of action in this case and common law fraud" supported its conclusion. *Id.* Of particular import to the

Court's analysis was Congress's "deliberate" use of "fraud" in the Securities Exchange Act. *See id.* The majority interpreted this word choice as indicating that Congress "incorporated prohibitions from common law fraud in federal securities law" and sought to target the same misconduct as common law fraud, e.g., misrepresenting or concealing material facts. *Id.* The public rights exception was thus inapplicable because, regardless of the actions "statutory origins," fraud "resemble[d] a traditional legal claim." *Id.* at 135.

Plaintiff leads with the assertion that "the suit in this case is virtually identical" to the one in *Jarkesy*. Mot. for Prelim. Inj. at 42. To be "virtually identical" to Plaintiff's suit, *Jarkesy* would need to have considered a facial challenge. It did not. The Supreme Court answered a "straightforward question: whether the Seventh Amendment entitles a defendant to a jury trial when the SEC seeks civil penalties against *him* for securities fraud." 603 U.S. at 120 (emphasis added). Nothing in *Jarkesy* limited agencies' power to seek civil fines for suits without a common law mirror or to pursue equitable remedies. Arbitration is thus obviously appropriate in at least one scenario where it will be applied—when the HIWU seeks exclusively equitable relief. 15 U.S.C. § 3057(d)(3)(A); *Patel*, 576 U.S. at 423.[6] Despite Plaintiff's contortion of the anti-doping rules into "common law" causes of action, the regulations also go far beyond traditional concerns of fair play and "warranties as to the quality of a racehorse for purchase." Mot. for Prelim. Inj. at 46. The possession violation itself is unlike any common law claim and he includes no support

[6] In his reply, Plaintiff argues that the Seventh Amendment entitles individuals to a jury trial even where the sole penalty is a suspension because suspensions are not equitable remedies since they are "intended to punish culpable individuals." Pl.'s Reply at 16 (quoting *Tull*, 481 U.S. at 412). Plaintiff's analysis relies on a misapprehension of what distinguishes legal remedies from equitable remedies. While English common law permitted courts of equity to award certain monetary damages, such as restitution, it did not permit courts of law to issue injunctive relief, such as abating a public nuisance. *Tull*, 481 U.S. at 424. Whether the fines the government seeks go beyond "restoring the status quo" is relevant for differentiating forms of monetary relief; it cannot be used to transform equitable relief into a legal remedy. *See generally id.* Here, suspension prohibits a covered person from participating in covered events. *See* HISA Rule 3229. It is a form of equitable relief aimed at preventing certain conduct. James Fleming, Jr., *Right to a Jury Trial in Civil Actions*, 72 YALE L.J. 655, 682 (1963). The Authority's ability to order disgorgement of an individual's winnings following a rigged race is another equitable remedy.

for the idea that private parties could have sued an equine veterinarian for possessing a drug near a racetrack; all of Plaintiff's authorities pertain to private parties who could sue for "purse money" following a rigged horse race. *Id.* at 46. Accordingly, to the extent that Plaintiff's facial challenge is meant to prove a "constitutional infringement" and "require no further showing of irreparable injury," it folds.

ii. Even if the Court construes Plaintiff's Seventh Amendment claim as an as-applied challenge, there is no evidence of irreparable harm.

Though Plaintiff shies away from an as-applied challenge, the Court addresses the question of a Seventh Amendment right for Plaintiff's arbitration since it is frequently referenced in his filings. Plaintiff insists that he will suffer a "hear-and-now injury [sic]" from proceeding before an arbitrator. Mot. for Prelim. Inj. at 10. He pulls the "here-and-now" language from the Supreme Court's decision in *Axon*. *See Axon Enter. v. Fed. Trade Comm'n*, 598 U.S. 175, 191 (2023). That statement was made in the context of determining whether the Supreme Court had jurisdiction under *Thunder Basin* to hear challenges to the constitutional authority of administrative law judges. *Id.* The case did not involve injunctive relief and, in fact, *Leachco* refused to equate the "here-and-now" injury with irreparable harm because *Axon* "did not address the issue of irreparable harm, or any other issue regarding entitlement to injunctive relief." 103 F.4th at 758; *cf. Vape Central Grp., LLC v. U.S. Food & Drug Admin.*, Civil Action No. 24-3354, 2025 WL 637416, at *9 (D.D.C. Feb. 27, 2027) ("[I]t is far from clear that [company] will even suffer a "there-and-then injury" at some later time, since the company has yet to identify any genuine dispute of material fact that might, under any circumstances, support a Seventh Amendment claim.").

Plaintiff offers no other caselaw to prove that his "individual" Seventh Amendment injury

is irreparable.[7] Courts have consistently reached the opposite conclusion. "It is well established that in the Seventh Amendment context, 'the harm resulting from the denial of a jury trial can be remedied on appeal, even after the case has already been tried' because a reviewing court can "simply order[ ] a new trial.'" *Lukezic v. Fin. Indus. Regul. Auth., Inc.*, No. 25-CV-00623 (DLF), 2025 WL 2305859, at *3 (D.D.C. Aug. 10, 2025). Accordingly, "merely being subject to a proceeding before an ALJ where a particular remedy sought is allegedly unconstitutional or not statutorily permissible does not leave YAPP without a remedy." *YAPP USA Auto. Sys., Inc. v. Nat'l Lab. Rels. Bd.*, 748 F. Supp. 3d 497, 517 (E.D. Mich. 2024), *appeal dismissed*, No. 24-1754, 2025 WL 2606098 (6th Cir. Aug. 4, 2025); *Vape Cent. Grp., LLC v. U.S. Food & Drug Admin.*, No. CV 24-3354 (RDM), 2025 WL 637416, at *6 (D.D.C. Feb. 27, 2025) ("It is thus unsurprising that every district court that has considered the question post-*Jarkesy* has held that the relevant statutory procedures for challenging final administrative orders provide a sufficient opportunity for 'meaningful review' of any Seventh Amendment defense.").

The Court therefore finds that Plaintiff has not established irreparable harm for any of his claims. The request for a preliminary injunction is denied. *Env'tl Prot. Agency*, 989 F.3d at 890.

CONCLUSION

IT IS THEREFORE ORDERED that Plaintiff's motion for a preliminary injunction, Doc. 8, is **DENIED**.

SARAH M. DAVENPORT
UNITED STATES DISTRICT JUDGE

[7] Plaintiff's reliance on cases finding that the loss of a professional license is a type of forfeiture, and therefore require a jury, are inapposite. Pl.'s Reply at 11. The Authority cannot revoke Dr. Scott's veterinary license; it can only prevent him from participating in covered races and events. *See* HISA Rule 3229.

TAB 3

MOTOR VEHICLE MANUFACTURERS ASSOCIATION OF THE UNITED STATES, INC., ET AL. *v.* STATE FARM MUTUAL AUTOMOBILE INSURANCE CO. ET AL.

CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 82–354. Argued April 26, 1983—Decided June 24, 1983*

The National Traffic and Motor Vehicle Safety Act of 1966 (Act) directs the Secretary of Transportation to issue motor vehicle safety standards that "shall be practicable, shall meet the need for motor vehicle safety, and shall be stated in objective terms." In issuing these standards, the Secretary is directed to consider "relevant available motor vehicle safety data," whether the proposed standard is "reasonable, practicable and appropriate" for the particular type of motor vehicle for which it is prescribed, and "the extent to which such standards will contribute to carrying out the purposes" of the Act. The Act authorizes judicial review, under the Administrative Procedure Act, of "all orders establishing, amending, or revoking" a motor vehicle safety standard. The National Highway Traffic Safety Administration (NHTSA), to which the Secretary has delegated his authority to promulgate safety standards, rescinded the requirement of Modified Standard 208 that new motor vehicles produced after September 1982 be equipped with passive restraints (automatic seatbelts or airbags) to protect the safety of the occupants of the vehicle in the event of a collision. In explaining the rescission, NHTSA maintained that it was no longer able to find, as it had in 1977 when Modified Standard 208 was issued, that the automatic restraint requirement would produce significant safety benefits. In 1977, NHTSA had assumed that airbags would be installed in 60% of all new cars and automatic seatbelts in 40%. But by 1981 it became apparent that automobile manufacturers planned to install automatic seatbelts in approximately 99% of the new cars and that the overwhelming majority of such seatbelts could be easily detached and left that way permanently, thus precluding the realization of the lifesaving potential of airbags and requiring the same type of affirmative action that was the stumbling block

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*Together with No. 82–355, *Consumer Alert et al.* v. *State Farm Mutual Automobile Insurance Co. et al.*; and No. 82–398, *United States Department of Transportation et al.* v. *State Farm Mutual Automobile Insurance Co. et al.*, also on certiorari to the same court.

to achieving high usage of manual belts. For this reason, NHTSA concluded that there was no longer a basis for reliably predicting that Modified Standard 208 would lead to any significant increased usage of restraints. Hence, in NHTSA's view, the automatic restraint requirement was no longer reasonable or practicable. Moreover, given the high expense of implementing such a requirement and the limited benefits arising therefrom, NHTSA feared that many consumers would regard Modified Standard 208 as an instance of ineffective regulation. On petitions for review of NHTSA's rescission of the passive restraint requirement, the Court of Appeals held that the rescission was arbitrary and capricious on the grounds that NHTSA's conclusion that it could not reliably predict an increase in belt usage under the Standard was an insufficient basis for the rescission, that NHTSA inadequately considered the possibility of requiring manufacturers to install nondetachable rather than detachable passive belts, and that the agency failed to give any consideration to requiring compliance with the Standard by the installation of airbags. The court found that congressional reaction to various versions of the Standard "raised doubts" that NHTSA's rescission "necessarily demonstrates an effort to fulfill its statutory mandate" and that therefore the agency was obligated to provide "increasingly clear and convincing reasons" for its action.

Held: NHTSA's rescission of the passive restraint requirement in Modified Standard 208 was arbitrary and capricious; the agency failed to present an adequate basis and explanation for rescinding the requirement and must either consider the matter further or adhere to or amend the Standard along lines which its analysis supports. Pp. 40–57.

(a) The rescission of an occupant crash protection standard is subject to the same standard of judicial review—the "arbitrary and capricious" standard—as is the promulgation of such a standard, and should not be judged by, as petitioner Motor Vehicle Manufacturers Association contends, the standard used to judge an agency's refusal to promulgate a rule in the first place. The Act expressly equates orders "revoking" and "establishing" safety standards. The Association's view would render meaningless Congress' authorization for judicial review of orders revoking safety standards. An agency changing its course by rescinding a rule is obligated to supply a reasoned analysis for the change beyond that which may be required when an agency does not act in the first instance. While the scope of review under the "arbitrary and capricious" standard is narrow and a court is not to substitute its judgment for that of the agency, the agency nevertheless must examine the relevant data and articulate a satisfactory explanation for its action. In reviewing that explanation, a court must consider whether the decision was based on a

consideration of the relevant factors and whether there was a clear error of judgment. Pp. 40–44.

(b) The Court of Appeals correctly found that the "arbitrary and capricious" standard of judicial review applied to rescission of agency regulations, but erred in intensifying the scope of its review based upon its reading of legislative events. While an agency's interpretation of a statute may be confirmed or ratified by subsequent congressional failure to change that interpretation, here, even an unequivocal ratification of the passive restraint requirement would not connote approval or disapproval of NHTSA's later decision to rescind the requirement. That decision remains subject to the "arbitrary and capricious" standard. Pp. 44–46.

(c) The first reason for finding NHTSA's rescission of Modified Standard 208 was arbitrary and capricious is that it apparently gave no consideration to modifying the Standard to require that airbag technology be utilized. Even if NHTSA's conclusion that detachable automatic seatbelts will not attain anticipated safety benefits because so many individuals will detach the mechanism were acceptable in its entirety, standing alone it would not justify any more than an amendment of the Standard to disallow compliance by means of one technology which will not provide effective passenger protection. It does not cast doubt on the need for a passive restraint requirement or upon the efficacy of airbag technology. The airbag is more than a policy alternative to the passive restraint requirement; it is a technology alternative within the ambit of the existing standard. Pp. 46–51.

(d) NHTSA was too quick to dismiss the safety benefits of automatic seatbelts. Its explanation for rescission of the passive restraint requirement is not sufficient to enable this Court to conclude that the rescission was the product of reasoned decisionmaking. The agency took no account of the critical difference between detachable automatic seatbelts and current manual seatbelts, failed to articulate a basis for not requiring nondetachable belts, and thus failed to offer the rational connection between facts and judgment required to pass muster under the "arbitrary and capricious" standard. Pp. 51–57.

220 U. S. App. D. C. 170, 680 F. 2d 206, vacated and remanded.

WHITE, J., delivered the opinion of the Court, in which BRENNAN, MARSHALL, BLACKMUN, and STEVENS, JJ., joined, and in all but Parts V–B and VI of which BURGER, C. J., and POWELL, REHNQUIST, and O'CONNOR, JJ., joined. REHNQUIST, J., filed an opinion concurring in part and dissenting in part, in which BURGER, C. J., and POWELL and O'CONNOR, JJ., joined, *post*, p. 57.

Solicitor General Lee argued the cause for petitioners in No. 82–398. With him on the briefs were *Assistant Attorney General McGrath, Deputy Solicitor General Geller, Edwin S. Kneedler, Robert E. Kopp, Michael F. Hertz, Frank Berndt, David W. Allen, Enid Rubenstein,* and *Eileen T. Leahy. Lloyd N. Cutler* argued the cause for petitioners in No. 82–354. With him on the briefs were *John H. Pickering, William R. Perlik, Andrew B. Weissman, William R. Richardson, Jr., Milton D. Andrews, Lance E. Tunick, William H. Crabtree, Edward P. Good, Henry R. Nolte, Jr., Otis M. Smith, Charles R. Sharp,* and *William L. Weber, Jr. Raymond M. Momboisse, Sam Kazman,* and *Ronald A. Zumbrun* filed briefs for petitioners in No. 82–355.

James F. Fitzpatrick argued the cause for respondents in all cases. With him on the brief for respondents State Farm Mutual Automobile Insurance Co. et al. were *Michael N. Sohn, John M. Quinn,* and *Merrick B. Garland. Robert Abrams,* Attorney General of New York, *Robert S. Hammer,* Assistant Attorney General, *Peter H. Schiff, Martin Minkowitz,* and *Milton L. Freedman* filed a brief for respondent Superintendent of Insurance of the State of New York. *Raymond J. Rasenberger, Lawrence C. Merthan, Jerry W. Cox,* and *Lowell R. Beck* filed a brief for respondents National Association of Independent Insurers et al.†

JUSTICE WHITE delivered the opinion of the Court.

The development of the automobile gave Americans unprecedented freedom to travel, but exacted a high price for

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†Briefs of *amici curiae* urging affirmance were filed by *Dennis J. Barbour* for the American College of Preventive Medicine et al.; by *Nathan Lewin* for the American Insurance Association; by *Philip R. Collins* and *Thomas C. McGrath, Jr.*, for the Automotive Occupant Protection Association; by *Alexandra K. Finucane* for the Epilepsy Foundation of America et al.; by *Katherine I. Hall* for the Center for Auto Safety et al.; by *Simon Lazarus III* for Mothers Against Drunk Drivers; and by *John H. Quinn, Jr.*, and *John Hardin Young* for the National Association of Insurance Commissioners.

enhanced mobility. Since 1929, motor vehicles have been the leading cause of accidental deaths and injuries in the United States. In 1982, 46,300 Americans died in motor vehicle accidents and hundreds of thousands more were maimed and injured.[1] While a consensus exists that the current loss of life on our highways is unacceptably high, improving safety does not admit to easy solution. In 1966, Congress decided that at least part of the answer lies in improving the design and safety features of the vehicle itself.[2] But much of the technology for building safer cars was undeveloped or untested. Before changes in automobile design could be mandated, the effectiveness of these changes had to be studied, their costs examined, and public acceptance considered. This task called for considerable expertise and Congress responded by enacting the National Traffic and Motor Vehicle Safety Act of 1966 (Act), 80 Stat. 718, as amended, 15 U. S. C. § 1381 *et seq.* (1976 ed. and Supp. V). The Act, created for the purpose of "reduc[ing] traffic accidents and deaths and injuries to persons resulting from traffic accidents," 15 U. S. C. § 1381, directs the Secretary of Transportation or his delegate to issue motor vehicle safety standards that "shall be practicable, shall meet the need for motor vehicle safety, and shall be stated in objective terms." 15 U. S. C. § 1392(a) (1976 ed., Supp. V). In issuing these standards, the Secretary is directed to consider "relevant available motor vehicle safety data," whether the proposed standard "is reasonable, practicable and appropriate" for the particular type of motor vehicle, and the "extent to which

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[1] National Safety Council, 1982 Motor Vehicle Deaths By States (May 16, 1983).

[2] The Senate Committee on Commerce reported:

"The promotion of motor vehicle safety through voluntary standards has largely failed. The unconditional imposition of mandatory standards at the earliest practicable date is the only course commensurate with the highway death and injury toll." S. Rep. No. 1301, 89th Cong., 2d Sess., 4 (1966).

such standards will contribute to carrying out the purposes" of the Act. 15 U. S. C. §§ 1392(f)(1), (3), (4).[3]

The Act also authorizes judicial review under the provisions of the Administrative Procedure Act (APA), 5 U. S. C. § 706, of all "orders establishing, amending, or revoking a Federal motor vehicle safety standard," 15 U. S. C. § 1392(b). Under this authority, we review today whether NHTSA acted arbitrarily and capriciously in revoking the requirement in Motor Vehicle Safety Standard 208 that new motor vehicles produced after September 1982 be equipped with passive restraints to protect the safety of the occupants of the vehicle in the event of a collision. Briefly summarized, we hold that the agency failed to present an adequate basis and explanation for rescinding the passive restraint requirement and that the agency must either consider the matter further or adhere to or amend Standard 208 along lines which its analysis supports.

I

The regulation whose rescission is at issue bears a complex and convoluted history. Over the course of approximately 60 rulemaking notices, the requirement has been imposed, amended, rescinded, reimposed, and now rescinded again.

As originally issued by the Department of Transportation in 1967, Standard 208 simply required the installation of seatbelts in all automobiles. 32 Fed. Reg. 2415. It soon became apparent that the level of seatbelt use was too low to reduce traffic injuries to an acceptable level. The Department therefore began consideration of "passive occupant restraint systems"—devices that do not depend for their effec-

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[3] The Secretary's general authority to promulgate safety standards under the Act has been delegated to the Administrator of the National Highway Traffic Safety Administration (NHTSA). 49 CFR § 1.50(a) (1982). This opinion will use the terms NHTSA and agency interchangeably when referring to the National Highway Traffic Safety Administration, the Department of Transportation, and the Secretary of Transportation.

tiveness upon any action taken by the occupant except that necessary to operate the vehicle. Two types of automatic crash protection emerged: automatic seatbelts and airbags. The automatic seatbelt is a traditional safety belt, which when fastened to the interior of the door remains attached without impeding entry or exit from the vehicle, and deploys automatically without any action on the part of the passenger. The airbag is an inflatable device concealed in the dashboard and steering column. It automatically inflates when a sensor indicates that deceleration forces from an accident have exceeded a preset minimum, then rapidly deflates to dissipate those forces. The lifesaving potential of these devices was immediately recognized, and in 1977, after substantial on-the-road experience with both devices, it was estimated by NHTSA that passive restraints could prevent approximately 12,000 deaths and over 100,000 serious injuries annually. 42 Fed. Reg. 34298.

In 1969, the Department formally proposed a standard requiring the installation of passive restraints, 34 Fed. Reg. 11148, thereby commencing a lengthy series of proceedings. In 1970, the agency revised Standard 208 to include passive protection requirements, 35 Fed. Reg. 16927, and in 1972, the agency amended the Standard to require full passive protection for all front seat occupants of vehicles manufactured after August 15, 1975. 37 Fed. Reg. 3911. In the interim, vehicles built between August 1973 and August 1975 were to carry either passive restraints or lap and shoulder belts coupled with an "ignition interlock" that would prevent starting the vehicle if the belts were not connected.[4] On review, the

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[4] Early in the process, it was assumed that passive occupant protection meant the installation of inflatable airbag restraint systems. See 34 Fed. Reg. 11148 (1969). In 1971, however, the agency observed that "[s]ome belt-based concepts have been advanced that appear to be capable of meeting the complete passive protection options," leading it to add a new section to the proposed standard "[t]o deal expressly with passive belts." 36 Fed. Reg. 12859.

agency's decision to require passive restraints was found to be supported by "substantial evidence" and upheld. *Chrysler Corp.* v. *Department of Transportation*, 472 F. 2d 659 (CA6 1972).[5]

In preparing for the upcoming model year, most car makers chose the "ignition interlock" option, a decision which was highly unpopular, and led Congress to amend the Act to prohibit a motor vehicle safety standard from requiring or permitting compliance by means of an ignition interlock or a continuous buzzer designed to indicate that safety belts were not in use. Motor Vehicle and Schoolbus Safety Amendments of 1974, Pub. L. 93–492, § 109, 88 Stat. 1482, 15 U. S. C. § 1410b(b). The 1974 Amendments also provided that any safety standard that could be satisfied by a system other than seatbelts would have to be submitted to Congress where it could be vetoed by concurrent resolution of both Houses. 15 U. S. C. § 1410b(b)(2).[6]

The effective date for mandatory passive restraint systems was extended for a year until August 31, 1976. 40 Fed. Reg. 16217 (1975); *id.*, at 33977. But in June 1976, Secretary of Transportation William T. Coleman, Jr., initiated a new rulemaking on the issue, 41 Fed. Reg. 24070. After hearing testimony and reviewing written comments, Coleman extended the optional alternatives indefinitely and suspended the passive restraint requirement. Although he found pas-

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[5] The court did hold that the testing procedures required of passive belts did not satisfy the Act's requirement that standards be "objective." 472 F. 2d, at 675.

[6] Because such a passive restraint standard was not technically in effect at this time due to the Sixth Circuit's invalidation of the testing requirements, see n. 5, *supra*, the issue was not submitted to Congress until a passive restraint requirement was reimposed by Secretary Adams in 1977. To comply with the Amendments, NHTSA proposed new warning systems to replace the prohibited continuous buzzers. 39 Fed. Reg. 42692 (1974). More significantly, NHTSA was forced to rethink an earlier decision which contemplated use of the interlocks in tandem with detachable belts. See n. 13, *infra*.

sive restraints technologically and economically feasible, the Secretary based his decision on the expectation that there would be widespread public resistance to the new systems. He instead proposed a demonstration project involving up to 500,000 cars installed with passive restraints, in order to smooth the way for public acceptance of mandatory passive restraints at a later date. Department of Transportation, The Secretary's Decision Concerning Motor Vehicle Occupant Crash Protection (Dec. 6, 1976), App. 2068.

Coleman's successor as Secretary of Transportation disagreed. Within months of assuming office, Secretary Brock Adams decided that the demonstration project was unnecessary. He issued a new mandatory passive restraint regulation, known as Modified Standard 208. 42 Fed. Reg. 34289 (1977); 49 CFR §571.208 (1978). The Modified Standard mandated the phasing in of passive restraints beginning with large cars in model year 1982 and extending to all cars by model year 1984. The two principal systems that would satisfy the Standard were airbags and passive belts; the choice of which system to install was left to the manufacturers. In *Pacific Legal Foundation* v. *Department of Transportation*, 193 U. S. App. D. C. 184, 593 F. 2d 1338, cert. denied, 444 U. S. 830 (1979), the Court of Appeals upheld Modified Standard 208 as a rational, nonarbitrary regulation consistent with the agency's mandate under the Act. The Standard also survived scrutiny by Congress, which did not exercise its authority under the legislative veto provision of the 1974 Amendments.[7]

Over the next several years, the automobile industry geared up to comply with Modified Standard 208. As late as July 1980, NHTSA reported:

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[7] No action was taken by the full House of Representatives. The Senate Committee with jurisdiction over NHTSA affirmatively endorsed the Standard, S. Rep. No. 95–481 (1977), and a resolution of disapproval was tabled by the Senate. 123 Cong. Rec. 33332 (1977).

> "On the road experience in thousands of vehicles equipped with air bags and automatic safety belts has confirmed agency estimates of the life-saving and injury-preventing benefits of such systems. When all cars are equipped with automatic crash protection systems, each year an estimated 9,000 more lives will be saved, and tens of thousands of serious injuries will be prevented." NHTSA, Automobile Occupant Crash Protection, Progress Report No. 3, p. 4; App. in No. 81–2220 (CADC), p. 1627 (hereinafter App.).

In February 1981, however, Secretary of Transportation Andrew Lewis reopened the rulemaking due to changed economic circumstances and, in particular, the difficulties of the automobile industry. 46 Fed. Reg. 12033. Two months later, the agency ordered a one-year delay in the application of the Standard to large cars, extending the deadline to September 1982, *id.*, at 21172, and at the same time, proposed the possible rescission of the entire Standard. *Id.*, at 21205. After receiving written comments and holding public hearings, NHTSA issued a final rule (Notice 25) that rescinded the passive restraint requirement contained in Modified Standard 208.

II

In a statement explaining the rescission, NHTSA maintained that it was no longer able to find, as it had in 1977, that the automatic restraint requirement would produce significant safety benefits. Notice 25, *id.*, at 53419. This judgment reflected not a change of opinion on the effectiveness of the technology, but a change in plans by the automobile industry. In 1977, the agency had assumed that airbags would be installed in 60% of all new cars and automatic seatbelts in 40%. By 1981 it became apparent that automobile manufacturers planned to install the automatic seatbelts in approximately 99% of the new cars. For this reason, the lifesaving potential of airbags would not be realized. Moreover, it now appeared that the overwhelming majority of passive belts

planned to be installed by manufacturers could be detached easily and left that way permanently. Passive belts, once detached, then required "the same type of affirmative action that is the stumbling block to obtaining high usage levels of manual belts." *Id.*, at 53421. For this reason, the agency concluded that there was no longer a basis for reliably predicting that the Standard would lead to any significant increased usage of restraints at all.

In view of the possibly minimal safety benefits, the automatic restraint requirement no longer was reasonable or practicable in the agency's view. The requirement would require approximately $1 billion to implement and the agency did not believe it would be reasonable to impose such substantial costs on manufacturers and consumers without more adequate assurance that sufficient safety benefits would accrue. In addition, NHTSA concluded that automatic restraints might have an adverse effect on the public's attitude toward safety. Given the high expense and limited benefits of detachable belts, NHTSA feared that many consumers would regard the Standard as an instance of ineffective regulation, adversely affecting the public's view of safety regulation and, in particular, "poisoning . . . popular sentiment toward efforts to improve occupant restraint systems in the future." *Id.*, at 53424.

State Farm Mutual Automobile Insurance Co. and the National Association of Independent Insurers filed petitions for review of NHTSA's rescission of the passive restraint Standard. The United States Court of Appeals for the District of Columbia Circuit held that the agency's rescission of the passive restraint requirement was arbitrary and capricious. 220 U. S. App. D. C. 170, 680 F. 2d 206 (1982). While observing that rescission is not unrelated to an agency's refusal to take action in the first instance, the court concluded that, in this case, NHTSA's discretion to rescind the passive restraint requirement had been restricted by various forms of congressional "reaction" to the passive restraint issue. It then

proceeded to find that the rescission of Standard 208 was arbitrary and capricious for three reasons. First, the court found insufficient as a basis for rescission NHTSA's conclusion that it could not reliably predict an increase in belt usage under the Standard. The court held that there was insufficient evidence in the record to sustain NHTSA's position on this issue, and that, "only a well justified refusal to seek more evidence could render rescission non-arbitrary." *Id.*, at 196, 680 F. 2d, at 232. Second, a majority of the panel[8] concluded that NHTSA inadequately considered the possibility of requiring manufacturers to install nondetachable rather than detachable passive belts. Third, the majority found that the agency acted arbitrarily and capriciously by failing to give any consideration whatever to requiring compliance with Modified Standard 208 by the installation of airbags.

The court allowed NHTSA 30 days in which to submit a schedule for "resolving the questions raised in th[e] opinion." *Id.*, at 206, 680 F. 2d, at 242. Subsequently, the agency filed a Notice of Proposed Supplemental Rulemaking setting forth a schedule for complying with the court's mandate. On August 4, 1982, the Court of Appeals issued an order staying the compliance date for the passive restraint requirement until September 1, 1983, and requested NHTSA to inform the court whether that compliance date was achievable. NHTSA informed the court on October 1, 1982, that based on representations by manufacturers, it did not appear that practicable compliance could be achieved before September 1985. On November 8, 1982, we granted certiorari, 459 U. S. 987, and on November 18, the Court of Appeals entered an order recalling its mandate.

III

Unlike the Court of Appeals, we do not find the appropriate scope of judicial review to be the "most troublesome

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[8] Judge Edwards did not join the majority's reasoning on these points.

question" in these cases. Both the Act and the 1974 Amendments concerning occupant crash protection standards indicate that motor vehicle safety standards are to be promulgated under the informal rulemaking procedures of the Administrative Procedure Act. 5 U. S. C. § 553. The agency's action in promulgating such standards therefore may be set aside if found to be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U. S. C. § 706(2)(A); *Citizens to Preserve Overton Park* v. *Volpe*, 401 U. S. 402, 414 (1971); *Bowman Transportation, Inc.* v. *Arkansas-Best Freight System, Inc.*, 419 U. S. 281 (1974). We believe that the rescission or modification of an occupant-protection standard is subject to the same test. Section 103(b) of the Act, 15 U. S. C. § 1392(b), states that the procedural and judicial review provisions of the Administrative Procedure Act "shall apply to all orders establishing, amending, or revoking a Federal motor vehicle safety standard," and suggests no difference in the scope of judicial review depending upon the nature of the agency's action.

Petitioner Motor Vehicle Manufacturers Association (MVMA) disagrees, contending that the rescission of an agency rule should be judged by the same standard a court would use to judge an agency's refusal to promulgate a rule in the first place—a standard petitioner believes considerably narrower than the traditional arbitrary-and-capricious test. We reject this view. The Act expressly equates orders "revoking" and "establishing" safety standards; neither that Act nor the APA suggests that revocations are to be treated as refusals to promulgate standards. Petitioner's view would render meaningless Congress' authorization for judicial review of orders revoking safety rules. Moreover, the revocation of an extant regulation is substantially different than a failure to act. Revocation constitutes a reversal of the agency's former views as to the proper course. A "settled course of behavior embodies the agency's informed judgment that, by pursuing that course, it will carry out the policies

committed to it by Congress. There is, then, at least a presumption that those policies will be carried out best if the settled rule is adhered to." *Atchison, T. & S. F. R. Co.* v. *Wichita Bd. of Trade*, 412 U. S. 800, 807–808 (1973). Accordingly, an agency changing its course by rescinding a rule is obligated to supply a reasoned analysis for the change beyond that which may be required when an agency does not act in the first instance.

In so holding, we fully recognize that "[r]egulatory agencies do not establish rules of conduct to last forever," *American Trucking Assns., Inc.* v. *Atchison, T. & S. F. R. Co.*, 387 U. S. 397, 416 (1967), and that an agency must be given ample latitude to "adapt their rules and policies to the demands of changing circumstances." *Permian Basin Area Rate Cases*, 390 U. S. 747, 784 (1968). But the forces of change do not always or necessarily point in the direction of deregulation. In the abstract, there is no more reason to presume that changing circumstances require the rescission of prior action, instead of a revision in or even the extension of current regulation. If Congress established a presumption from which judicial review should start, that presumption—contrary to petitioners' views—is not *against* safety regulation, but *against* changes in current policy that are not justified by the rulemaking record. While the removal of a regulation may not entail the monetary expenditures and other costs of enacting a new standard, and, accordingly, it may be easier for an agency to justify a deregulatory action, the direction in which an agency chooses to move does not alter the standard of judicial review established by law.

The Department of Transportation accepts the applicability of the "arbitrary and capricious" standard. It argues that under this standard, a reviewing court may not set aside an agency rule that is rational, based on consideration of the relevant factors, and within the scope of the authority delegated to the agency by the statute. We do not disagree with

this formulation.[9] The scope of review under the "arbitrary and capricious" standard is narrow and a court is not to substitute its judgment for that of the agency. Nevertheless, the agency must examine the relevant data and articulate a satisfactory explanation for its action including a "rational connection between the facts found and the choice made." *Burlington Truck Lines, Inc.* v. *United States*, 371 U. S. 156, 168 (1962). In reviewing that explanation, we must "consider whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment." *Bowman Transportation, Inc.* v. *Arkansas-Best Freight System, Inc.*, *supra*, at 285; *Citizens to Preserve Overton Park* v. *Volpe*, *supra*, at 416. Normally, an agency rule would be arbitrary and capricious if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise. The reviewing court should not attempt itself to make up for such deficiencies; we may not supply a reasoned basis for the agency's action that the agency itself has not given. *SEC* v. *Chenery Corp.*, 332 U. S. 194, 196 (1947). We will, however, "uphold a decision of less than ideal clarity if the agency's path may reasonably be discerned." *Bowman Transportation, Inc.* v. *Arkansas-Best Freight System, Inc.*, *supra*, at 286. See also *Camp* v. *Pitts*, 411 U. S. 138, 142–143 (1973) *(per curiam)*. For purposes of these cases, it is also relevant that Congress required a record of the rulemaking proceedings to be compiled

[9] The Department of Transportation suggests that the arbitrary-and-capricious standard requires no more than the minimum rationality a statute must bear in order to withstand analysis under the Due Process Clause. We do not view as equivalent the presumption of constitutionality afforded legislation drafted by Congress and the presumption of regularity afforded an agency in fulfilling its statutory mandate.

and submitted to a reviewing court, 15 U. S. C. § 1394, and intended that agency findings under the Act would be supported by "substantial evidence on the record considered as a whole." S. Rep. No. 1301, 89th Cong., 2d Sess., 8 (1966); H. R. Rep. No. 1776, 89th Cong., 2d Sess., 21 (1966).

IV

The Court of Appeals correctly found that the arbitrary-and-capricious test applied to rescissions of prior agency regulations, but then erred in intensifying the scope of its review based upon its reading of legislative events. It held that congressional reaction to various versions of Standard 208 "raise[d] doubts" that NHTSA's rescission "necessarily demonstrates an effort to fulfill its statutory mandate," and therefore the agency was obligated to provide "increasingly clear and convincing reasons" for its action. 220 U. S. App. D. C., at 186, 193, 680 F. 2d, at 222, 229. Specifically, the Court of Appeals found significance in three legislative occurrences:

> "In 1974, Congress banned the ignition interlock but did not foreclose NHTSA's pursuit of a passive restraint standard. In 1977, Congress allowed the standard to take effect when neither of the concurrent resolutions needed for disapproval was passed. In 1980, a majority of each house indicated support for the concept of mandatory passive restraints and a majority of each house supported the unprecedented attempt to require some installation of airbags." *Id.*, at 192, 680 F. 2d, at 228.

From these legislative acts and nonacts the Court of Appeals derived a "congressional commitment to the concept of automatic crash protection devices for vehicle occupants." *Ibid.*

This path of analysis was misguided and the inferences it produced are questionable. It is noteworthy that in this Court respondent State Farm expressly agrees that the post-enactment legislative history of the Act does not heighten the

standard of review of NHTSA's actions. Brief for Respondent State Farm Mutual Automobile Insurance Co. 13. State Farm's concession is well taken for this Court has never suggested that the *standard* of review is enlarged or diminished by subsequent congressional action. While an agency's interpretation of a statute may be confirmed or ratified by subsequent congressional failure to change that interpretation, *Bob Jones University* v. *United States*, 461 U. S. 574, 599–602 (1983); *Haig* v. *Agee*, 453 U. S. 280, 291–300 (1981), in the cases before us, even an unequivocal ratification—short of statutory incorporation—of the passive restraint standard would not connote approval or disapproval of an agency's later decision to rescind the regulation. That decision remains subject to the arbitrary-and-capricious standard.

That we should not be so quick to infer a congressional mandate for passive restraints is confirmed by examining the postenactment legislative events cited by the Court of Appeals. Even were we inclined to rely on inchoate legislative action, the inferences to be drawn fail to suggest that NHTSA acted improperly in rescinding Standard 208. First, in 1974 a mandatory passive restraint standard was technically not in effect, see n. 6, *supra;* Congress had no reason to foreclose that course. Moreover, one can hardly infer support for a mandatory standard from Congress' decision to provide that such a regulation would be subject to disapproval by resolutions of disapproval in both Houses. Similarly, no mandate can be divined from the tabling of resolutions of disapproval which were introduced in 1977. The failure of Congress to exercise its veto might reflect legislative deference to the agency's expertise and does not indicate that Congress would disapprove of the agency's action in 1981. And even if Congress favored the Standard in 1977, it—like NHTSA—may well reach a different judgment, given changed circumstances four years later. Finally, the Court of Appeals read too much into floor action on the 1980 authorization bill, a bill which was not enacted into law. Other

contemporaneous events could be read as showing equal congressional hostility to passive restraints.[10]

V

The ultimate question before us is whether NHTSA's rescission of the passive restraint requirement of Standard 208 was arbitrary and capricious. We conclude, as did the Court of Appeals, that it was. We also conclude, but for somewhat different reasons, that further consideration of the issue by the agency is therefore required. We deal separately with the rescission as it applies to airbags and as it applies to seatbelts.

A

The first and most obvious reason for finding the rescission arbitrary and capricious is that NHTSA apparently gave no consideration whatever to modifying the Standard to require that airbag technology be utilized. Standard 208 sought to achieve automatic crash protection by requiring automobile manufacturers to install either of two passive restraint devices: airbags or automatic seatbelts. There was no suggestion in the long rulemaking process that led to Standard 208 that if only one of these options were feasible, no passive restraint standard should be promulgated. Indeed, the agency's original proposed Standard contemplated the installation of inflatable restraints in all cars.[11] Automatic belts

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[10] For example, an overwhelming majority of the Members of the House of Representatives voted in favor of a proposal to bar NHTSA from spending funds to administer an occupant restraint standard unless the standard permitted the purchaser of the vehicle to select manual rather than passive restraints. 125 Cong. Rec. 36926 (1979).

[11] While NHTSA's 1970 passive restraint requirement permitted compliance by means other than the airbag, 35 Fed. Reg. 16927, "[t]his rule was a de facto air bag mandate since no other technologies were available to comply with the standard." Graham & Gorham, NHTSA and Passive Restraints: A Case of Arbitrary and Capricious Deregulation, 35 Ad. L. Rev. 193, 197 (1983). See n. 4, *supra*.

were added as a means of complying with the Standard because they were believed to be as effective as airbags in achieving the goal of occupant crash protection. 36 Fed. Reg. 12859 (1971). At that time, the passive belt approved by the agency could not be detached.[12] Only later, at a manufacturer's behest, did the agency approve of the detachability feature—and only after assurances that the feature would not compromise the safety benefits of the restraint.[13] Although it was then foreseen that 60% of the new cars would contain airbags and 40% would have automatic seatbelts, the ratio between the two was not significant as long as the passive belt would also assure greater passenger safety.

The agency has now determined that the detachable automatic belts will not attain anticipated safety benefits because so many individuals will detach the mechanism. Even if this conclusion were acceptable in its entirety, see *infra*, at 51–54, standing alone it would not justify any more than an amendment of Standard 208 to disallow compliance by means of the one technology which will not provide effective passenger protection. It does not cast doubt on the need for a passive restraint standard or upon the efficacy of airbag technology. In its most recent rulemaking, the agency again acknowledged the lifesaving potential of the airbag:

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[12] Although the agency suggested that passive restraint systems contain an emergency release mechanism to allow easy extrication of passengers in the event of an accident, the agency cautioned that "[i]n the case of passive safety belts, it would be required that the release not cause belt separation, and that the system be self-restoring after operation of the release." 36 Fed. Reg. 12866 (1971).

[13] In April 1974, NHTSA adopted the suggestion of an automobile manufacturer that emergency release of passive belts be accomplished by a conventional latch—provided the restraint system was guarded by an ignition interlock and warning buzzer to encourage reattachment of the passive belt. 39 Fed. Reg. 14593. When the 1974 Amendments prohibited these devices, the agency simply eliminated the interlock and buzzer requirements, but continued to allow compliance by a detachable passive belt.

> "The agency has no basis at this time for changing its earlier conclusions in 1976 and 1977 that basic air bag technology is sound and has been sufficiently demonstrated to be effective in those vehicles in current use . . . ." NHTSA Final Regulatory Impact Analysis (RIA) XI–4 (Oct. 1981), App. 264.

Given the effectiveness ascribed to airbag technology by the agency, the mandate of the Act to achieve traffic safety would suggest that the logical response to the faults of detachable seatbelts would be to require the installation of airbags. At the very least this alternative way of achieving the objectives of the Act should have been addressed and adequate reasons given for its abandonment. But the agency not only did not require compliance through airbags, it also did not even consider the possibility in its 1981 rulemaking. Not one sentence of its rulemaking statement discusses the airbags-only option. Because, as the Court of Appeals stated, "NHTSA's . . . analysis of airbags was nonexistent," 220 U. S. App. D. C., at 200, 680 F. 2d, at 236, what we said in *Burlington Truck Lines, Inc.* v. *United States*, 371 U. S., at 167, is apropos here:

> "There are no findings and no analysis here to justify the choice made, no indication of the basis on which the [agency] exercised its expert discretion. We are not prepared to and the Administrative Procedure Act will not permit us to accept such . . . practice. . . . Expert discretion is the lifeblood of the administrative process, but 'unless we make the requirements for administrative action strict and demanding, *expertise*, the strength of modern government, can become a monster which rules with no practical limits on its discretion.' *New York* v. *United States*, 342 U. S. 882, 884 (dissenting opinion)" (footnote omitted).

We have frequently reiterated that an agency must cogently explain why it has exercised its discretion in a given manner,

Atchison, T. & S. F. R. Co. v. *Wichita Bd. of Trade*, 412 U. S., at 806; *FTC* v. *Sperry & Hutchinson Co.*, 405 U. S. 233, 249 (1972); *NLRB* v. *Metropolitan Life Ins. Co.*, 380 U. S. 438, 443 (1965); and we reaffirm this principle again today.

The automobile industry has opted for the passive belt over the airbag, but surely it is not enough that the regulated industry has eschewed a given safety device. For nearly a decade, the automobile industry waged the regulatory equivalent of war against the airbag[14] and lost—the inflatable restraint was proved sufficiently effective. Now the automobile industry has decided to employ a seatbelt system which will not meet the safety objectives of Standard 208. This hardly constitutes cause to revoke the Standard itself. Indeed, the Act was necessary because the industry was not sufficiently responsive to safety concerns. The Act intended that safety standards not depend on current technology and could be "technology-forcing" in the sense of inducing the development of superior safety design. See *Chrysler Corp.* v. *Department of Transportation*, 472 F. 2d, at 672–673. If, under the statute, the agency should not defer to the industry's failure to develop safer cars, which it surely should not do, *a fortiori* it may not revoke a safety standard which can be satisfied by current technology simply because the industry has opted for an ineffective seatbelt design.

Although the agency did not address the mandatory airbag option and the Court of Appeals noted that "airbags seem to have none of the problems that NHTSA identified in passive seatbelts," 220 U. S. App. D. C., at 201, 680 F. 2d, at 237, petitioners recite a number of difficulties that they

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[14] See, *e. g.*, Comments of Chrysler Corp., Docket No. 69–07, Notice 11 (Aug. 5, 1971) (App. 2491); Chrysler Corp. Memorandum on Proposed Alternative Changes to FMVSS 208, Docket No. 44, Notice 76–8 (1976) (App. 2241); General Motors Corp. Response to the Dept. of Transportation Proposal on Occupant Crash Protection, Docket No. 74–14, Notice 08 (May 27, 1977) (App. 1745). See also *Chrysler Corp.* v. *Department of Transportation*, 472 F. 2d 659 (CA6 1972).

believe would be posed by a mandatory airbag standard. These range from questions concerning the installation of airbags in small cars to that of adverse public reaction. But these are not the agency's reasons for rejecting a mandatory airbag standard. Not having discussed the possibility, the agency submitted no reasons at all. The short—and sufficient—answer to petitioners' submission is that the courts may not accept appellate counsel's *post hoc* rationalizations for agency action. *Burlington Truck Lines, Inc.* v. *United States*, 371 U. S., at 168. It is well established that an agency's action must be upheld, if at all, on the basis articulated by the agency itself. *Ibid.; SEC* v. *Chenery Corp.*, 332 U. S., at 196; *American Textile Mfrs. Institute, Inc.* v. *Donovan*, 452 U. S. 490, 539 (1981).[15]

Petitioners also invoke our decision in *Vermont Yankee Nuclear Power Corp.* v. *Natural Resources Defense Council, Inc.*, 435 U. S. 519 (1978), as though it were a talisman under which any agency decision is by definition unimpeachable. Specifically, it is submitted that to require an agency to consider an airbags-only alternative is, in essence, to dictate to the agency the procedures it is to follow. Petitioners both misread *Vermont Yankee* and misconstrue the nature of the remand that is in order. In *Vermont Yankee*, we held that a court may not impose additional procedural requirements upon an agency. We do not require today any specific proce-

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[15] The Department of Transportation expresses concern that adoption of an airbags-only requirement would have required a new notice of proposed rulemaking. Even if this were so, and we need not decide the question, it would not constitute sufficient cause to rescind the passive restraint requirement. The Department also asserts that it was reasonable to withdraw the requirement as written to avoid forcing manufacturers to spend resources to comply with an ineffective safety initiative. We think that it would have been permissible for the agency to temporarily suspend the passive restraint requirement or to delay its implementation date while an airbag mandate was studied. But, as we explain in text, that option had to be considered before the passive restraint requirement could be revoked.

dures which NHTSA must follow. Nor do we broadly require an agency to consider all policy alternatives in reaching decision. It is true that rulemaking "cannot be found wanting simply because the agency failed to include every alternative device and thought conceivable by the mind of man . . . regardless of how uncommon or unknown that alternative may have been . . . ." *Id.*, at 551. But the airbag is more than a policy alternative to the passive restraint Standard; it is a technological alternative within the ambit of the existing Standard. We hold only that given the judgment made in 1977 that airbags are an effective and cost-beneficial lifesaving technology, the mandatory passive restraint rule may not be abandoned without any consideration whatsoever of an airbags-only requirement.

B

Although the issue is closer, we also find that the agency was too quick to dismiss the safety benefits of automatic seatbelts. NHTSA's critical finding was that, in light of the industry's plans to install readily detachable passive belts, it could not reliably predict "even a 5 percentage point increase as the minimum level of expected usage increase." 46 Fed. Reg. 53423 (1981). The Court of Appeals rejected this finding because there is "not one iota" of evidence that Modified Standard 208 will fail to increase nationwide seatbelt use by at least 13 percentage points, the level of increased usage necessary for the Standard to justify its cost. Given the lack of probative evidence, the court held that "only a well justified refusal to seek more evidence could render rescission non-arbitrary." 220 U. S. App. D. C., at 196, 680 F. 2d, at 232.

Petitioners object to this conclusion. In their view, "substantial uncertainty" that a regulation will accomplish its intended purpose is sufficient reason, without more, to rescind a regulation. We agree with petitioners that just as an agency reasonably may decline to issue a safety standard if it is uncertain about its efficacy, an agency may also revoke a

standard on the basis of serious uncertainties if supported by the record and reasonably explained. Rescission of the passive restraint requirement would not be arbitrary and capricious simply because there was no evidence in direct support of the agency's conclusion. It is not infrequent that the available data do not settle a regulatory issue, and the agency must then exercise its judgment in moving from the facts and probabilities on the record to a policy conclusion. Recognizing that policymaking in a complex society must account for uncertainty, however, does not imply that it is sufficient for an agency to merely recite the terms "substantial uncertainty" as a justification for its actions. As previously noted, the agency must explain the evidence which is available, and must offer a "rational connection between the facts found and the choice made." *Burlington Truck Lines, Inc.* v. *United States*, *supra*, at 168. Generally, one aspect of that explanation would be a justification for rescinding the regulation before engaging in a search for further evidence.

In these cases, the agency's explanation for rescission of the passive restraint requirement is *not* sufficient to enable us to conclude that the rescission was the product of reasoned decisionmaking. To reach this conclusion, we do not upset the agency's view of the facts, but we do appreciate the limitations of this record in supporting the agency's decision. We start with the accepted ground that if used, seatbelts unquestionably would save many thousands of lives and would prevent tens of thousands of crippling injuries. Unlike recent regulatory decisions we have reviewed, *Industrial Union Dept.* v. *American Petroleum Institute*, 448 U. S. 607 (1980); *American Textile Mfrs. Institute, Inc.* v. *Donovan*, 452 U. S. 490 (1981), the safety benefits of wearing seatbelts are not in doubt, and it is not challenged that were those benefits to accrue, the monetary costs of implementing the Standard would be easily justified. We move next to the fact that there is no direct evidence in support of the agency's finding that detachable automatic belts cannot be predicted

to yield a substantial increase in usage. The empirical evidence on the record, consisting of surveys of drivers of automobiles equipped with passive belts, reveals more than a doubling of the usage rate experienced with manual belts.[16] Much of the agency's rulemaking statement—and much of the controversy in these cases—centers on the conclusions that should be drawn from these studies. The agency maintained that the doubling of seatbelt usage in these studies could not be extrapolated to an across-the-board mandatory standard because the passive seatbelts were guarded by ignition interlocks and purchasers of the tested cars are somewhat atypical.[17] Respondents insist these studies demonstrate that Modified Standard 208 will substantially increase seatbelt usage. We believe that it is within the agency's discretion to pass upon the generalizability of these field studies. This is precisely the type of issue which rests within the expertise of NHTSA, and upon which a reviewing court must be most hesitant to intrude.

But accepting the agency's view of the field tests on passive restraints indicates only that there is no reliable real-world experience that usage rates will substantially increase. To be sure, NHTSA opines that "it cannot reliably predict even a 5 percentage point increase as the minimum level of

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[16] Between 1975 and 1980, Volkswagen sold approximately 350,000 Rabbits equipped with detachable passive seatbelts that were guarded by an ignition interlock. General Motors sold 8,000 1978 and 1979 Chevettes with a similar system, but eliminated the ignition interlock on the 13,000 Chevettes sold in 1980. NHTSA found that belt usage in the Rabbits averaged 34% for manual belts and 84% for passive belts. RIA, at IV–52, App. 108. For the 1978–1979 Chevettes, NHTSA calculated 34% usage for manual belts and 72% for passive belts. On 1980 Chevettes, the agency found these figures to be 31% for manual belts and 70% for passive belts. *Ibid.*

[17] "NHTSA believes that the usage of automatic belts in Rabbits and Chevettes would have been substantially lower if the automatic belts in those cars were not equipped with a use-inducing device inhibiting detachment." Notice 25, 46 Fed. Reg. 53422 (1981).

expected increased usage." Notice 25, 46 Fed. Reg. 53423 (1981). But this and other statements that passive belts will not yield substantial increases in seatbelt usage apparently take no account of the critical difference between detachable automatic belts and current manual belts. A detached passive belt does require an affirmative act to reconnect it, but—unlike a manual seatbelt—the passive belt, once reattached, will continue to function automatically unless again disconnected. Thus, inertia—a factor which the agency's own studies have found significant in explaining the current low usage rates for seatbelts[18]—works in *favor* of, not *against*, use of the protective device. Since 20% to 50% of motorists currently wear seatbelts on some occasions,[19] there would seem to be grounds to believe that seatbelt use by occasional users will be substantially increased by the detachable passive belts. Whether this is in fact the case is a matter for the agency to decide, but it must bring its expertise to bear on the question.

The agency is correct to look at the costs as well as the benefits of Standard 208. The agency's conclusion that the incremental costs of the requirements were no longer reasonable was predicated on its prediction that the safety benefits of the regulation might be minimal. Specifically, the

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[18] NHTSA commissioned a number of surveys of public attitudes in an effort to better understand why people were not using manual belts and to determine how they would react to passive restraints. The surveys reveal that while 20% to 40% of the public is opposed to wearing manual belts, the larger proportion of the population does not wear belts because they forgot or found manual belts inconvenient or bothersome. RIA, at IV–25, App. 81. In another survey, 38% of the surveyed group responded that they would welcome automatic belts, and 25% would "tolerate" them. See RIA, at IV–37, App. 93. NHTSA did not comment upon these attitude surveys in its explanation accompanying the rescission of the passive restraint requirement.

[19] Four surveys of manual belt usage were conducted for NHTSA between 1978 and 1980, leading the agency to report that 40% to 50% of the people use their belts at least some of the time. RIA, at IV–25, App. 81.

agency's fears that the public may resent paying more for the automatic belt systems is expressly dependent on the assumption that detachable automatic belts will not produce more than "negligible safety benefits." *Id.*, at 53424. When the agency reexamines its findings as to the likely increase in seatbelt usage, it must also reconsider its judgment of the reasonableness of the monetary and other costs associated with the Standard. In reaching its judgment, NHTSA should bear in mind that Congress intended safety to be the pre-eminent factor under the Act:

> "The Committee intends that safety shall be the overriding consideration in the issuance of standards under this bill. The Committee recognizes . . . that the Secretary will necessarily consider reasonableness of cost, feasibility and adequate leadtime." S. Rep. No. 1301, 89th Cong., 2d Sess., 6 (1966).
>
> "In establishing standards the Secretary must conform to the requirement that the standard be practicable. This would require consideration of all relevant factors, including technological ability to achieve the goal of a particular standard as well as consideration of economic factors.
>
> "Motor vehicle safety is the paramount purpose of this bill and each standard must be related thereto." H. R. Rep. No. 1776, 89th Cong., 2d Sess., 16 (1966).

The agency also failed to articulate a basis for not requiring nondetachable belts under Standard 208. It is argued that the concern of the agency with the easy detachability of the currently favored design would be readily solved by a continuous passive belt, which allows the occupant to "spool out" the belt and create the necessary slack for easy extrication from the vehicle. The agency did not separately consider the continuous belt option, but treated it together with the ignition interlock device in a category it titled "Option of Adopting Use-Compelling Features." 46 Fed. Reg. 53424

(1981). The agency was concerned that use-compelling devices would "complicate the extrication of [an] occupant from his or her car." *Ibid.* "[T]o require that passive belts contain use-compelling features," the agency observed, "could be counterproductive [, given] . . . widespread, latent and irrational fear in many members of the public that they could be trapped by the seat belt after a crash." *Ibid.* In addition, based on the experience with the ignition interlock, the agency feared that use-compelling features might trigger adverse public reaction.

By failing to analyze the continuous seatbelts option in its own right, the agency has failed to offer the rational connection between facts and judgment required to pass muster under the arbitrary-and-capricious standard. We agree with the Court of Appeals that NHTSA did not suggest that the emergency release mechanisms used in nondetachable belts are any less effective for emergency egress than the buckle release system used in detachable belts. In 1978, when General Motors obtained the agency's approval to install a continuous passive belt, it assured the agency that nondetachable belts with spool releases were as safe as detachable belts with buckle releases. 43 Fed. Reg. 21912, 21913–21914 (1978). NHTSA was satisfied that this belt design assured easy extricability: "[t]he agency does not believe that the use of [such] release mechanisms will cause serious occupant egress problems . . . ." *Id.*, at 52493, 52494. While the agency is entitled to change its view on the acceptability of continuous passive belts, it is obligated to explain its reasons for doing so.

The agency also failed to offer any explanation why a continuous passive belt would engender the same adverse public reaction as the ignition interlock, and, as the Court of Appeals concluded, "every indication in the record points the other way." 220 U. S. App. D. C., at 198, 680 F. 2d, at 234.[20]

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[20] The Court of Appeals noted previous agency statements distinguishing interlocks from passive restraints. 42 Fed. Reg. 34290 (1977); 36 Fed. Reg. 8296 (1971); RIA, at II–4, App. 30.

We see no basis for equating the two devices: the continous belt, unlike the ignition interlock, does not interfere with the operation of the vehicle. More importantly, it is the agency's responsibility, not this Court's, to explain its decision.

VI

"An agency's view of what is in the public interest may change, either with or without a change in circumstances. But an agency changing its course must supply a reasoned analysis . . . ." *Greater Boston Television Corp.* v. *FCC*, 143 U. S. App. D. C. 383, 394, 444 F. 2d 841, 852 (1970) (footnote omitted), cert. denied, 403 U. S. 923 (1971). We do not accept all of the reasoning of the Court of Appeals but we do conclude that the agency has failed to supply the requisite "reasoned analysis" in this case. Accordingly, we vacate the judgment of the Court of Appeals and remand the cases to that court with directions to remand the matter to the NHTSA for further consideration consistent with this opinion.[21]

So ordered.

JUSTICE REHNQUIST, with whom THE CHIEF JUSTICE, JUSTICE POWELL, and JUSTICE O'CONNOR join, concurring in part and dissenting in part.

I join Parts I, II, III, IV, and V–A of the Court's opinion. In particular, I agree that, since the airbag and continuous

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[21] Petitioners construe the Court of Appeals' order of August 4, 1982, as setting an implementation date for Standard 208, in violation of *Vermont Yankee*'s injunction against imposing such time constraints. *Vermont Yankee Nuclear Power Corp.* v. *Natural Resources Defense Council, Inc.*, 435 U. S. 519, 544–545 (1978). Respondents maintain that the Court of Appeals simply stayed the effective date of Standard 208, which, not having been validly rescinded, would have required mandatory passive restraints for new cars after September 1, 1982. We need not choose between these views because the agency had sufficient justification to suspend, although not to rescind, Standard 208, pending the further consideration required by the Court of Appeals, and now, by us.

spool automatic seatbelt were explicitly approved in the Standard the agency was rescinding, the agency should explain why it declined to leave those requirements intact. In this case, the agency gave no explanation at all. Of course, if the agency can provide a rational explanation, it may adhere to its decision to rescind the entire Standard.

I do not believe, however, that NHTSA's view of detachable automatic seatbelts was arbitrary and capricious. The agency adequately explained its decision to rescind the Standard insofar as it was satisfied by detachable belts.

The statute that requires the Secretary of Transportation to issue motor vehicle safety standards also requires that "[e]ach such . . . standard shall be practicable [and] shall meet the need for motor vehicle safety." 15 U. S. C. § 1392(a) (1976 ed., Supp. V). The Court rejects the agency's explanation for its conclusion that there is substantial uncertainty whether requiring installation of detachable automatic belts would substantially increase seatbelt usage. The agency chose not to rely on a study showing a substantial increase in seatbelt usage in cars equipped with automatic seatbelts *and* an ignition interlock to prevent the car from being operated when the belts were not in place *and* which were voluntarily purchased with this equipment by consumers. See *ante*, at 53, n. 16. It is reasonable for the agency to decide that this study does not support any conclusion concerning the effect of automatic seatbelts that are installed in all cars whether the consumer wants them or not and are not linked to an ignition interlock system.

The Court rejects this explanation because "there would seem to be grounds to believe that seatbelt use by occasional users will be substantially increased by the detachable passive belts," *ante*, at 54, and the agency did not adequately explain its rejection of these grounds. It seems to me that the agency's explanation, while by no means a model, is adequate. The agency acknowledged that there would probably be some increase in belt usage, but concluded that the increase would be small and not worth the cost of manda-

tory detachable automatic belts. 46 Fed. Reg. 53421–53423 (1981). The agency's obligation is to articulate a "'rational connection between the facts found and the choice made.'" *Ante*, at 42, 52, quoting *Burlington Truck Lines, Inc.* v. *United States*, 371 U. S. 156, 168 (1962). I believe it has met this standard.

The agency explicitly stated that it will increase its educational efforts in an attempt to promote public understanding, acceptance, and use of passenger restraint systems. 46 Fed. Reg. 53425 (1981). It also stated that it will "initiate efforts with automobile manufacturers to ensure that the public will have [automatic crash protection] technology available. If this does not succeed, the agency will consider regulatory action to assure that the last decade's enormous advances in crash protection technology will not be lost." *Id.*, at 53426.

The agency's changed view of the standard seems to be related to the election of a new President of a different political party. It is readily apparent that the responsible members of one administration may consider public resistance and uncertainties to be more important than do their counterparts in a previous administration. A change in administration brought about by the people casting their votes is a perfectly reasonable basis for an executive agency's reappraisal of the costs and benefits of its programs and regulations. As long as the agency remains within the bounds established by Congress,* it is entitled to assess administrative records and evaluate priorities in light of the philosophy of the administration.

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*Of course, a new administration may not refuse to enforce laws of which it does not approve, or to ignore statutory standards in carrying out its regulatory functions. But in this case, as the Court correctly concludes, *ante*, at 44–46, Congress has not required the agency to require passive restraints.

TAB 4

CITIZENS TO PRESERVE OVERTON PARK, INC., ET AL. *v.* VOLPE, SECRETARY OF TRANSPORTATION, ET AL.

CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

No. 1066. Argued January 11, 1971—Decided March 2, 1971

Under § 4 (f) of the Department of Transportation Act of 1966 and § 138 of the Federal-Aid Highway Act of 1968, the Secretary of Transportation may not authorize use of federal funds to finance construction of highways through public parks if a "feasible and prudent" alternative route exists. If no such route is available, he may approve construction only if there has been "all possible planning to minimize harm" to the park. Petitioners contend that the Secretary has violated these statutes by authorizing a six-lane interstate highway through a Memphis public park. In April 1968 the Secretary announced that he agreed with the local officials that the highway go through the park; in September 1969 the State acquired the right-of-way inside the park; and in November 1969 the Secretary announced final approval, including the design, of the road. Neither announcement of the Secretary was accompanied by factual findings. Respondents introduced affidavits in the District Court, indicating that the Secretary had made the decision and that it was supportable. Petitioners filed counter affidavits and sought to take the deposition of a former federal highway administrator. The District Court and the Court of Appeals found that formal findings were not required and refused to order the deposition of the former administrator. Both courts held that the affidavits afforded no basis for determining that the Secretary exceeded his authority. *Held:*

1. The Secretary's action is subject to judicial review pursuant to § 701 of the Administrative Procedure Act. Pp. 409–413.

(a) There is no indication here that Congress sought to limit or prohibit judicial review. P. 410.

(b) The exemption for action "committed to agency discretion" does not apply as the Secretary does have "law to apply," rather than wide-ranging discretion. Pp. 410–413.

2. Although under § 706 of the Act *de novo* review is not required here and the Secretary's approval of the route need not

meet the substantial-evidence test, the reviewing court must conduct a substantial inquiry and determine whether the Secretary acted within the scope of his authority, whether his decision was within the small range of available choices, and whether he could have reasonably believed that there were no feasible alternatives. The court must find that the actual choice was not "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," and that the Secretary followed the necessary procedural requirements. Pp. 413–416.

3. Formal findings by the Secretary are not required in this case. Pp. 417–419.

(a) The relevant statutes do not require formal findings, and there is no ambiguity in the Secretary's action. P. 417.

(b) Although a regulation requiring formal findings was issued after the Secretary had approved the route, a remand to him is not necessary as there is an administrative record facilitating full and prompt review of the Secretary's action. Pp. 417–419.

4. The case is remanded to the District Court for plenary review of the Secretary's decision. Pp. 419–420.

(a) The lower courts' review was based on litigation affidavits, which are not the whole record and are an inadequate basis for review. P. 419.

(b) In view of the lack of formal findings, the court may require the administrative officials who participated in the decision to give testimony explaining their action or require the Secretary to make formal findings. P. 420.

432 F. 2d 1307, reversed and remanded.

MARSHALL, J., wrote the opinion of the Court, in which BURGER, C. J., and HARLAN, STEWART, WHITE, and BLACKMUN, JJ., joined. BLACK, J., filed a separate opinion, in which BRENNAN, J., joined, *post*, p. 421. BLACKMUN, J., filed a separate statement, *post*, p. 422. DOUGLAS, J., took no part in the consideration or decision of this case.

John W. Vardaman, Jr., argued the cause for petitioners. With him on the briefs was *Edward Bennett Williams*.

Solicitor General Griswold argued the cause for respondent Volpe. With him on the brief were *Assistant*

Attorney General Gray, Alan S. Rosenthal, and *Daniel Joseph. J. Alan Hanover* argued the cause for respondent Speight. With him on the brief were *David M. Pack,* Attorney General of Tennessee, *Lurton C. Goodpasture,* Assistant Attorney General, and *James B. Jalenak.*

Briefs of *amici curiae* were filed by *James M. Manire* and *Jack Petree* for the city of Memphis et al., and by *Roberts B. Owen* and *Gerald P. Norton* for the Committee of 100 on the Federal City, Inc., et al.

Opinion of the Court by MR. JUSTICE MARSHALL, announced by MR. JUSTICE STEWART.

The growing public concern about the quality of our natural environment has prompted Congress in recent years to enact legislation [1] designed to curb the accelerating destruction of our country's natural beauty. We are concerned in this case with § 4 (f) of the Department of Transportation Act of 1966, as amended,[2] and § 18 (a) of

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[1] See, *e. g.,* The National Environmental Policy Act of 1969, 83 Stat. 852, 42 U. S. C. § 4321 *et seq.* (1964 ed., Supp. V); Environmental Education Act, 84 Stat. 1312, 20 U. S. C. § 1531 *et seq.* (1970 ed.); Air Quality Act of 1967, 81 Stat. 485, 42 U. S. C. § 1857 *et seq.* (1964 ed., Supp. V); Environmental Quality Improvement Act of 1970, 84 Stat. 114, 42 U. S. C. §§ 4371–4374 (1970 ed.).

[2] "It is hereby declared to be the national policy that special effort should be made to preserve the natural beauty of the countryside and public park and recreation lands, wildlife and waterfowl refuges, and historic sites. The Secretary of Transportation shall cooperate and consult with the Secretaries of the Interior, Housing and Urban Development, and Agriculture, and with the States in developing transportation plans and programs that include measures to maintain or enhance the natural beauty of the lands traversed. After August 23, 1968, the Secretary shall not approve any program or project which requires the use of any publicly owned land from a public park, recreation area, or wildlife and waterfowl refuge of national, State, or local significance as determined by the Federal, State, or

the Federal-Aid Highway Act of 1968, 82 Stat. 823, 23 U. S. C. § 138 (1964 ed., Supp. V) (hereafter § 138).[3] These statutes prohibit the Secretary of Transportation from authorizing the use of federal funds to finance the construction of highways through public parks if a "feasible and prudent" [4] alternative route exists. If no such route is available, the statutes allow him to approve construction through parks only if there has been "all possible planning to minimize harm" [5] to the park.

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local officials having jurisdiction thereof, or any land from an historic site of national, State, or local significance as so determined by such officials unless (1) there is no feasible and prudent alternative to the use of such land, and (2) such program includes all possible planning to minimize harm to such park, recreational area, wildlife and waterfowl refuge, or historic site resulting from such use." 82 Stat. 824, 49 U. S. C. § 1653 (f) (1964 ed., Supp. V).

[3] "It is hereby declared to be the national policy that special effort should be made to preserve the natural beauty of the countryside and public park and recreation lands, wildlife and waterfowl refuges, and historic sites. The Secretary of Transportation shall cooperate and consult with the Secretaries of the Interior, Housing and Urban Development, and Agriculture, and with the States in developing transportation plans and programs that include measures to maintain or enhance the natural beauty of the lands traversed. After the effective date of the Federal-Aid Highway Act of 1968, the Secretary shall not approve any program or project which requires the use of any publicly owned land from a public park, recreation area, or wildlife and waterfowl refuge of national, State, or local significance as determined by the Federal, State, or local officials having jurisdiction thereof, or any land from an historic site of national, State, or local significance as so determined by such officials unless (1) there is no feasible and prudent alternative to the use of such land, and (2) such program includes all possible planning to minimize harm to such park, recreational area, wildlife and waterfowl refuge, or historic site resulting from such use." 23 U. S. C. § 138 (1964 ed., Supp. V).

[4] 49 U. S. C. § 1653 (f) (1964 ed., Supp. V); 23 U. S. C. § 138 (1964 ed., Supp. V).

[5] *Ibid.*

Petitioners, private citizens as well as local and national conservation organizations, contend that the Secretary has violated these statutes by authorizing the expenditure of federal funds [6] for the construction of a six-lane interstate highway through a public park in Memphis, Tennessee. Their claim was rejected by the District Court,[7] which granted the Secretary's motion for summary judgment, and the Court of Appeals for the Sixth Circuit affirmed.[8] After oral argument, this Court granted a stay that halted construction and, treating the application for the stay as a petition for certiorari, granted review.[9] 400 U. S. 939. We now reverse the judgment below and remand for further proceedings in the District Court.

Overton Park is a 342-acre city park located near the center of Memphis. The park contains a zoo, a nine-hole municipal golf course, an outdoor theater, nature trails, a bridle path, an art academy, picnic areas, and 170 acres of forest. The proposed highway, which is to be a six-lane, high-speed, expressway,[10] will sever the zoo from the rest of the park. Although the roadway will be depressed below ground level except where it crosses a small creek, 26 acres of the park will be destroyed. The highway is to be a segment of Interstate Highway I–40, part of the National System of Interstate and

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[6] See 23 U. S. C. § 103.

[7] The case originated in the United States District Court for the District of Columbia. On application of the Secretary of Transportation it was transferred to the United States District Court for the Western District of Tennessee, which entered the summary judgment.

[8] 432 F. 2d 1307 (CA6 1970).

[9] This Court ordered the case to be heard on an expedited schedule.

[10] The proposed right-of-way will be 250 to 450 feet wide and will follow the route of a presently existing, nonaccess bus route, which carries occasional bus traffic along a 40- to 50-foot right-of-way.

Defense Highways.[11] I–40 will provide Memphis with a major east-west expressway which will allow easier access to downtown Memphis from the residential areas on the eastern edge of the city.[12]

Although the route through the park was approved by the Bureau of Public Roads in 1956 [13] and by the Federal Highway Administrator in 1966, the enactment of § 4 (f) of the Department of Transportation Act prevented distribution of federal funds for the section of the highway designated to go through Overton Park until the Secretary of Transportation determined whether the requirements of § 4 (f) had been met. Federal funding for the rest of the project was, however, available; and the state acquired a right-of-way on both sides of the park.[14] In April 1968, the Secretary announced that he concurred in the judgment of local officials that I–40 should be built through the park. And in September 1969 the State acquired the right-of-way inside Overton Park from the city.[15] Final approval for the project—the route as well as the design—was not announced until November 1969, after Congress had reiterated in § 138 of the Federal-Aid Highway Act

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[11] See 23 U. S. C. § 103 (d) (1964 ed., Supp. V).

[12] I–40 will also provide an express bypass for east-west traffic through Memphis.

[13] At that time the Bureau of Public Roads was a part of the Department of Commerce. The Department of Transportation Act, 49 U. S. C. § 1651 *et seq.* (1964 ed., Supp. V), which became effective on April 1, 1967, transferred the Bureau to the new Department of Transportation.

[14] The Secretary approved these acquisitions in 1967 shortly after the effective date of § 4 (f).

[15] The State paid the City $2,000,000 for the 26-acre right-of-way and $206,000 to the Memphis Park Commission to replace park facilities that were to be destroyed by the highway. The city of Memphis has used $1,000,000 of these funds to pay for a new 160-acre park and it is anticipated that additional parkland will be acquired with the remaining money.

that highway construction through public parks was to be restricted. Neither announcement approving the route and design of I–40 was accompanied by a statement of the Secretary's factual findings. He did not indicate why he believed there were no feasible and prudent alternative routes or why design changes could not be made to reduce the harm to the park.

Petitioners contend that the Secretary's action is invalid without such formal findings [16] and that the Secretary did not make an independent determination but merely relied on the judgment of the Memphis City Council.[17] They also contend that it would be "feasible and prudent" to route I–40 around Overton Park either to the north or to the south. And they argue that if these alternative routes are not "feasible and prudent," the present plan does not include "all possible" methods for reducing harm to the park. Petitioners claim that I–40 could be built under the park by using either of two possible tunneling methods,[18] and they claim that, at a

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[16] Respondents argue that the only issue raised by petitioners' pleadings is the failure of the Secretary to make formal findings. But when petitioners' complaint is read in the revealing light of *Conley* v. *Gibson,* 355 U. S. 41 (1957), it is clear that petitioners have also challenged the merits of the Secretary's decision.

[17] Petitioners contend that former Federal Highway Administrator Bridwell's account of an April 3, 1968, meeting with the Memphis City Council given to the Senate Subcommittee on Roads of the Senate Committee on Public Works supports this charge. See Hearings on Urban Highway Planning, Location, and Design before the Subcommittee on Roads of the Senate Committee on Public Works, 90th Cong., 1st and 2d Sess., pt. 2, pp. 478–480 (1968).

[18] Petitioners argue that either a bored tunnel or a cut-and-cover tunnel, which is a fully depressed route covered after construction, could be built. Respondents contend that the construction of a tunnel by either method would greatly increase the cost of the project, would create safety hazards, and because of increases in air pollution would not reduce harm to the park.

minimum, by using advanced drainage techniques [19] the expressway could be depressed below ground level along the entire route through the park including the section that crosses the small creek.

Respondents argue that it was unnecessary for the Secretary to make formal findings, and that he did, in fact, exercise his own independent judgment which was supported by the facts. In the District Court, respondents introduced affidavits, prepared specifically for this litigation, which indicated that the Secretary had made the decision and that the decision was supportable. These affidavits were contradicted by affidavits introduced by petitioners, who also sought to take the deposition of a former Federal Highway Administrator [20] who had participated in the decision to route I–40 through Overton Park.

The District Court and the Court of Appeals found that formal findings by the Secretary were not necessary and refused to order the deposition of the former Federal Highway Administrator because those courts believed that probing of the mental processes of an administrative decisionmaker was prohibited. And, believing that the Secretary's authority was wide and reviewing courts' authority narrow in the approval of highway routes, the lower courts held that the affidavits contained no basis for a determination that the Secretary had exceeded his authority.

We agree that formal findings were not required. But we do not believe that in this case judicial review based solely on litigation affidavits was adequate.

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[19] Petitioners contend that adequate drainage could be provided by using mechanical pumps or some form of inverted siphon. They claim that such devices are often used in expressway construction.

[20] Petitioners wanted to question former Highway Administrator Bridwell. See n. 17, *supra*.

A threshold question—whether petitioners are entitled to any judicial review—is easily answered. Section 701 of the Administrative Procedure Act, 5 U. S. C. § 701 (1964 ed., Supp. V), provides that the action of "each authority of the Government of the United States," which includes the Department of Transportation,[21] is subject to judicial review except where there is a statutory prohibition on review or where "agency action is committed to agency discretion by law." In this case, there is no indication that Congress sought to prohibit judicial review and there is most certainly no "showing of 'clear and convincing evidence' of a . . . legislative intent" to restrict access to judicial review. *Abbott Laboratories* v. *Gardner,* 387 U. S. 136, 141 (1967). *Brownell* v. *We Shung,* 352 U. S. 180, 185 (1956).[22]

Similarly, the Secretary's decision here does not fall within the exception for action "committed to agency discretion." This is a very narrow exception.[23] Berger, Administrative Arbitrariness and Judicial Review, 65 Col. L. Rev. 55 (1965). The legislative history of the Administrative Procedure Act indicates that it is applicable in those rare instances where "statutes are drawn in such broad terms that in a given case there is no law to apply." S. Rep. No. 752, 79th Cong., 1st Sess., 26 (1945).

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[21] In addition, the Department of Transportation Act makes the Administrative Procedure Act applicable to proceedings of the Department of Transportation. 49 U. S. C. § 1655 (h) (1964 ed., Supp. V).

[22] See also *Rusk* v. *Cort,* 369 U. S. 367, 379–380 (1962).

[23] The scope of this exception has been the subject of extensive commentary. See, *e. g.,* Berger, Administrative Arbitrariness: A Synthesis, 78 Yale L. J. 965 (1969); Saferstein, Nonreviewability: A Functional Analysis of "Committed to Agency Discretion," 82 Harv. L. Rev. 367 (1968); Davis, Administrative Arbitrariness is Not Always Reviewable, 51 Minn. L. Rev. 643 (1967); Berger, Administrative Arbitrariness: A Sequel, 51 Minn. L. Rev. 601 (1967).

Section 4 (f) of the Department of Transportation Act and § 138 of the Federal-Aid Highway Act are clear and specific directives. Both the Department of Transportation Act and the Federal-Aid Highway Act provide that the Secretary "shall not approve any program or project" that requires the use of any public parkland "unless (1) there is no feasible and prudent alternative to the use of such land, and (2) such program includes all possible planning to minimize harm to such park . . . ." 23 U. S. C. § 138 (1964 ed., Supp. V); 49 U. S. C. § 1653 (f) (1964 ed., Supp. V). This language is a plain and explicit bar to the use of federal funds for construction of highways through parks—only the most unusual situations are exempted.

Despite the clarity of the statutory language, respondents argue that the Secretary has wide discretion. They recognize that the requirement that there be no "feasible" alternative route admits of little administrative discretion. For this exemption to apply the Secretary must find that as a matter of sound engineering it would not be feasible to build the highway along any other route.[24] Respondents argue, however, that the requirement that there be no other "prudent" route requires the Secretary to engage in a wide-ranging balancing of competing interests. They contend that the Secretary should weigh the detriment resulting from the destruction of parkland against the cost of other routes, safety considerations, and other factors, and determine on the basis of the importance that he attaches to these other factors whether, on balance, alternative feasible routes would be "prudent."

But no such wide-ranging endeavor was intended. It is obvious that in most cases considerations of cost, directness of route, and community disruption will indicate that parkland should be used for highway construction

[24] See 114 Cong. Rec. 19915 (statement by Rep. Holifield).

whenever possible. Although it may be necessary to transfer funds from one jurisdiction to another,[25] there will always be a smaller outlay required from the public purse [26] when parkland is used since the public already owns the land and there will be no need to pay for right-of-way. And since people do not live or work in parks, if a highway is built on parkland no one will have to leave his home or give up his business. Such factors are common to substantially all highway construction. Thus, if Congress intended these factors to be on an equal footing with preservation of parkland there would have been no need for the statutes.

Congress clearly did not intend that cost and disruption of the community were to be ignored [27] by the Secretary.[28] But the very existence of the statutes [29] indicates that protection of parkland was to be given para-

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[25] See n. 15, *supra*.

[26] See 114 Cong. Rec. 24037 (statement by Sen. Yarborough).

[27] See, *e. g.*, S. Rep. No. 1340, 90th Cong., 2d Sess., 18–19; H. R. Rep. No. 1584, 90th Cong., 2d Sess., 12.

[28] The legislative history indicates that the Secretary is not to limit his consideration to information supplied by state and local officials but is to go beyond this information and reach his own independent decision. 114 Cong. Rec. 24036–24037.

[29] The legislative history of both § 4 (f) of the Department of Transportation Act, 49 U. S. C. § 1653 (f) (1964 ed., Supp. V), and § 138 of the Federal-Aid Highway Act, 23 U. S. C. § 138 (1964 ed., Supp. V), is ambiguous. The legislative committee reports tend to support respondents' view that the statutes are merely general directives to the Secretary requiring him to consider the importance of parkland as well as cost, community disruption, and other factors. See, *e. g.*, S. Rep. No. 1340, 90th Cong., 2d Sess., 19; H. R. Rep. No. 1584, 90th Cong., 2d Sess., 12. Statements by proponents of the statutes as well as the Senate committee report on § 4 (f) indicate, however, that the Secretary was to have limited authority. See, *e. g.*, 114 Cong. Rec. 24033–24037; S. Rep. No. 1659, 89th Cong., 2d Sess., 22. See also H. R. Conf. Rep. No. 2236, 89th Cong., 2d Sess., 25. Because of this ambiguity it is clear that we must look primarily to the statutes themselves to find the legislative intent.

mount importance. The few green havens that are public parks were not to be lost unless there were truly unusual factors present in a particular case or the cost or community disruption resulting from alternative routes reached extraordinary magnitudes. If the statutes are to have any meaning, the Secretary cannot approve the destruction of parkland unless he finds that alternative routes present unique problems.

Plainly, there is "law to apply" and thus the exemption for action "committed to agency discretion" is inapplicable. But the existence of judicial review is only the start: the standard for review must also be determined. For that we must look to § 706 of the Administrative Procedure Act, 5 U. S. C. § 706 (1964 ed., Supp. V), which provides that a "reviewing court shall . . . hold unlawful and set aside agency action, findings, and conclusions found" not to meet six separate standards.[30] In all cases

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[30] "To the extent necessary to decision and when presented, the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action. The reviewing court shall—

"(1) compel agency action unlawfully withheld or unreasonably delayed; and

"(2) hold unlawful and set aside agency action, findings, and conclusions found to be—

"(A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;

"(B) contrary to constitutional right, power, privilege, or immunity;

"(C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right;

"(D) without observance of procedure required by law;

"(E) unsupported by substantial evidence in a case subject to sections 556 and 557 of this title or otherwise reviewed on the record of an agency hearing provided by statute; or

"(F) unwarranted by the facts to the extent that the facts are subject to trial de novo by the reviewing court.

"In making the foregoing determinations, the court shall review the

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agency action must be set aside if the action was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" or if the action failed to meet statutory, procedural, or constitutional requirements. 5 U. S. C. §§ 706 (2)(A), (B), (C), (D) (1964 ed., Supp. V). In certain narrow, specifically limited situations, the agency action is to be set aside if the action was not supported by "substantial evidence." And in other equally narrow circumstances the reviewing court is to engage in a *de novo* review of the action and set it aside if it was "unwarranted by the facts." 5 U. S. C. §§ 706 (2)(E), (F) (1964 ed., Supp. V).

Petitioners argue that the Secretary's approval of the construction of I–40 through Overton Park is subject to one or the other of these latter two standards of limited applicability. First, they contend that the "substantial evidence" standard of § 706 (2)(E) must be applied. In the alternative, they claim that § 706 (2)(F) applies and that there must be a *de novo* review to determine if the Secretary's action was "unwarranted by the facts." Neither of these standards is, however, applicable.

Review under the substantial-evidence test is authorized only when the agency action is taken pursuant to a rulemaking provision of the Administrative Procedure Act itself, 5 U. S. C. § 553 (1964 ed., Supp. V), or when the agency action is based on a public adjudicatory hearing. See 5 U. S. C. §§ 556, 557 (1964 ed., Supp. V). The Secretary's decision to allow the expenditure of federal funds to build I–40 through Overton Park was plainly not an exercise of a rulemaking function. See 1 K. Davis, Administrative Law Treatise § 5.01 (1958). And the only hearing that is required by either the Administrative Procedure Act or the statutes regulating the dis-

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whole record or those parts of it cited by a party, and due account shall be taken of the rule of prejudicial error." 5 U. S. C. § 706 (1964 ed., Supp. V).

tribution of federal funds for highway construction is a public hearing conducted by local officials for the purpose of informing the community about the proposed project and eliciting community views on the design and route. 23 U. S. C. § 128 (1964 ed., Supp. V). The hearing is nonadjudicatory, quasi-legislative in nature. It is not designed to produce a record that is to be the basis of agency action—the basic requirement for substantial-evidence review. See H. R. Rep. No. 1980, 79th Cong., 2d Sess.

Petitioners' alternative argument also fails. *De novo* review of whether the Secretary's decision was "unwarranted by the facts" is authorized by § 706 (2)(F) in only two circumstances. First, such *de novo* review is authorized when the action is adjudicatory in nature and the agency factfinding procedures are inadequate. And, there may be independent judicial factfinding when issues that were not before the agency are raised in a proceeding to enforce nonadjudicatory agency action. H. R. Rep. No. 1980, 79th Cong., 2d Sess. Neither situation exists here.

Even though there is no *de novo* review in this case and the Secretary's approval of the route of I–40 does not have ultimately to meet the substantial-evidence test, the generally applicable standards of § 706 require the reviewing court to engage in a substantial inquiry. Certainly, the Secretary's decision is entitled to a presumption of regularity. See, *e. g., Pacific States Box & Basket Co.* v. *White,* 296 U. S. 176, 185 (1935); *United States* v. *Chemical Foundation,* 272 U. S. 1, 14–15 (1926). But that presumption is not to shield his action from a thorough, probing, in-depth review.

The court is first required to decide whether the Secretary acted within the scope of his authority. *Schilling* v. *Rogers,* 363 U. S. 666, 676–677 (1960). This determination naturally begins with a delineation of the scope of

the Secretary's authority and discretion. L. Jaffe, Judicial Control of Administrative Action 359 (1965). As has been shown, Congress has specified only a small range of choices that the Secretary can make. Also involved in this initial inquiry is a determination of whether on the facts the Secretary's decision can reasonably be said to be within that range. The reviewing court must consider whether the Secretary properly construed his authority to approve the use of parkland as limited to situations where there are no feasible alternative routes or where feasible alternative routes involve uniquely difficult problems. And the reviewing court must be able to find that the Secretary could have reasonably believed that in this case there are no feasible alternatives or that alternatives do involve unique problems.

Scrutiny of the facts does not end, however, with the determination that the Secretary has acted within the scope of his statutory authority. Section 706 (2)(A) requires a finding that the actual choice made was not "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U. S. C. § 706 (2)(A) (1964 ed., Supp. V). To make this finding the court must consider whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment. Jaffe, *supra,* at 182. See *McBee* v. *Bomar*, 296 F. 2d 235, 237 (CA6 1961); *In re Josephson,* 218 F. 2d 174, 182 (CA1 1954); *Western Addition Community Organization* v. *Weaver,* 294 F. Supp. 433 (ND Cal. 1968). See also *Wong Wing Hang* v. *Immigration and Naturalization Serv.,* 360 F. 2d 715, 719 (CA2 1966). Although this inquiry into the facts is to be searching and careful, the ultimate standard of review is a narrow one. The court is not empowered to substitute its judgment for that of the agency.

The final inquiry is whether the Secretary's action followed the necessary procedural requirements. Here the only procedural error alleged is the failure of the Secretary to make formal findings and state his reason for allowing the highway to be built through the park.

Undoubtedly, review of the Secretary's action is hampered by his failure to make such findings, but the absence of formal findings does not necessarily require that the case be remanded to the Secretary. Neither the Department of Transportation Act nor the Federal-Aid Highway Act requires such formal findings. Moreover, the Administrative Procedure Act requirements that there be formal findings in certain rulemaking and adjudicatory proceedings do not apply to the Secretary's action here. See 5 U. S. C. §§ 553 (a)(2), 554 (a) (1964 ed., Supp. V). And, although formal findings may be required in some cases in the absence of statutory directives when the nature of the agency action is ambiguous, those situations are rare. See *City of Yonkers* v. *United States,* 320 U. S. 685 (1944); *American Trucking Assns.* v. *United States,* 344 U. S. 298, 320 (1953). Plainly, there is no ambiguity here; the Secretary has approved the construction of I–40 through Overton Park and has approved a specific design for the project.

Petitioners contend that although there may not be a statutory requirement that the Secretary make formal findings and even though this may not be a case for the reviewing court to impose a requirement that findings be made, Department of Transportation regulations require them. This argument is based on DOT Order 5610.1,[31] which requires the Secretary to make formal

[31] The regulation was promulgated pursuant to Executive Order 11514, dated March 5, 1970, 35 Fed. Reg. 4247, which instructed all federal agencies to initiate procedures needed to direct their policies and programs toward meeting national environmental goals.

findings when he approves the use of parkland for highway construction but which was issued after the route for I–40 was approved.[32] Petitioners argue that even though the order was not in effect at the time approval was given to the Overton Park project and even though the order was not intended to have retrospective effect the order represents the law at the time of this Court's decision and under *Thorpe* v. *Housing Authority*, 393 U. S. 268, 281–282 (1969), should be applied to this case.

The *Thorpe* litigation resulted from an attempt to evict a tenant from a federally funded housing project under circumstances that suggested that the eviction was prompted by the tenant's objections to the management of the project. Despite repeated requests, the Housing Authority would not give an explanation for its action. The tenant claimed that the eviction interfered with her exercise of First Amendment rights and that the failure to state the reasons for the eviction and to afford her a hearing denied her due process. After denial of relief in the state courts, this Court granted certiorari "to consider whether [the tenant] was denied due process by the Housing Authority's refusal to state the reasons for her eviction and to afford her a hearing at which she could contest the sufficiency of those reasons." 393 U. S., at 272.

While the case was pending in this Court, the Department of Housing and Urban Development issued regulations requiring Housing Authority officials to inform tenants of the reasons for an eviction and to give a tenant the opportunity to reply. The case was then remanded to the state courts to determine if the HUD regulations were applicable to that case. The state court held them not to be applicable and this Court reversed on the

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[32] DOT Order 5610.1 was issued on October 7, 1970.

ground that the general rule is "that an appellate court must apply the law in effect at the time it renders its decision." 393 U. S., at 281.

While we do not question that DOT Order 5610.1 constitutes the law in effect at the time of our decision, we do not believe that *Thorpe* compels us to remand for the Secretary to make formal findings.[33] Here, unlike the situation in *Thorpe,* there has been a change in circumstances—additional right-of-way has been cleared and the 26-acre right-of-way inside Overton Park has been purchased by the State. Moreover, there is an administrative record that allows the full, prompt review of the Secretary's action that is sought without additional delay which would result from having a remand to the Secretary.

That administrative record is not, however, before us. The lower courts based their review on the litigation affidavits that were presented. These affidavits were merely *"post hoc"* rationalizations, *Burlington Truck Lines* v. *United States,* 371 U. S. 156, 168–169 (1962), which have traditionally been found to be an inadequate basis for review. *Burlington Truck Lines* v. *United States, supra; SEC* v. *Chenery Corp.,* 318 U. S. 80, 87 (1943). And they clearly do not constitute the "whole record" compiled by the agency: the basis for review required by § 706 of the Administrative Procedure Act. See n. 30, *supra.*

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[33] Even if formal findings by the Secretary were mandatory, the proper course would be to remand the case to the District Court directing that court to order the Secretary to make formal findings. See R. Robertson & F. Kirkham, Jurisdiction of the Supreme Court of the United States § 446, p. 929 (R. Wolfson & P. Kurland ed. 1951). Of course, the District Court is not prohibited from remanding the case to the Secretary. See *infra,* at 420.

Thus it is necessary to remand this case to the District Court for plenary review of the Secretary's decision. That review is to be based on the full administrative record that was before the Secretary at the time he made his decision.[34] But since the bare record may not disclose the factors that were considered or the Secretary's construction of the evidence it may be necessary for the District Court to require some explanation in order to determine if the Secretary acted within the scope of his authority and if the Secretary's action was justifiable under the applicable standard.

The court may require the administrative officials who participated in the decision to give testimony explaining their action. Of course, such inquiry into the mental processes of administrative decisionmakers is usually to be avoided. *United States* v. *Morgan*, 313 U. S. 409, 422 (1941). And where there are administrative findings that were made at the same time as the decision, as was the case in *Morgan*, there must be a strong showing of bad faith or improper behavior before such inquiry may be made. But here there are no such formal findings and it may be that the only way there can be effective judicial review is by examining the decisionmakers themselves. See *Shaughnessy* v. *Accardi*, 349 U. S. 280 (1955).

The District Court is not, however, required to make such an inquiry. It may be that the Secretary can prepare formal findings including the information required by DOT Order 5610.1 that will provide an adequate explanation for his action. Such an explanation will, to some extent, be a "*post hoc* rationalization" and thus must be viewed critically. If the District Court decides

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[34] The Solicitor General now urges that in order to avoid additional delay the proper course is to remand the case to the District Court for review of the full administrative record.

that additional explanation is necessary, that court should consider which method will prove the most expeditious so that full review may be had as soon as possible.

Reversed and remanded.

MR. JUSTICE DOUGLAS took no part in the consideration or decision of this case.

Separate opinion of MR. JUSTICE BLACK, with whom MR. JUSTICE BRENNAN joins.

I agree with the Court that the judgment of the Court of Appeals is wrong and that its action should be reversed. I do not agree that the whole matter should be remanded to the District Court. I think the case should be sent back to the Secretary of Transportation. It is apparent from the Court's opinion today that the Secretary of Transportation completely failed to comply with the duty imposed upon him by Congress not to permit a federally financed public highway to run through a public park "unless (1) there is no feasible and prudent alternative to the use of such land, and (2) such program includes all possible planning to minimize harm to such park . . . ." 23 U. S. C. § 138 (1964 ed., Supp. V); 49 U. S. C. § 1653 (f) (1964 ed., Supp. V). That congressional command should not be taken lightly by the Secretary or by this Court. It represents a solemn determination of the highest law-making body of this Nation that the beauty and health-giving facilities of our parks are not to be taken away for public roads without hearings, factfindings, and policy determinations under the supervision of a Cabinet officer—the Secretary of Transportation. The Act of Congress in connection with other federal highway aid legislation,[1] it seems to me,

[1] See 23 U. S. C. § 128 (1964 ed., Supp. V) and regulations promulgated thereunder, 34 Fed. Reg. 727–730 (1969).

calls for hearings—hearings that a court can review, hearings that demonstrate more than mere arbitrary defiance by the Secretary. Whether the findings growing out of such hearings are labeled "formal" or "informal" appears to me to be no more than an exercise in semantics. Whatever the hearing requirements might be, the Department of Transportation failed to meet them in this case. I regret that I am compelled to conclude for myself that, except for some too-late formulations, apparently coming from the Solicitor General's office, this record contains not one word to indicate that the Secretary raised even a finger to comply with the command of Congress. It is our duty, I believe, to remand this whole matter back to the Secretary of Transportation for him to give this matter the hearing it deserves in full good-faith obedience to the Act of Congress. That Act was obviously passed to protect our public parks from forays by road builders except in the most extraordinary and imperative circumstances.[2] This record does not demonstrate the existence of such circumstances. I dissent from the Court's failure to send the case back to the Secretary, whose duty has not yet been performed.

MR. JUSTICE BLACKMUN.

I fully join the Court in its opinion and in its judgment. I merely wish to state the obvious: (1) The case comes to this Court as the end product of more than a decade of endeavor to solve the interstate highway problem at Memphis. (2) The administrative decisions under attack here are not those of a single Secretary; some were made by the present Secretary's predecessor and, before him, by the Department of Commerce's Bureau of Public

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[2] See also *Named Individual Members of the San Antonio Conservation Society* v. *Texas Highway Department*, 400 U. S. 968, 972 (1970) (dissents from the denial of certiorari).

Roads. (3) The 1966 Act and the 1968 Act have cut across former methods and here have imposed new standards and conditions upon a situation that already was largely developed.

This undoubtedly is why the record is sketchy and less than one would expect if the project were one which had been instituted after the passage of the 1966 Act.

TAB 5

Syllabus

NOTE: Where it is feasible, a syllabus (headnote) will be released, as is being done in connection with this case, at the time the opinion is issued. The syllabus constitutes no part of the opinion of the Court but has been prepared by the Reporter of Decisions for the convenience of the reader. See *United States* v. *Detroit Timber & Lumber Co.,* 200 U. S. 321, 337.

SUPREME COURT OF THE UNITED STATES

Syllabus

FEDERAL COMMUNICATIONS COMMISSION ET AL. *v.* PROMETHEUS RADIO PROJECT ET AL.

CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

No. 19–1231. Argued January 19, 2021—Decided April 1, 2021*

Under its broad authority to regulate broadcast media in the public interest, the Federal Communications Commission (FCC) has long maintained several ownership rules that limit the number of radio stations, television stations, and newspapers that a single entity may own in a given market. Section 202(h) of the Telecommunications Act of 1996 directs the FCC to review its media ownership rules every four years and to repeal or modify any rules that no longer serve the public interest.

In 2017, the FCC concluded that three of its ownership rules were no longer necessary to promote competition, localism, or viewpoint diversity. The Commission further concluded that the record evidence did not suggest that repealing or modifying those three rules was likely to harm minority and female ownership. Based on that analysis, the agency decided to repeal two of those three ownership rules and modify the third. Prometheus Radio Project and several other public interest and consumer advocacy groups (collectively, Prometheus) petitioned for review, arguing that the FCC's decision to repeal or modify the three rules was arbitrary and capricious under the Administrative Procedure Act (APA). The Third Circuit vacated the FCC's reconsideration order, holding that the record did not support the agency's conclusion that the rule changes would have minimal effect on minority and female ownership.

Held: The FCC's decision to repeal or modify the three ownership rules

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*Together with No. 19–1241, *National Association of Broadcasters et al.* v. *Prometheus Radio Project et al.*, also on certiorari to the same court.

Syllabus

was not arbitrary and capricious for purposes of the APA. In analyzing whether to repeal or modify its existing ownership rules, the FCC considered the record evidence and reasonably concluded that the three ownership rules at issue were no longer necessary to serve the agency's public interest goals of competition, localism, and viewpoint diversity, and that the rule changes were not likely to harm minority and female ownership.

In challenging the FCC's order, Prometheus argues that the Commission's assessment of the likely impact of the rule changes on minority and female ownership rested on flawed data. But the FCC acknowledged the gaps in the data sets it relied on, and noted that, despite its repeated requests for additional data, it had received no countervailing evidence suggesting that changing the three ownership rules was likely to harm minority and female ownership. Prometheus also asserts that the FCC ignored two studies submitted by a commenter that purported to show that past relaxations of the ownership rules had led to decreases in minority and female ownership levels. But the record demonstrates that the FCC considered those studies and simply interpreted them differently.

In assessing the effects of the rule changes on minority and female ownership, the FCC did not have perfect empirical or statistical data. But that is not unusual in day-to-day agency decisionmaking within the Executive Branch. The APA imposes no general obligation on agencies to conduct or commission their own empirical or statistical studies. And nothing in the Telecommunications Act requires the FCC to conduct such studies before exercising its discretion under Section 202(h). In light of the sparse record on minority and female ownership and the FCC's findings with respect to competition, localism, and viewpoint diversity, the Court cannot say that the agency's decision to repeal or modify the ownership rules fell outside the zone of reasonableness for purposes of the APA. Pp. 7–13.

939 F. 3d 567, reversed.

KAVANAUGH, J., delivered the opinion for a unanimous Court. THOMAS, J., filed a concurring opinion.

SUPREME COURT OF THE UNITED STATES

Nos. 19–1231 and 19–1241

FEDERAL COMMUNICATIONS COMMISSION, ET AL., PETITIONERS
19–1231 *v.*
PROMETHEUS RADIO PROJECT, ET AL.

NATIONAL ASSOCIATION OF BROADCASTERS, ET AL., PETITIONERS
19–1241 *v.*
PROMETHEUS RADIO PROJECT, ET AL.

ON WRITS OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

[April 1, 2021]

JUSTICE KAVANAUGH delivered the opinion of the Court.

Under the Communications Act of 1934, the Federal Communications Commission possesses broad authority to regulate broadcast media in the public interest. Exercising that statutory authority, the FCC has long maintained strict ownership rules. The rules limit the number of radio stations, television stations, and newspapers that a single entity may own in a given market. Under Section 202(h) of the Telecommunications Act of 1996, the FCC must review the ownership rules every four years, and must repeal or modify any ownership rules that the agency determines are no longer in the public interest.

In a 2017 order, the FCC concluded that three of its ownership rules no longer served the public interest. The FCC

therefore repealed two of those rules—the Newspaper/Broadcast Cross-Ownership Rule and the Radio/Television Cross-Ownership Rule. And the Commission modified the third—the Local Television Ownership Rule. In conducting its public interest analysis under Section 202(h), the FCC considered the effects of the rules on competition, localism, viewpoint diversity, and minority and female ownership of broadcast media outlets. The FCC concluded that the three rules were no longer necessary to promote competition, localism, and viewpoint diversity, and that changing the rules was not likely to harm minority and female ownership.

A non-profit advocacy group known as Prometheus Radio Project, along with several other public interest and consumer advocacy groups, petitioned for review, arguing that the FCC's decision was arbitrary and capricious under the Administrative Procedure Act. In particular, Prometheus contended that the record evidence did not support the FCC's predictive judgment regarding minority and female ownership. Over Judge Scirica's dissent, the U. S. Court of Appeals for the Third Circuit agreed with Prometheus and vacated the FCC's 2017 order.

On this record, we conclude that the FCC's 2017 order was reasonable and reasonably explained for purposes of the APA's deferential arbitrary-and-capricious standard. We therefore reverse the judgment of the Third Circuit.

I

The Federal Communications Commission possesses broad statutory authority to regulate broadcast media "as public convenience, interest, or necessity requires." 47 U. S. C. §303; see also §309(a). Exercising that authority, the FCC has historically maintained several strict ownership rules. The rules limit the number of radio stations, television stations, and newspapers that a single entity may own in a given market. See *FCC* v. *National Citizens*

Comm. for Broadcasting, 436 U. S. 775, 780–781, and nn. 1–3, 783–784 (1978). The FCC has long explained that the ownership rules seek to promote competition, localism, and viewpoint diversity by ensuring that a small number of entities do not dominate a particular media market. See *id.*, at 780–781, 808; *In re 2002 Biennial Regulatory Review—Notice of Proposed Rulemaking*, 17 FCC Rcd. 18503, 18515–18527 (2002).

This case concerns three of the FCC's current ownership rules. The first is the Newspaper/Broadcast Cross-Ownership Rule. Initially adopted in 1975, that rule prohibits a single entity from owning a radio or television broadcast station and a daily print newspaper in the same media market. The second is the Radio/Television Cross-Ownership Rule. Initially adopted in 1970, that rule limits the number of combined radio stations and television stations that an entity may own in a single market. And the third is the Local Television Ownership Rule. Initially adopted in 1964, that rule restricts the number of local television stations that an entity may own in a single market.

The FCC adopted those rules in an early-cable and pre-Internet age when media sources were more limited. By the 1990s, however, the market for news and entertainment had changed dramatically. Technological advances led to a massive increase in alternative media options, such as cable television and the Internet. Those technological advances challenged the traditional dominance of daily print newspapers, local radio stations, and local television stations. See, *e.g., In re 2002 Biennial Regulatory Review—Report and Order and Notice of Proposed Rulemaking*, 18 FCC Rcd. 13620, 13647–13667 (2003) (2002 Review).

In 1996, Congress passed and President Clinton signed the Telecommunications Act. To ensure that the FCC's ownership rules do not remain in place simply through inertia, Section 202(h) of the Act directs the FCC to review its ownership rules every four years to determine whether

those rules remain "necessary in the public interest as the result of competition." §202(h), 110 Stat. 111–112, as amended §629, 118 Stat. 99–100, note following 47 U. S. C. §303. After conducting each quadrennial Section 202(h) review, the FCC "shall repeal or modify" any rules that it determines are "no longer in the public interest." *Ibid.* Section 202(h) establishes an iterative process that requires the FCC to keep pace with industry developments and to regularly reassess how its rules function in the marketplace. See *In re 2002 Biennial Regulatory Review—Report*, 18 FCC Rcd. 4726, 4732 (2003).

Soon after Section 202(h) was enacted, the FCC stated that the agency's traditional public interest goals of promoting competition, localism, and viewpoint diversity would inform its Section 202(h) analyses. 2002 Review, 18 FCC Rcd., at 13627; see also *In re 1998 Biennial Regulatory Review*, 15 FCC Rcd. 11058, 11061–11062 (2000). The FCC has also said that, as part of its public interest analysis under Section 202(h), it would assess the effects of the ownership rules on minority and female ownership. 2002 Review, 18 FCC Rcd., at 13627, 13634, and n. 67; see also *In re 2010 Quadrennial Regulatory Review—Notice of Inquiry*, 25 FCC Rcd. 6086, 6106 (2010); cf. *In re Amendment of Section 73.3555 [formerly Sections 73.35, 73.240 and 73.636] of the Commission's Rules Relating to Multiple Ownership of AM, FM and Television Broadcast Stations*, 100 F. C. C. 2d 74, 97 (1985).

Since 2002, the Commission has repeatedly sought to change several of its ownership rules—including the three rules at issue here—as part of its Section 202(h) reviews. See 2002 Review, 18 FCC Rcd., at 13622–13623 (eliminating strict caps on newspaper/broadcast and radio/television cross-ownership and modifying the Local Television Ownership Rule); *In re 2006 Quadrennial Regulatory Review—Report and Order and Order on Reconsideration*, 23 FCC Rcd. 2010, 2021 (2008) (relaxing the Newspaper/Broadcast

Cross-Ownership Rule). But for the last 17 years, the Third Circuit has rejected the FCC's efforts as unlawful under the APA. See *Prometheus Radio Project* v. *FCC*, 373 F. 3d 372 (2004); *Prometheus Radio Project* v. *FCC*, 652 F. 3d 431 (2011); see also 824 F. 3d 33 (2016). As a result, those three ownership rules exist in substantially the same form today as they did in 2002.[1]

The current dispute arises out of the FCC's most recent attempt to change its ownership rules. In its quadrennial Section 202(h) order issued in 2016, the FCC concluded that the Newspaper/Broadcast Cross-Ownership, Radio/Television Cross-Ownership, and Local Television Ownership Rules remained necessary to serve the agency's public interest goals of promoting "competition and a diversity of viewpoints in local markets." *In re 2014 Quadrennial Regulatory Review—Second Report and Order*, 31 FCC Rcd. 9864, 9865 (2016) (2016 Order). The FCC therefore chose to retain the existing rules with only "minor modifications." *Ibid.*

A number of groups sought reconsideration of the 2016 Order. In 2017, the Commission (with a new Chair) granted reconsideration. *In re 2014 Quadrennial Regulatory Review—Order on Reconsideration and Notice of Proposed Rulemaking*, 32 FCC Rcd. 9802 (2017) (2017 Reconsideration Order). On reconsideration, the FCC performed a new public interest analysis. The agency explained that

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[1] The FCC currently has two other ownership rules that are subject to its quadrennial Section 202(h) review: (1) the Local Radio Ownership Rule, which limits the number of radio stations that an entity may own in a single market, and (2) the Dual Network Rule, which prohibits mergers among the top four television broadcast networks (ABC, CBS, Fox, and NBC). The FCC has one additional ownership rule, the National Television Ownership Rule, which is not subject to review under Section 202(h). That rule limits the number of television stations that a single entity may own nationwide. Those other rules are not at issue in this case.

rapidly evolving technology and the rise of new media outlets—particularly cable and Internet—had transformed how Americans obtain news and entertainment, rendering some of the ownership rules obsolete. See, *e.g., id.,* at 9811–9815. As a result of those market changes, the FCC concluded that the three ownership rules no longer served the agency's public interest goals of fostering competition, localism, and viewpoint diversity. *Id.,* at 9810, 9830, and n. 197, 9835–9836. The FCC explained that permitting efficient combinations among radio stations, television stations, and newspapers would benefit consumers. See *id.*, at 9819, 9830, 9835–9836.

The Commission also considered the likely impact of any changes to its ownership rules on minority and female ownership. The FCC concluded that repealing or modifying the three ownership rules was not likely to harm minority and female ownership. *Id.,* at 9822–9824, 9830–9831, 9839–9840.[2]

Based on its analysis of the relevant factors, the FCC decided to repeal the Newspaper/Broadcast and Radio/Television Cross-Ownership Rules, and to modify the Local Television Ownership Rule. *Id.,* at 9803.

Prometheus and several other public interest and consumer advocacy groups petitioned for review, arguing that the FCC's decision to repeal or modify those three rules was arbitrary and capricious under the APA.

The Third Circuit vacated the 2017 Reconsideration Order. The court did not dispute the FCC's conclusion that

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[2] 2017 Reconsideration Order, 32 FCC Rcd., at 9822 ("We find that repealing the" Newspaper/Broadcast Cross-Ownership Rule "will not have a material impact on minority and female ownership"); *id.,* at 9830 ("[W]e find that the record fails to demonstrate that eliminating the Radio/Television Cross-Ownership Rule is likely to harm minority and female ownership"); *id.,* at 9839 ("We find that the modifications we adopt to the Local Television Ownership Rule are not likely to harm minority and female ownership").

those three ownership rules no longer promoted the agency's public interest goals of competition, localism, and viewpoint diversity. But the court held that the record did not support the FCC's conclusion that the rule changes would "have minimal effect" on minority and female ownership. 939 F. 3d 567, 584 (2019). The court directed the Commission, on remand, to "ascertain on record evidence" the effect that any rule changes were likely to have on minority and female ownership, "whether through new empirical research or an in-depth theoretical analysis." *Id.,* at 587.

Judge Scirica dissented in relevant part. In his view, the FCC reasonably analyzed the record evidence and made a reasonable predictive judgment that the rule changes were not likely to harm minority and female ownership. *Id.,* at 590.

The FCC and a number of industry groups petitioned for certiorari. We granted certiorari. 591 U. S. ___ (2020).

II

In the 2017 Reconsideration Order, the FCC changed three of its ownership rules because it concluded that the rules were no longer in the public interest. In particular, the FCC concluded that the rules no longer served the agency's goals of fostering competition, localism, and viewpoint diversity, and further concluded that repealing or modifying the rules was not likely to harm minority and female ownership.

Prometheus argues that the FCC's predictive judgment regarding minority and female ownership was arbitrary and capricious under the APA. See 5 U. S. C. §706(2)(A). We disagree.

The APA's arbitrary-and-capricious standard requires that agency action be reasonable and reasonably explained. Judicial review under that standard is deferential, and a court may not substitute its own policy judgment for that of

the agency. A court simply ensures that the agency has acted within a zone of reasonableness and, in particular, has reasonably considered the relevant issues and reasonably explained the decision. See *FCC* v. *Fox Television Stations, Inc.*, 556 U. S. 502, 513–514 (2009); *Motor Vehicle Mfrs. Assn. of United States, Inc.* v. *State Farm Mut. Automobile Ins. Co.*, 463 U. S. 29, 43 (1983); see also *FCC* v. *WNCN Listeners Guild*, 450 U. S. 582, 596 (1981).

In its 2017 Reconsideration Order, the FCC analyzed the significant record evidence of dramatic changes in the media market over the past several decades. See, *e.g.,* 32 FCC Rcd., at 9803, 9807, 9825, 9834. After thoroughly examining that record evidence, the Commission determined that the Newspaper/Broadcast Cross-Ownership, Radio/Television Cross-Ownership, and Local Television Ownership Rules were no longer necessary to serve the agency's public interest goals of promoting competition, localism, and viewpoint diversity. The FCC therefore concluded that repealing the two cross-ownership rules and modifying the Local Television Ownership Rule would fulfill "the mandates of Section 202(h)" and "deliver on the Commission's promise to adopt broadcast ownership rules that reflect the present, not the past." *Id.,* at 9803.

In analyzing whether to repeal or modify those rules, the FCC also addressed the possible impact on minority and female ownership. The Commission explained that it had sought public comment on the issue of minority and female ownership during multiple Section 202(h) reviews, but "no arguments were made" that would lead the FCC to conclude that the existing rules were "necessary to protect or promote minority and female ownership." *Id.,* at 9822; see also *id.,* at 9831, 9839; cf. *In re 2006 Quadrennial Regulatory Review—Further Notice of Proposed Rulemaking*, 21 FCC Rcd. 8834, 8837 (2006) (soliciting evidence on minority and female ownership); *In re 2010 Quadrennial Regulatory Review—Notice of Inquiry*, 25 FCC Rcd., at 6106, 6108–6109

(same); *In re 2014 Quadrennial Regulatory Review—Further Notice of Proposed Rulemaking and Report and Order*, 29 FCC Rcd. 4371, 4460, and n. 595, 4470 (2014) (same). Indeed, the FCC stated that it had received several comments suggesting the opposite—namely, comments suggesting that eliminating the Newspaper/Broadcast Cross-Ownership Rule "potentially could *increase* minority ownership of newspapers and broadcast stations." 2017 Reconsideration Order, 32 FCC Rcd., at 9823 (emphasis added). Based on the record, the Commission concluded that repealing or modifying the three rules was not likely to harm minority and female ownership. See *id.*, at 9822, 9830, 9839.

In challenging the 2017 Reconsideration Order in this Court, Prometheus does not seriously dispute the FCC's conclusion that the existing rules no longer serve the agency's public interest goals of competition, localism, and viewpoint diversity. Rather, Prometheus targets the FCC's assessment that altering the ownership rules was not likely to harm minority and female ownership.

Prometheus asserts that the FCC relied on flawed data in assessing the likely impact of changing the rules on minority and female ownership. Prometheus further argues that the FCC ignored superior data available in the record.

Prometheus initially points to two data sets on which the FCC relied in the 2016 Order and the 2017 Reconsideration Order. Those data sets measured the number of minority-owned media outlets before and after the Local Television Ownership Rule and the Local Radio Ownership Rule were relaxed in the 1990s. Together, the data sets showed a slight decrease in the number of minority-owned media outlets immediately after the rules were relaxed, followed by an eventual increase in later years. The 2016 Order cited those data sets and explained that the number of minority-owned media outlets had increased over time. But the FCC added that there was no record evidence suggesting that past changes to the ownership rules had caused minority

ownership levels to increase. See 31 FCC Rcd., at 9894–9895; *id.,* at 9911–9912.

In the 2017 Reconsideration Order, the FCC referred to the 2016 Order's analysis of those data sets. The FCC stated that data in the record suggested that the previous relaxations of the Local Television Ownership and Local Radio Ownership Rules "have not resulted in reduced levels of minority and female ownership." 2017 Reconsideration Order, 32 FCC Rcd., at 9831; see also *id.,* at 9823; *id.,* at 9839. The FCC further explained that "no party" had "presented contrary evidence or a compelling argument demonstrating why" altering the rules would have a different impact today. *Id.,* at 9839; see also *id.*, at 9823, and n. 138; *id.,* at 9831, and n. 201. The FCC therefore concluded that "the record provides no information to suggest" that eliminating or modifying the existing rules would harm minority and female ownership. *Id.,* at 9831; see also *id.,* at 9823; *id.,* at 9839.

Prometheus insists that the FCC's numerical comparison was overly simplistic and that the data sets were materially incomplete. But the FCC acknowledged the gaps in the data. And despite repeatedly asking for data on the issue, the Commission received no other data on minority ownership and no data at all on female ownership levels. See 2016 Order, 31 FCC Rcd., at 9894–9895, nn. 211–212; *id.*, at 9911, n. 325; 2017 Reconsideration Order, 32 FCC Rcd., at 9822–9823, and n. 138 (incorporating 2016 Order's discussion of data sets); *id.,* at 9831, and n. 201 (same); *id.*, at 9839, and n. 243 (same). The FCC therefore relied on the data it had (and the absence of any countervailing evidence) to predict that changing the rules was not likely to harm minority and female ownership.

Prometheus also asserts that countervailing—and superior—evidence was in fact in the record, and that the FCC ignored that evidence. Prometheus identifies two studies submitted to the FCC by Free Press, a media reform group.

Those studies purported to show that past relaxations of the ownership rules and increases in media market concentration had led to decreases in minority and female ownership levels. According to Prometheus, the Free Press studies undercut the FCC's prediction that its rule changes were unlikely to harm minority and female ownership.

The FCC did not ignore the Free Press studies. The FCC simply interpreted them differently. In particular, in the 2016 Order, the Commission explained that its data sets and the Free Press studies showed the same long-term increase in minority ownership after the Local Television Ownership and Local Radio Ownership Rules were relaxed. 31 FCC Rcd., at 9895, and n. 215; *id.,* at 9912, and n. 329. Moreover, as counsel for Prometheus forthrightly acknowledged at oral argument, the Free Press studies were purely backward-looking, and offered no statistical analysis of the likely future effects of the FCC's proposed rule changes on minority and female ownership. See Tr. of Oral Arg. 75–76.

In short, the FCC's analysis was reasonable and reasonably explained for purposes of the APA's deferential arbitrary-and-capricious standard. The FCC considered the record evidence on competition, localism, viewpoint diversity, and minority and female ownership, and reasonably concluded that the three ownership rules no longer serve the public interest. The FCC reasoned that the historical justifications for those ownership rules no longer apply in today's media market, and that permitting efficient combinations among radio stations, television stations, and newspapers would benefit consumers. The Commission further explained that its best estimate, based on the sparse record evidence, was that repealing or modifying the three rules at issue here was not likely to harm minority and female ownership. The APA requires no more.[3]

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[3] Because we hold that the Third Circuit's judgment must be reversed under ordinary principles of arbitrary-and-capricious review, we need

To be sure, in assessing the effects on minority and female ownership, the FCC did not have perfect empirical or statistical data. Far from it. But that is not unusual in day-to-day agency decisionmaking within the Executive Branch. The APA imposes no general obligation on agencies to conduct or commission their own empirical or statistical studies. Cf. *Fox Television*, 556 U. S., at 518–520; *Vermont Yankee Nuclear Power Corp.* v. *Natural Resources Defense Council, Inc.*, 435 U. S. 519, 524 (1978). And nothing in the Telecommunications Act (or any other statute) requires the FCC to conduct its own empirical or statistical studies before exercising its discretion under Section 202(h). Here, the FCC repeatedly asked commenters to submit empirical or statistical studies on the relationship between the ownership rules and minority and female ownership. See, *e.g., In re 2014 Quadrennial Review*, 29 FCC Rcd., at 4460, and n. 595. Despite those requests, no commenter produced such evidence indicating that changing the rules was likely to harm minority and female ownership. In the absence of additional data from commenters, the FCC made a reasonable predictive judgment based on the evidence it had. See *State Farm*, 463 U. S., at 52.

In light of the sparse record on minority and female ownership and the FCC's findings with respect to competition, localism, and viewpoint diversity, we cannot say that the agency's decision to repeal or modify the ownership rules fell outside the zone of reasonableness for purposes of the APA.[4]

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not reach the industry petitioners' alternative argument that the text of Section 202(h) does not authorize (or at least does not require) the FCC to consider minority and female ownership when the Commission conducts its quadrennial reviews. We also need not consider the industry petitioners' related argument that the FCC, in its Section 202(h) review of an ownership rule, may not consider minority and female ownership unless promoting minority and female ownership was part of the FCC's original basis for that ownership rule.

[4]The Third Circuit also vacated the FCC's separate 2018 Incubator

* * *

We reverse the judgment of the U. S. Court of Appeals for the Third Circuit.

It is so ordered.

Order and the 2016 Order's definition of "eligible entity." But the Third Circuit did not offer any independent reasons for doing so. Instead, it vacated those agency actions based solely on its conclusion that the FCC failed to adequately consider minority and female ownership in the 2017 Reconsideration Order. Because we reverse the judgment of the Third Circuit as to the 2017 Reconsideration Order, it follows that the Third Circuit's judgment as to the Incubator Order and "eligible entity" definition is also reversed.

SUPREME COURT OF THE UNITED STATES

Nos. 19–1231 and 19–1241

FEDERAL COMMUNICATIONS COMMISSION, ET AL., PETITIONERS
19–1231 *v.*
PROMETHEUS RADIO PROJECT, ET AL.

NATIONAL ASSOCIATION OF BROADCASTERS, ET AL., PETITIONERS
19–1241 *v.*
PROMETHEUS RADIO PROJECT, ET AL.

ON WRITS OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

[April 1, 2021]

JUSTICE THOMAS, concurring.

As the Court correctly holds, the Federal Communications Commission's orders were not arbitrary and capricious. Based on the record evidence available, the FCC reasonably concluded that modifying its broadcast ownership rules would not harm minority and female ownership of broadcast media. I write separately to note another, independent reason why reversal is warranted: The Third Circuit improperly imposed nonstatutory procedural requirements on the FCC by forcing it to consider ownership diversity in the first place.

The FCC had no obligation to consider minority and female ownership. Nothing in §202(h) of the Telecommunications Act of 1996 directs the FCC to consider rates of minority and female ownership. See note following 47 U. S. C. §303 (requiring the FCC simply to consider "'the public interest as the result of competition'"). Nor could any court

force the FCC to consider ownership diversity: Courts have no authority to impose "judge-made procedur[es]" on agencies. *Perez* v. *Mortgage Bankers Assn.*, 575 U. S. 92, 102 (2015).

Disregarding these limits, the Third Circuit imposed on the FCC a nonstatutory requirement to consider minority and female ownership. The court first did so in 2004 when it vacated the FCC's modification of its Local Television Ownership Rule, faulting the FCC for "failing to mention anything about the effect this change would have on potential minority station owners." 373 F. 3d 372, 420 (2004). It then directed the FCC on remand to "consider . . . proposals for enhancing ownership opportunities for women and minorities." *Id.*, at 435, n. 82; accord, 652 F. 3d 431, 471 (2011) (reiterating that its "prior remand requir[ed] the Commission to consider the effect of its rules on minority and female ownership"). Repeating this error in 2016, the Third Circuit mandated that the FCC, "in addition to §202(h)'s requirement . . . , include a determination about 'the effect of the rules on minority and female ownership.'" 824 F. 3d 33, 54, n. 13 (quoting 652 F. 3d, at 471; brackets omitted).

Respondents try to defend the Third Circuit's ruling by noting that the FCC has previously discussed ownership diversity when considering its ownership rules. They contend that the FCC thus believed that a purpose of those rules is to promote minority and female ownership. And because an agency cannot "depart from a prior policy *sub silentio*," *FCC* v. *Fox Television Stations, Inc.*, 556 U. S. 502, 515 (2009), they argue that the FCC either had to consider ownership diversity or expressly repudiate its prior policy. That argument fails because the FCC's ownership rules—unlike some of its *non*ownership rules—were never designed to foster ownership diversity.

From its infancy, the FCC has generally focused on consumers, not producers. The year after it was established, the agency that would later become the FCC made clear

that "'emphasis must be first and foremost on the interest, the convenience, and the necessity of the listening public, and not on the interest, convenience, or necessity of the individual broadcaster.'" *FCC* v. *Pottsville Broadcasting Co.*, 309 U. S. 134, 139, n. 2 (1940) (quoting a 1928 agency document).

The FCC kept true to that design when promulgating ownership rules. For example, when it created the Newspaper/Broadcast Cross-Ownership Rule at issue here, the agency explained that its "ownership rules rest on two foundations: the twin goals of diversity of viewpoints and economic competition," and that viewpoint diversity is the "higher" policy. 50 F. C. C. 2d 1046, 1074 (1975); see also 22 F. C. C. 2d 306, 313, ¶25 (1970) (stating that the "principal purpose" of the Radio/Television Cross-Ownership Rule is "promot[ing] diversity of viewpoints" and a secondary purpose is "promot[ing] competition"). To these two consumer-focused goals, the FCC has also added a third: localism. 18 FCC Rcd. 13620, 13624, ¶8, 13645, ¶81 (2003). None of these objectives advances demographic diversity of owners for the sake of owners.

To be sure, the FCC has sometimes considered minority and female ownership of broadcast media when discussing ownership rules. Time after time, however, it has viewed those forms of diversity not "as policy goals in and of themselves, but as proxies for viewpoint diversity." 17 FCC Rcd. 18503, 18519, ¶41, and n. 116, 18521, ¶50 (2002); accord, *e.g.,* 18 FCC Rcd., at 13774, ¶389 ("diversity of ownership promotes diversity of viewpoints"); *id.,* at 13636, ¶51, 13760, ¶355 (similar); 10 FCC Rcd. 2788, ¶¶1–2 (1995) ("promoting minority ownership of broadcasting and cable television facilities serves to enhance the diversity of viewpoints presented"). The FCC has also said that ownership diversity "promote[s] competition." *Id.*, at 2789, ¶6; accord, 22 F. C. C. 2d, at 313, ¶25. And although the FCC has oc-

casionally used language that, read in isolation, could suggest a freestanding goal of promoting ownership diversity, *e.g.,* 17 FCC Rcd., at 18521, ¶50 ("[T]he Commission has historically used the ownership rules to foster ownership by diverse groups, such as minorities, women and small businesses"), these comments must be viewed in the light of the FCC's repeated statements that "the core Commission goal [is] maximizing the diversity of points of view available to the public" and that "promoting minority [and female] ownership of broadcasting and cable television facilities serves" this core goal. *E.g.,* 10 FCC Rcd., at 2788, ¶¶1–2.

Even while trying to abide by the Third Circuit's improper mandate, the FCC clarified in this proceeding that it considered ownership diversity a potential means to pursue viewpoint diversity, not a freestanding goal of its ownership rules. To cite just a few examples, in its 2016 order the FCC explained that it "has a long history of promulgating rules and regulations intended to promote diversity of ownership among broadcast licensees, and *thereby* foster a diversity of voices." App. 335 (emphasis added). It afforded certain companies waivers from various rules to "serve our broader goal of diversity of ownership, and *thus* viewpoint diversity." *Id.,* at 337 (emphasis added). And it noted that it could not promulgate a race-conscious regulation without first "demonstrat[ing] a connection between minority ownership and viewpoint diversity" that would "satisfy strict scrutiny." *Id.,* at 397; cf. *Metro Broadcasting, Inc.* v. *FCC*, 497 U. S. 547, 566–568 (1990) (upholding race-conscious "minority ownership policies" because they were "substantially related to the achievement of . . . broadcast diversity"—*i.e.,* viewpoint diversity), overruled by *Adarand Constructors, Inc.* v. *Peña*, 515 U. S. 200, 227 (1995) (requiring strict scrutiny for "all racial classifications").

The Third Circuit erred by disregarding this history. For example, when the FCC modified its Local Television Ownership Rule in 2003, the court faulted the FCC for "failing

to mention anything about the effect this change would have on potential minority station owners." 373 F. 3d, at 420. But as with its other ownership rules, the stated "objectives" for that rule were fostering viewpoint diversity and competition. 14 FCC Rcd. 12903, 12910–12912, ¶¶15, 17 (1999).[1]

Here, as in 2003, once the FCC determined that none of its policy objectives for ownership rules—viewpoint diversity, competition, and localism—justified retaining its rules, the FCC was free to modify or repeal them without considering ownership diversity. Indeed, the FCC has long been clear that "it would be inappropriate to retain multiple ownership regulations for the sole purpose of promoting minority ownership." 100 F. C. C. 2d 74, 94, ¶45 (1985). The Third Circuit had no authority to require the FCC to consider minority and female ownership. So in future reviews, the FCC is under no obligation to do so.[2]

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[1] The FCC reiterated these objectives when modifying the rule in 2003. 18 FCC Rcd. 13620, 13708, ¶¶225–226.

[2] The FCC has recently questioned the validity of the assumption that ownership diversity promotes viewpoint diversity. 32 FCC Rcd. 9802, 9810, ¶15, n. 49 (2017). Its previous acceptance of that assumption in no way precludes the FCC from rejecting it in the future.

TAB 6

Nat'l Wildlife Fed'n v. Nat'l Marine Fisheries Serv.

United States Court of Appeals for the Ninth Circuit

July 13, 2005, Argued and Submitted ; September 1, 2005, Decided ; July 26, 2005, Filed

No. 05-35569, No. 05-35646, No. 05-35570

Reporter
422 F.3d 782 *; 2005 U.S. App. LEXIS 15318 **; 60 ERC (BNA) 1929

NATIONAL WILDLIFE FEDERATION; IDAHO WILDLIFE FEDERATION; WASHINGTON WILDLIFE FEDERATION; SIERRA CLUB; TROUT UNLIMITED; PACIFIC COAST FEDERATION OF FISHERMEN'S ASSOCIATIONS; INSTITUTE FOR FISHERIES RESOURCES; IDAHO RIVERS UNITED; IDAHO STEELHEAD AND SALMON UNITED; NORTHWEST SPORT FISHING INDUSTRY ASSOCIATION, SALMON FOR ALL; COLUMBIA RIVERKEEPER; NW ENERGY COALITION; FEDERATION OF FLY FISHERS; AMERICAN RIVERS, INC., Plaintiffs-Appellees, v. NATIONAL MARINE FISHERIES SERVICE; UNITED STATES ARMY CORPS OF ENGINEERS; U.S. BUREAU OF RECLAMATION, Defendants, FRANKLIN COUNTY FARM BUREAU FEDERATION; GRANT COUNTY FARM BOARD FEDERATION; WASHINGTON FARM BUREAU FEDERATION; STATE OF IDAHO; CLARKSON GOLF & COUNTRY CLUB, Defendants-Intervenors, and NORTHWEST IRRIGATION UTILITIES; PUBLIC POWER COUNCIL; PACIFIC NORTHWEST GENERATING COOPERATIVE; BPA CUSTOMER GROUP, Defendants-Intervenors-Appellants, v. STATE OF OREGON, Plaintiff-Intervenor-Appellee. NATIONAL WILDLIFE FEDERATION; IDAHO WILDLIFE FEDERATION; WASHINGTON WILDLIFE FEDERATION; SIERRA CLUB; TROUT UNLIMITED; PACIFIC COAST FEDERATION OF FISHERMEN'S ASSOCIATIONS; INSTITUTE FOR FISHERIES RESOURCES; IDAHO RIVERS UNITED; IDAHO STEELHEAD AND SALMON UNITED; NORTHWEST SPORT FISHING INDUSTRY ASSOCIATION, SALMON FOR ALL; COLUMBIA RIVERKEEPER; NW ENERGY COALITION; FEDERATION OF FLY FISHERS; AMERICAN RIVERS, INC., Plaintiffs-Appellees, v. NATIONAL MARINE FISHERIES SERVICE; UNITED STATES ARMY CORPS OF ENGINEERS; U.S. BUREAU OF RECLAMATION, Defendants, NORTHWEST IRRIGATION UTILITIES; PUBLIC POWER COUNCIL; PACIFIC NORTHWEST GENERATING COOPERATIVE; BPA CUSTOMER GROUP; FRANKLIN COUNTY FARM BUREAU FEDERATION; GRANT COUNTY FARM BOARD FEDERATION; WASHINGTON FARM BUREAU FEDERATION; CLARKSON GOLF & COUNTRY CLUB, Defendants-Intervenors, and STATE OF IDAHO, Defendant-Intervenor-Appellant, v. STATE OF OREGON, Plaintiff-Intervenor-Appellee. NATIONAL WILDLIFE FEDERATION; IDAHO WILDLIFE FEDERATION; WASHINGTON WILDLIFE FEDERATION; SIERRA CLUB; TROUT UNLIMITED; PACIFIC COAST FEDERATION OF FISHERMEN'S ASSOCIATIONS; INSTITUTE FOR FISHERIES RESOURCES; IDAHO RIVERS UNITED; IDAHO STEELHEAD AND SALMON UNITED; NORTHWEST SPORT FISHING INDUSTRY ASSOCIATION, SALMON FOR ALL; COLUMBIA RIVERKEEPER; NW ENERGY COALITION; FEDERATION OF FLY FISHERS; AMERICAN RIVERS, INC., Plaintiffs-Appellees, v. NATIONAL MARINE FISHERIES SERVICE; UNITED STATES ARMY CORPS OF ENGINEERS; U.S. BUREAU OF RECLAMATION, Defendants-Appellants, and NORTHWEST IRRIGATION UTILITIES; PUBLIC POWER COUNCIL; PACIFIC NORTHWEST GENERATING COOPERATIVE; BPA CUSTOMER GROUP; FRANKLIN COUNTY FARM BUREAU FEDERATION; GRANT COUNTY FARM BOARD FEDERATION; WASHINGTON FARM BUREAU FEDERATION; STATE OF IDAHO; CLARKSON GOLF & COUNTRY CLUB, Defendants-Intervenors, v. STATE OF OREGON, Plaintiff-Intervenor-Appellee.

Subsequent History: Remanded by *Nat'l Wildlife Fed'n v. Nat'l Marine Fisheries Serv., 2005 U.S. Dist. LEXIS 48580 (D. Or., Oct. 7, 2005)*

Prior History: [1]** Appeal from the United States District Court for the District of Oregon. James A. Redden, District Judge, Presiding.

Nat'l Wildlife Fed'n v. Nat'l Marine Fisheries Serv., 418 F.3d 971, 2005 U.S. App. LEXIS 24268 (9th Cir. Or., 2005)
Nat'l Wildlife Fed'n v. Nat'l Marine Fisheries Serv., 2004 U.S. Dist. LEXIS 15239 (D. Or., July 29, 2004)

Disposition: AFFIRMED AND REMANDED.

Core Terms

district court, species, preliminary injunction, salmon, dam, habitat, endangered species, injunction, spill, biological, migrate, modify, fish, survival, jeopardize, base line, jeopardy, juvenile, snake, agency's action, injunctive relief, steelhead, threatened species, proposed action, transport, modify, irreparable, scientific, deference, issuance

Case Summary

Procedural Posture

Defendants, National Marine Fisheries Service (NMFS) and the Army Corps of Engineers, appealed from an order of the United States District Court for the District of Oregon that granted a preliminary injunction to the National Wildlife Foundation (NWF), based on a violation of the Endangered Species Act (ESA), *16 U.S.C.S. §§ 1531-1544*, requiring them to pass a specified amount of water through the spill gates of dams to benefit fish populations.

Overview

Thirteen species of Columbia, Snake, and Willamette River salmon and steelhead were protected by the ESA. NMFS operated the Federal Columbia River Power System (FCRPS), which involved the dams and power plants on those rivers. The district court granted summary judgment for NWF, holding that NMFS had violated the ESA in the issuance of its 2004 biological opinion, which formed the basis of the federal agencies' operating plans for the FCRPS. The court found that the 2004 biological opinion was legally insufficient for several reasons, and was not entitled to deference because it represented a complete reversal from the prior 2000 opinion. The opinion failed to use an aggregation of the impacts from the proposed action, the environmental baseline, and the cumulative impacts as the basis for the jeopardy analysis. The court specified that its summary judgment order was not final or appealable, but also granted an injunction requiring a greater number of fish to be allowed through the spill gates, where their chances of survival were increased. The court of appeals affirmed the injunction, finding the district court's conclusions were well grounded in the ESA.

Outcome

The district court's issuance of a preliminary injunction was affirmed, but the question of whether the injunction should be more narrowly tailored or modified was remanded to the district court. The court expressed no opinion on the ultimate merits of the summary judgment decision before the district court.

LexisNexis® Headnotes

Environmental Law > Natural Resources & Public Lands > Endangered Species Act > General Overview

Environmental Law > Natural Resources & Public Lands > Endangered Species Act > Critical Habitats

Environmental Law > Natural Resources & Public Lands > Endangered Species Act > Federal Agencies

Environmental Law > Natural Resources & Public Lands > Endangered Species Act > Species Lists

Environmental Law > Natural Resources & Public Lands > Fish & Wildlife Protection

Governments > Federal Government > Claims By & Against

International Trade Law > Trade Agreements > Environmental Provisions > Endangered Species

HN1 The Endangered Species Act, *16 U.S.C.S. §§ 1531-1544*, requires federal agencies to insure that any action authorized, funded, or carried out by such agency is not likely to jeopardize the continued existence of any endangered species or threatened species or result in the destruction or adverse modification of designated critical habitat. *16 U.S.C.S. § 1536(a)(2)*.

Administrative Law > Agency Rulemaking > Formal Rulemaking

Environmental Law > Natural Resources & Public Lands > Endangered Species Act > General Overview

Environmental Law > Natural Resources & Public Lands > Endangered Species Act > Federal Agencies

Environmental Law > Natural Resources & Public

Lands > Endangered Species Act > Species Lists

Governments > Federal Government > Claims By & Against

International Trade Law > Trade Agreements > Environmental Provisions > Endangered Species

HN2 To ensure that a federal agency meets its substantive duties under the Endangered Species Act (ESA), *16 U.S.C.S. §§ 1531-1544*, the ESA imposes a procedural consultation duty whenever a federal action may affect an ESA-listed species. To that end, the agency planning the action, usually known as the "action agency," must consult with any consulting agency. That process is known as a "Section 7" consultation. The process is usually initiated by a formal written request by the action agency to the consulting agency. After consultation and analysis, the consulting agency then prepares a biological opinion.

Administrative Law > Agency Rulemaking > Formal Rulemaking

Environmental Law > Natural Resources & Public Lands > Endangered Species Act > General Overview

Environmental Law > Natural Resources & Public Lands > Endangered Species Act > Critical Habitats

Environmental Law > Natural Resources & Public Lands > Endangered Species Act > Federal Agencies

HN3 A consulting agency evaluates the effects of the proposed action on the survival of species and any potential destruction or adverse modification of critical habitat in a biological opinion, *16 U.S.C.S. § 1536(b)*, based on the best scientific and commercial data available, *16 U.S.C.S. § 1536(a)(2)*. The biological opinion includes a summary of the information upon which the opinion is based, a discussion of the effects of the action on listed species or critical habitat, and the consulting agency's opinion on whether the action is likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of critical habitat. *50 C.F.R. § 402.14(h)*. In making its jeopardy determination, the consulting agency evaluates the current status of the listed species or critical habitat, the effects of the action, and cumulative effects. *50 C.F.R. § 402.14(g)(2)-(3)*. "Effects of the action" include both direct and indirect effects of an action that will be added to the environmental baseline. *50 C.F.R. § 402.02*. The environmental baseline includes the past and present impacts of all Federal, State or private actions and other human activities in the action area and the anticipated impacts of all proposed Federal projects in the action area that have already undergone formal or early Section 7 consultation.

Environmental Law > Natural Resources & Public Lands > Endangered Species Act > General Overview

Environmental Law > Natural Resources & Public Lands > Endangered Species Act > Critical Habitats

Environmental Law > Natural Resources & Public Lands > Endangered Species Act > Federal Agencies

Environmental Law > Natural Resources & Public Lands > Endangered Species Act > Takings

International Trade Law > Trade Agreements > Environmental Provisions > Endangered Species

Real Property Law > Inverse Condemnation > General Overview

HN4 Where a biological opinion concludes that jeopardy to an endangered species is not likely and that there will not be adverse modification of critical habitat, or that there is a reasonable and prudent alternative to the agency action that avoids jeopardy and adverse modification and that the incidental taking of endangered or threatened species will not violate § 7(a)(2) of the Endangered Species Act (ESA), *16 U.S.C.S. §§ 1531-1544*, the consulting agency can issue an "Incidental Take Statement" which, if followed, exempts the action agency from the prohibition on takings found in § 9 of the ESA. *16 U.S.C.S. § 1536(b)(4)*.

Environmental Law > Natural Resources & Public Lands > Endangered Species Act > General Overview

Environmental Law > Natural Resources & Public Lands > Endangered Species Act > Federal Agencies

Environmental Law > Natural Resources & Public Lands > Endangered Species Act > Takings

International Trade Law > Trade Agreements > Environmental Provisions > Endangered Species

HN5 The term "take" as used in the Endangered Species Act, *16 U.S.C.S. §§ 1531-1544*, means to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct. *16 U.S.C.S. § 1532(19)*.

Administrative Law > Agency Rulemaking > Formal Rulemaking

Environmental Law > Natural Resources & Public Lands > Endangered Species Act > General Overview

Environmental Law > Natural Resources & Public Lands > Endangered Species Act > Critical Habitats

Environmental Law > Natural Resources & Public Lands > Endangered Species Act > Federal Agencies

International Trade Law > Trade Agreements > Environmental Provisions > Endangered Species

HN6 Where a consulting agency under the Endangered Species Act (ESA), 16 U.S.C.S. §§ 1531-1544, concludes that an action agency's action may jeopardize the survival of species protected by the ESA, or adversely modify a species' critical habitat, the action must be modified. The consulting agency may recommend a reasonable and prudent alternative to the agency's proposed action. 16 U.S.C.S. § 1536(b)(3)(A).

Administrative Law > Judicial Review > General Overview

Administrative Law > Judicial Review > Reviewability > Reviewable Agency Action

Environmental Law > Administrative Proceedings & Litigation > Judicial Review

Environmental Law > Natural Resources & Public Lands > Endangered Species Act > General Overview

Environmental Law > Natural Resources & Public Lands > Endangered Species Act > Federal Agencies

International Trade Law > Trade Agreements > Environmental Provisions > Endangered Species

HN7 The issuance of a biological opinion under the Endangered Species Act, 16 U.S.C.S. §§ 1531-1544, is considered a final agency action, and therefore subject to judicial review.

Environmental Law > Natural Resources & Public Lands > Endangered Species Act > General Overview

Environmental Law > Natural Resources & Public Lands > Endangered Species Act > Critical Habitats

Environmental Law > Natural Resources & Public Lands > Endangered Species Act > Federal Agencies

Environmental Law > Natural Resources & Public Lands > Fish & Wildlife Protection

International Trade Law > Trade Agreements > Environmental Provisions > Endangered Species

International Trade Law > Trade Agreements > Environmental Provisions > Fish & Fishing Rights

HN8 The Endangered Species Act (ESA), 16 U.S.C.S. §§ 1531-1544, as it applies to protection of anadromous fish, requires action agencies to consult the agency formerly known as the National Marine Fisheries Service of the National Oceanic and Atmospheric Administration (since renamed NOAA Fisheries), to ensure that an agency's actions do not jeopardize an ESA-protected species or adversely modify their critical habitat. 16 U.S.C.S. § 1536(a)-(b).

Civil Procedure > Remedies > Injunctions > Preliminary & Temporary Injunctions

Civil Procedure > Appeals > Standards of Review > Clearly Erroneous Review

HN9 A district court's order with respect to preliminary injunctive relief is subject to limited appellate review, and an appellate court will reverse only if the district court abused its discretion or based its decision on an erroneous legal standard or on clearly erroneous findings of fact. Such review is limited and deferential. In considering a preliminary injunction appeal, a reviewing court ordinarily does not decide the ultimate merits of the case, but only the temporal rights of the parties until the district court renders judgment on the merits of the case based on a fully developed record. Mere disagreement with the district court's conclusions is not sufficient reason for us to reverse the district court's decision regarding a preliminary injunction.

Civil Procedure > Remedies > Injunctions > Preliminary & Temporary Injunctions

Environmental Law > Natural Resources & Public Lands > Endangered Species Act > General Overview

International Trade Law > Trade Agreements > Environmental Provisions > Endangered Species

HN10 The traditional preliminary injunction analysis does not apply to injunctions issued pursuant to the

Endangered Species Act (ESA), *16 U.S.C.S. §§ 1531-1544*. In cases involving the ESA, Congress removed from the courts their traditional equitable discretion in injunction proceedings of balancing the parties' competing interests. Congress has spoken in the plainest of words, making it abundantly clear that the balance has been struck in favor of affording endangered species the highest of priorities. Accordingly, courts may not use equity's scale's to strike a different balance. Congress has determined that under the ESA the balance of hardships always tips sharply in favor of endangered or threatened species.

Civil Procedure > ... > Summary Judgment > Appellate Review > Standards of Review

Civil Procedure > ... > Injunctions > Grounds for Injunctions > Likelihood of Success

Civil Procedure > Remedies > Injunctions > Preliminary & Temporary Injunctions

Environmental Law > Natural Resources & Public Lands > Endangered Species Act > General Overview

International Trade Law > Trade Agreements > Environmental Provisions > Endangered Species

HN11 To establish a substantial likelihood of success on the merits sufficient to pass appellate review of a district court's grant of a preliminary injunction, plaintiffs under the Endangered Species Act, *16 U.S.C.S. §§ 1531-1544* are only obligated to show a fair chance of success.

Civil Procedure > Remedies > Injunctions > Preliminary & Temporary Injunctions

Civil Procedure > Appeals > Standards of Review > Clearly Erroneous Review

Civil Procedure > Appeals > Standards of Review > Reversible Errors

HN12 On appellate review in the context of a district court's grant of a preliminary injunction, a reviewing court considers a finding of fact to be clearly erroneous if it is implausible in light of the record, viewed in its entirety, or if the record contains no evidence to support it.

Civil Procedure > Remedies > Injunctions > Preliminary & Temporary Injunctions

Civil Procedure > Appeals > Standards of Review > Clearly Erroneous Review

HN13 An appellate court's task in reviewing a district court's preliminary injunction decision is not to resolve the factual controversies before the district court. Clear error is not demonstrated by pointing to conflicting evidence in the record. Rather, as long as findings are plausible in light of the record viewed in its entirety, a reviewing court may not reverse even if convinced it would have reached a different result.

Civil Procedure > Remedies > Injunctions > Preliminary & Temporary Injunctions

Environmental Law > Natural Resources & Public Lands > Endangered Species Act > General Overview

Governments > Federal Government > US Congress

International Trade Law > Trade Agreements > Environmental Provisions > Endangered Species

HN14 Although not every statutory violation leads to the automatic issuance of an injunction, in the context of the Endangered Species Act (ESA), *16 U.S.C.S. §§ 1531-1544*, the test for determining if equitable relief is appropriate is whether an injunction is necessary to effectuate the congressional purpose behind the statute. A court therefore holds that injunctive relief was necessary to effectuate Congress's clear intent by requiring compliance with the substantive and procedural provisions of the ESA.

Administrative Law > Judicial Review > Standards of Review > General Overview

HN15 Courts, as a general matter, ought to defer to an agency's scientific or technical expertise. Deference to the informed discretion of the responsible federal agencies is especially important, where, as here, the agency's decision involves a high level of technical expertise. However, the deference accorded an agency's scientific or technical expertise is not unlimited. Deference is not owed when the agency has completely failed to address some factor consideration of which was essential to making an informed decision.

Administrative Law > Judicial Review > Standards of Review > General Overview

HN16 An agency interpretation of a relevant provision which conflicts with the agency's earlier interpretation is entitled to considerably less deference, than a consistently held agency view.

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John C. Bruning, Attorney General, David D. Cookson, Assistant Attorney General, State of Nebraska, Lincoln, Nebraska; Thomas R. Wilmoth, Special Assistant Attorney General, Fennemore Craig, P.C., Lincoln, Nebraska, for amicus curiae State of Nebraska.

Judges: Before: A. Wallace Tashima, Sidney R. Thomas, and **[**3]** Richard A. Paez, Circuit Judges.

Opinion

[*787] AMENDED OPINION

PER CURIAM:

The defendants appeal the district court's grant of a preliminary injunction, based on a violation of the Endangered Species Act (or "ESA"), *16 U.S.C. §§ 1531-1544*, **[*788]** requiring the United States to pass a specified amount of water through the spillgates of four dams on the Snake River, and one dam on the Columbia River during the summer months of 2005, rather than passing the water through turbines for power generation. We affirm in part and remand in part.

I

The Columbia River is the fourth largest river on the North American continent. It drains approximately 259,000 square miles, including territory in seven states and one Canadian province. It flows for more than 1,200 miles from the base of the Canadian Rockies to the Pacific Ocean. As part of the cycle of life in the Columbia River system, every year hundreds of thousands of salmon and steelhead travel up and down the river and its tributaries, hatching in fresh water, migrating downstream to the sea to achieve adulthood, and then returning upstream to spawn. The Snake River is the Columbia River's main **[**4]** tributary.

As part of the modern cycle of life in the Columbia River System, each year brings litigation to the federal courts of the Northwest over the operation of the Federal Columbia River Power System ("FCRPS" or "Columbia River System") [1] and, in particular, the effects of system operation on the anadromous salmon and steelhead protected by the Endangered Species Act.

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[1] The FCRPS consists of 14 sets of dams and related facilities: Bonneville, The Dales, John Day, and McNary dams in the lower Columbia River Basin; Chief Joseph, Grand Coulee, Libby, Hungry Horse, and Albeni Falls dams in the upper Columbia River Basin; and Ice Harbor, Lower Monumental, Little Goose, Lower Granite, and Dworshak Dams in the lower Snake River Basin. The United States Bureau of Reclamation manages the Grand Coulee and Hungry Horse dams; the remainder are managed by the United States Army Corps of Engineers.

No one disputes that the wild Pacific salmon population has significantly decreased; indeed, in recent years, salmon **[**5]** runs have declined to a small percentage of their historic abundance. There are now thirteen species of Columbia, Snake, and Willamette River salmon and steelhead that are protected by the Endangered Species Act. [2] The district court found in this case that "the listed species are in serious decline and not evidencing signs of recovery." Each of the thirteen affected stocks migrate at different times of the year to different parts of the Columbia Basin. For example, Upper Columbia spring Chinook adults return to their spawning grounds in the spring of each year; Snake River fall Chinook adults return to the Snake River Basin in the fall. Juveniles of these stocks generally migrate seaward between mid-April and early September. The spring and summer Chinook, steelhead, and sockeye salmon migrate as yearling juveniles in the spring. Subyearling fall Chinook migrate down the river during the mid-to-late summer. Some salmon migrate downstream after spending a year in fresh water; others migrate the same year.

[6]** The primary focus of the present lawsuit is the survival of the fall juvenile Chinook salmon and steelhead migrating downstream to the Pacific Ocean. These fish **[*789]** must pass a number of FCRPS dams on their journey to the sea and suffer a very high mortality rate in doing so, sometimes as high as 92%. As the fish migrate downstream, they first encounter reservoirs behind the dams, which slows their progress and exposes them to predatory fish, such as the northern pikeminnow. After passage through each dam's reservoir, the juvenile salmon and steelhead must pass each dam. There are four main methods by which salmon may navigate the Columbia and Snake River hydroelectric projects while migrating from upriver areas to the ocean: (1) spill over the dams; (2) passage through turbines; (3) in-river bypass systems; and (4) transportation bypass systems. Of these options, passage through turbines unquestionably causes the highest mortality rate. Historically, spill has been considered to cause the lowest mortality. However, spill must be carefully managed to avoid gas supersaturation, which is harmful to the fish. [3]

[7]** Each dam in the migration corridor of the mainstream Snake and Columbia rivers has a bypass system. At some dams, the bypass consists of screens in front of the turbine intakes that divert the salmon and steelhead into a passageway through the dam and downstream. At others, the bypass system diverts the fish into barges for transportation around the dam.

The operation of the Columbia River System is complex. The Army Corps of Engineers and the Bureau of Reclamation manage the dams for multi-purpose operations; the Bonneville Power Administration manages federal power generated from the dams; and the Federal Energy Regulatory Commission plays a number of roles, including licensing of non-federal hydro-power projects. Although the focus of this litigation is the effect of Columbia River System operation on endangered species, in the day-to-day operation, federal agencies must manage the system to deliver needed power and water to Northwest consumers.

States also have an influence on the Columbia River System, directly in their governance of water diversions from the river, and indirectly through their own fish and wildlife conservation programs. The operation of the Columbia River **[**8]** System is also impacted by treaties with a number of federally recognized Indian Tribes, which reserve to the tribes certain fishing rights that are affected by the management of the FCRPS. [4]

In the last several decades, the management of the Columbia River System has been strongly influenced by the Endangered Species Act, which requires federal

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[2] Snake River Chinook salmon (fall-run); Snake River Chinook salmon (spring/summer-run); Snake River sockeye salmon; Upper Columbia River steelhead; Snake River Basin steelhead; Lower Columbia River coho salmon; Lower Columbia River steelhead; Middle Columbia River steelhead; Upper Willamette River steelhead; Lower Columbia River Chinook salmon; Upper Willamette River Chinook salmon; Upper Columbia River Chinook salmon (spring-run); and Columbia River chum salmon.

[3] Falling water over the dam increases the amount of atmospheric gases that are dissolved in the water. If the level of dissolved atmospheric gases is too high, fish can experience "gas bubble trauma," which is similar to the "bends" experienced by human divers who return to the surface too quickly.

[4] *See, e.g.*Treaty with the Nez Perces, 12 Stat. 957, Art. 3 (June 11, 1855); ***Treaty with the Tribes of the Middle Oregon (Confederated Tribes of the Warm Springs Reservation of Oregon), 12 Stat. 963 (June 25, 1855)***; ***Treaty with the Yakima, 12 Stat. 951 (June 9, 1855)***; ***Treaty with the Wallawalla, Cayuse, et. al. (Confederated Tribes of the Umatilla Indian Reservation), 12 Stat. 945 (June 9, 1855)***. In their amici brief, the treaty tribes support the position of the National Wildlife Federation in this action.

agencies to, in consultation with what is known as the "consulting agency," conserve species listed under the ESA. **[**9]** ***HN1*** The ESA requires federal agencies to "insure that any action authorized, funded, or carried out by such agency . . . is not likely to jeopardize the continued existence of any endangered species or threatened species or result in the destruction or adverse modification of [designated critical] habitat. . . ." **[*790]** *16 U.S.C. § 1536(a)(2)*. ***HN2*** To ensure that the agency would meet its substantive ESA duties, the ESA imposes a procedural consultation duty whenever a federal action may affect an ESA-listed species. *Thomas v. Peterson, 753 F.2d 754, 763 (9th Cir. 1985)*. To that end, the agency planning the action, usually known as the "action agency," must consult with the consulting agency. This process is known as a "*Section 7*" consultation. The process is usually initiated by a formal written request by the action agency to the consulting agency. After consultation and analysis, the consulting agency then prepares a biological opinion. *See generally Ariz. Cattle Growers' Ass'n v. United States Fish & Wildlife Serv., 273 F.3d 1229, 1239 (9th Cir. 2001)*.

[10]** ***HN3*** The consulting agency evaluates the effects of the proposed action on the survival of species and any potential destruction or adverse modification of critical habitat in a biological opinion, *16 U.S.C. § 1536(b)*, based on "the best scientific and commercial data available," *id.* at *§ 1536(a)(2)*. The biological opinion includes a summary of the information upon which the opinion is based, a discussion of the effects of the action on listed species or critical habitat, and the consulting agency's opinion on "whether the action is likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of critical habitat. . . ." *50 C.F.R. § 402.14(h)*. In making its jeopardy determination, the consulting agency evaluates "the current status of the listed species or critical habitat," the "effects of the action," and "cumulative effects." *50 C.F.R. § 402.14(g)(2)-(3)*. "Effects of the action" include both direct and indirect effects of an action that will be added to the "environmental baseline." *50 C.F.R. § 402.02* **[**11]** . The environmental baseline includes "the past and present impacts of all Federal, State or private actions and other human activities in the action area" and "the anticipated impacts of all proposed Federal projects in the action area that have already undergone formal or early *section 7* consultation." *Id.*

HN4 If the biological opinion concludes that jeopardy is not likely and that there will not be adverse modification of critical habitat, or that there is a "reasonable and prudent alternative" to the agency action that avoids jeopardy and adverse modification and that the incidental taking of endangered or threatened species will not violate *section 7(a)(2)*, the consulting agency can issue an "Incidental Take Statement" which, if followed, exempts the action agency from the prohibition on takings [5] found in *Section 9 of the ESA*. *16 U.S.C. § 1536(b)(4)*; *Aluminum Co. of America v. Administrator, Bonneville Power Administration, 175 F.3d 1156, 1159 (9th Cir. 1999)*.

[12]** ***HN6*** If the consulting agency concludes that an action agency's action may jeopardize the survival of species protected by the ESA, or adversely modify a species' critical habitat, the action must be modified. *Id.* The consulting agency may recommend a "reasonable and prudent alternative" to the agency's proposed action. *Id.* at *§ 1536(b)(3)(A)*.

HN7 The issuance of a biological opinion is considered a final agency action, and therefore subject to judicial review. *Bennett v. Spear, 520 U.S. 154, 178, 137 L. Ed. 2d 281, 117 S. Ct. 1154 (1997)*; *Ariz. Cattle Growers' Ass'n, 273 F.3d at 1235*.

HN8 The Endangered Species Act, as it applies here to protection of anadromous fish, requires action agencies to consult the **[*791]** agency formerly known as the National Marine Fisheries Service of the National Oceanic and Atmospheric Administration ("NMFS"), [6] to ensure that an agency's actions do not jeopardize an ESA-protected species or adversely modify their critical habitat. *16 U.S.C. § 1536(a)-(b)*.

[13]** Snake River fall Chinook salmon were listed as threatened species in 1992. In 1993, NMFS issued a biological opinion concluding that FCRPS operations would not jeopardize the listed species. The district court held that NMFS's action in issuing the 1993 biological opinion was arbitrary and capricious. *Idaho Dep't of Fish & Game v. Nat'l Marine Fisheries Serv., 850 F. Supp. 886, 900 (D. Or. 1994)*. The district court found that NMFS had failed to give an adequate

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[5] ***HN5*** "The term 'take' means to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct." *16 U.S.C. § 1532(19)*.

[6] The agency has now been renamed "NOAA Fisheries." Because many of the documents refer to the agency by its former name, it shall be referenced as "NMFS" throughout this opinion for convenience of reference.

explanation for several of the key assumptions that went into its jeopardy analysis. This decision was vacated on appeal as moot because NMFS had issued a subsequent biological opinion. *Idaho Dep't of Fish & Game v. Nat'l Marine Fisheries Serv., 56 F.3d 1071, 1075 (9th Cir. 1995)*. After further litigation and agency action not directly relevant to this case, NMFS issued a new biological opinion on December 21, 2000, (the "2000 BiOp") that superseded the previous biological opinions.

In its 2000 BiOp, NMFS determined that the continued operation of FCRPS as proposed by the action agencies would jeopardize eight listed salmon and steelhead species; specifically, NMFS found that the "effects **[**14]** of the proposed or continuing action, the effects of the environmental baseline, and any cumulative effects, and considering measures for survival and recovery specific to other life stages" would leave the eight species with too low a likelihood of survival and potential for population recovery. NMFS thus developed reasonable and prudent alternatives to the proposed operation and analyzed whether these alternatives, in conjunction with the environmental baseline and cumulative effects, would avoid jeopardizing the species. NMFS found these alternatives insufficient. NMFS therefore assessed whether the additional impact of off-site mitigation activities unrelated to FCRPS operations, including hatchery and habitat initiatives, would avoid jeopardy, and found that it did.

Plaintiff National Wildlife Federation ("NWF") brought this present action challenging the 2000 BiOp in U.S. District Court for the District of Oregon. The district court concluded that the 2000 BiOp was invalid because to reach its jeopardy determination, NMFS improperly relied on off-site federal mitigation actions that had not undergone Section 7 consultation, and thus were not properly included in the environmental **[**15]** baseline, [7] and on non-federal mitigation actions that were not reasonably certain to occur, and thus were not properly included in cumulative effects. *Nat'l Wildlife Fed'n v. Nat'l Marine Fisheries Servs., 254 F. Supp. 2d 1196, 1211-12 (D. Or. 2003)*. The district court remanded to provide NMFS an opportunity to correct the 2000 BiOp. *Id. at 1215*.

[*792] Rather than correct the 2000 BiOp, NMFS issued an entirely new biological opinion on November 30, 2004 (the "2004 BiOp"), which formed the basis of the federal agencies' operating plans for the FCRPS during **[**16]** the summer of 2005. In the 2004 BiOp, NMFS conducted a jeopardy analysis which utilized the novel approach of including in the environmental baseline the existing FCRPS, the nondiscretionary dam operations, and all past and present impacts from discretionary operations. As opposed to assessing whether the salmon and steelhead would be jeopardized by the aggregate of the proposed agency action, the environmental baseline, cumulative effects, and current status of the species, NMFS instead evaluated whether the proposed agency action, consisting of only the proposed discretionary operation of the FCRPS, would have no net effect on a species when compared to the environmental baseline. By using this comparative approach rather than the aggregate approach, NMFS was able to conclude that the proposed action would not jeopardize the continued existence of any listed species or destroy or adversely modify critical habitat for three of these species.

NWF and the State of Oregon challenged the following aspects of 2004 BiOp, specifically and as relevant to this appeal: (1) the segregation of the existing FCRPS, the non-discretionary dam operations, and all past and present impacts of discretionary **[**17]** operations from the proposed discretionary operations; (2) the basic analytical framework NMFS employed to come to its no-jeopardy and critical habitat determinations; and (3) the critical habitat determinations which plaintiffs alleged did not analyze what habitat conditions are necessary for recovery. [8]

The district court granted summary judgment for NWF and Oregon, holding that NMFS had violated the ESA in the issuance of its 2004 BiOp. The district court found the 2004 BiOp legally insufficient for four independent reasons:

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[7] The 2004 BiOp concluded that NMFS could not distinguish the effects of the discretionary and nondiscretionary FCRPS operations, and therefore created a hypothetical "reference operation" to which it compared the discretionary proposed action. The reference operation was developed to "maximize fish benefits" and it "overestimates the beneficial effects that the Action Agencies can actually achieve." 2004 BiOp at 5-6.

[8] The State of Oregon supports the substantive position of NWF, but takes no position on the preliminary injunction. The State of Washington supports NWF's position that the 2004 BiOp is invalid, but opposes the preliminary injunction remedy. The States of Idaho and Nebraska support the federal government's position on both the merits and the preliminary injunction remedy.

. The opinion failed to conduct a jeopardy analysis on the basis of all elements of the proposed action, **[**18]** including the so-called non-discretionary operations of the dams;

. The opinion failed to use an aggregation of the impacts from the proposed action, the environmental baseline, and the cumulative impacts as the basis for the jeopardy analysis;

. The opinion's critical habitat determination was flawed because it failed to determine separately whether the proposed action would destroy or adversely modify critical habitat necessary for the recovery as well as survival of the listed species; and

. The opinion's jeopardy analysis failed to address both recovery and survival of the listed species.

The order granting summary judgment to the plaintiffs "invalidated" the 2004 BiOp. However, the district court specified that its summary judgment order was not final or appealable. Following the district court's decision to invalidate the 2004 BiOp, NWF moved for a preliminary injunction requiring NMFS to: (1) withdraw the 2004 BiOp; (2) comply with and implement all of the reasonable and prudent alternative mitigation actions described in the 2000 BiOp (with certain exceptions); **[*793]** (3) as to the 2005 summer flow, decrease the water particle travel time by 10% in specified **[**19]** areas; and (4) provide water spill over specified dams during the summer of 2005.

The district court, based on its determination that the 2004 BiOp was procedurally and substantively flawed and its finding that the operations of FCRPS strongly contribute to the endangerment of the listed species and will cause irreparable injury if not changed, granted in part the motion for a preliminary injunction. The district court announced its intention to order the withdrawal of the 2004 BiOp, but declined to do so until after a fall status conference. The court denied the request to order the decrease of water particle travel time by at least 10% in the specified areas. The court granted the request to order summer spills at specified areas in order to avoid irreparable harm to juvenile fall chinook and other listed species. Specifically, the district court ordered the affected agencies to: (1) provide spill from June 20, 2005, through August 31, 2005, of all water in excess of that required for station service, on a 24-hour basis, at the Lower Granite, Little Goose, Lower Monumental, and Ice Harbor Dams on the lower Snake River; and (2) provide spill from July 1, 2005, through August 31, 2005, of **[**20]** all flows above 50,000 cubic feet per second, on a 24-hour basis, at the McNary Dam on the Columbia River.

The district court also held in its order that the respective Records of Consultation and Statements of Decision issued by the Army Corps of Engineers on January 3, 2005, and by the Bureau of Reclamation on January 12, 2005, violated the ESA because they were based on the invalid 2004 BiOp.

The defendants filed an emergency motion for a stay of the injunction order pending appeal. A motions panel denied the defendants' stay motion, but ordered an expedited hearing on the preliminary injunction appeal. Oral argument on the preliminary injunction appeal was held July 13, 2005. The panel expresses its appreciation to the parties for providing extensive briefing on short notice and on an accelerated time schedule.

II

HN9 A district court's order with respect to preliminary injunctive relief is subject to limited appellate review, and we will reverse only if the district court "abused its discretion or based its decision on an erroneous legal standard or on clearly erroneous findings of fact." *United States v. Peninsula Communications, Inc., 287 F.3d 832, 839 (9th Cir. 2002)* **[**21]** . "Our review is limited and deferential." *Southwest Voter Registration Educ. Project v. Shelley, 344 F.3d 914, 918 (9th Cir. 2003)* (en banc). In considering a preliminary injunction appeal, we ordinarily do not decide the ultimate merits of the case, but only the temporal rights of the parties until the district court renders judgment on the merits of the case based on a fully developed record. *Gilder v. PGA Tour, Inc., 936 F.2d 417, 422 (9th Cir. 1991)*. Mere disagreement with the district court's conclusions is not sufficient reason for us to reverse the district court's decision regarding a preliminary injunction. *Sports Form, Inc. v. United Press Int'l, Inc., 686 F.2d 750, 752 (9th Cir. 1982)*; *see also Ranchers Cattlemen Action Legal Fund United Stockgrowers of Am. v. United States Dep't of Agric. ("R-CALF"), 415 F.3d 1078, 2005 U.S. App. LEXIS 15148, *28, No. 05-35264 (9th Cir. Jul. 25 2005)* (setting forth standard of review).

HN10 The traditional preliminary injunction analysis does not apply to injunctions issued pursuant to the ESA. *Nat'l Wildlife Fed'n v. Burlington N. R.R., Inc., 23 F.3d 1508, 1510 (9th Cir. 1994)* **[**22]** . "In **[*794]** cases involving the ESA, Congress removed from the courts their traditional equitable discretion in injunction

proceedings of balancing the parties' competing interests." *Id. at 1511* (citing *Friends of the Earth v. United States Navy, 841 F.2d 927, 933 (9th Cir. 1988)*). As the Supreme Court has noted, "Congress has spoken in the plainest of words, making it abundantly clear that the balance has been struck in favor of affording endangered species the highest of priorities." *TVA v. Hill, 437 U.S. 153, 194, 57 L. Ed. 2d 117, 98 S. Ct. 2279 (1978)*. Accordingly, courts "may not use equity's scales to strike a different balance." *Sierra Club v. Marsh, 816 F.2d 1376, 1383 (9th Cir. 1987)*; *see also Marbled Murrelet v. Babbitt, 83 F.3d 1068, 1073 (9th Cir. 1996)* ("Congress has determined that under the ESA the balance of hardships always tips sharply in favor of endangered or threatened species.").

A

Given this clear authority, we must at the onset reject the argument of the federal appellants that the district court erred as a matter of law by failing to conduct a traditional preliminary **[**23]** injunction analysis and, in particular, by failing to weigh economic harm to the public in reaching its conclusion. As the Supreme Court has instructed, such an analysis does not apply to ESA cases because Congress has already struck the balance. *Id.* Therefore, we conclude that the district court did not apply an incorrect legal standard in this case.

We decline to address the legal issues raised by the district court's summary judgment order. We review the merits only in the very confined context of determining whether the district court abused its discretion in granting the preliminary injunction. ***HN11*** To establish a substantial likelihood of success on the merits sufficient to pass appellate review of a district court's grant of a preliminary injunction, the plaintiffs were only obligated to show "a fair chance of success." *Republic of the Philippines v. Marcos, 862 F.2d 1355, 1362 (9th Cir. 1988)* (en banc). Based on our review of the record and briefs in this emergency appeal, we conclude that the plaintiffs have met this burden by raising substantial questions as to whether the agencies have violated *Section 7 of the ESA* **[**24]** by improperly circumscribing the scope of the consultation or failing to aggregate the impacts of the proposed action. However, in making this threshold determination, we express no opinion on the ultimate merits of the district court's summary judgment decision, leaving that final determination to the district court in the first instance.

B

We also conclude that the district court's grant of a preliminary injunction was not based on clearly erroneous findings of fact. Although the facts and scientific analysis underlying the district court's decision are hotly contested by the parties, our review in the preliminary injunction context is very deferential. ***HN12*** On appellate review in this context, we consider a finding of fact to be clearly erroneous if it is implausible in light of the record, viewed in its entirety, *Serv. Employees Int'l Union v. Fair Political Practices Comm'n, 955 F.2d 1312, 1317 n.7 (9th Cir. 1992)*, or if the record contains no evidence to support it, *Oregon Natural Resources Council v. Marsh, 52 F.3d 1485, 1492 (9th Cir. 1995)*. Having reviewed the extensive, albeit incomplete, record provided to us by the parties in this expedited **[**25]** proceeding, we find no reversible error in the factual findings made by the district court.

[*795] One of the important factual findings made by the district court was that the federal operation of the Columbia and Snake River dams "strongly contribute to the endangerment of the listed species and irreparable injury will result if changes are not made." The federal appellants contest this finding, arguing that the data show that returns of fall chinook salmon have increased. The district court concluded otherwise in its orders, finding in a 2004 order that the "predicted survival improvement for fall chinook juveniles has not materialized." The government's own recent data show that between 78-92% of juvenile fall chinook salmon that remain in-river for their migration are killed by operation of the dams even with use of mitigating measures, with a mean estimated kill of 86% of the salmon migrating in-river. [9] NWF strongly argues that the government's assertion of recovery is based on a single, scientifically flawed, study. NWF also claims, through expert testimony, that the increased returns were due to large releases of hatchery fish, rather than successful fish transport **[**26]** over dams, and that the mortality rate for migrating juvenile salmon is actually increasing. The federal agencies dispute this, and offer counter-testimony. The record is replete with differing opinions by various experts. One of the few undisputed points, however, is that the fall chinook salmon remain a species listed under the ESA as "likely to become endangered in the foreseeable future."

HN13 Our task in reviewing a district court's preliminary injunction decision is not to resolve these controversies.

[9] Although a non-trivial level of mortality would likely occur under free-flowing river conditions, FCRPS operations account for most of the mortality.

"Clear error is not demonstrated by pointing to conflicting evidence in the record." *United States v. Frank, 956 F.2d 872, 875 (9th Cir. 1991)*. Rather, "as long as findings are plausible in light of the record viewed in its entirety, a reviewing court may not reverse even if convinced it would have reached a different result." *Wardley Int'l Bank, Inc. v. Nasipit Bay Vessel, 841 F.2d 259, 262 n.1 (9th Cir.1988)* **[**27]** (citing *Anderson v. Bessemer City, 470 U.S. 564, 574, 84 L. Ed. 2d 518, 105 S. Ct. 1504 (1985)*). Viewing the record as a whole with our deferential standard of review, we cannot say that the district court's factual finding concerning irreparable harm was clearly erroneous.

III

Having determined that the district court did not use an incorrect legal standard in its preliminary injunction analysis and did not make clearly erroneous factual findings, we must decide whether the district court abused its discretion in granting the preliminary injunction.

A

As we have discussed, the district court's preliminary injunction order was premised on its finding that the agencies had violated both the substantive and procedural requirements of *ESA § 7*. Thus, the question before the district court was what interim remedy was appropriate to redress the ESA violations.

HN14 Although not every statutory violation leads to the "automatic" issuance of an injunction, in the context of the ESA, "the test for determining if equitable relief is appropriate is whether an injunction is necessary to effectuate the congressional purpose behind the statute." *Biodiversity Legal Found. v. Badgley, 309 F.3d 1166, 1177 (9th Cir. 2002)* **[**28]** (citing *TVA, 437 U.S. at 194*). We therefore have **[*796]** held that injunctive relief was necessary to effectuate Congress's clear intent by requiring compliance with the substantive and procedural provisions of the ESA. *Id. at 1177* (holding that the district court was "compelled" to grant injunctive relief to remedy a violation of the ESA); *Sierra Club, 816 F.2d at 1384* (holding that the Sierra Club was entitled to injunctive relief if the agency violated substantive or procedural provisions of the ESA).

Given this legal backdrop, we conclude that the district court did not abuse its discretion in granting a preliminary injunction. It had rejected the biological opinion upon which the summer operations were premised, and it had concluded that continuation of the status quo could result in irreparable harm to a threatened species. Those are precisely the circumstances in which our precedent indicates that the issuance of an injunction is appropriate.

This case is unlike the circumstances presented in our recent decision in *R-CALF*. In *R-CALF,* we concluded that the district court had misread the governing statute. *R-CALF, 2005 U.S. App. LEXIS 15148 at *33* **[**29]** . We also concluded that the agency had acted in conformity with the governing statute. *415 F.3d 1078, 2005 U.S. App. LEXIS 15148 at *32-33*. We further concluded that none of the reasons listed by the district court supported its conclusion that the agency's adoption of the final rule at issue was arbitrary and capricious. *415 F.3d 1078, 2005 U.S. App. LEXIS 15148 at *34*.

Here, in contrast, the district court's conclusions were well grounded in the governing statute; the agency had altered its own interpretation of the statute significantly; and the record supported the district court's reasoning in declaring the 2004 BiOp to be invalid. Further, the operations involved in this case have had a long history. The district court has monitored the situation carefully over the past few years and has found that the status quo will not lead to recovery of the listed species. Thus, although we do not reach the merits of the summary judgment order, the record supports the district court's analysis that the plaintiffs are likely to prevail on the merits of their claim that the 2004 BiOp violates *Section 7 of the ESA* and is arbitrary and capricious **[**30]** under the *Administrative Procedures Act*. Finally, as we have discussed, the standard for injunctive relief under the ESA is far different from the usual standard governing preliminary injunctions that applied in the *R-CALF* case. In ESA cases such as the one at bar, "the balance has been struck in favor of affording endangered species the highest of priorities." *TVA, 437 U.S. at 194*. For these reasons, this case is quite distinguishable from *RCALF*, and we conclude that the district court did not commit reversible error in deciding to grant a preliminary injunction.

B

Having concluded that the district court did not err in deciding to grant preliminary injunctive relief, we must also examine the nature and scope of relief ordered by the district court. One of the primary complications of this case is that the operations in question are, by necessity, ongoing. Thus, our situation is unlike that of a timber sale, which can be postponed in order to permit

the agency to correct the ESA violations before the planned operation commences. *See, e.g.*, *Native Ecosystems Council v. Dombeck, 304 F.3d 886, 900-03 (9th Cir. 2002)* **[**31]** (enjoining timber sale for ESA and NEPA violations). Here, the district court was faced with a continuing operation that it had concluded would cause irreparable harm to threatened species. Thus, the district court was confronted with two choices: (1) continue the status quo, the **[*797]** foundation of which the court had rejected as violative of the ESA and the continuation of which it had concluded could irreparably harm listed species, or (2) order modifications. After considering the positions of the parties, the district court adopted one of the plaintiffs' suggestions: mandatory summer spills over selected dams. It rejected the plaintiffs' other major request, namely that the court order a decrease in the water particle travel time by 10% in specified areas. [10]

The district court's selection **[**32]** of a remedy of selected spills was based on expert opinion tendered by the plaintiffs and evidence in the historical record. Frederick Olney, a former fishery biologist for the U.S. Fish and Wildlife Service with thirty-five years of experience in the field, testified by affidavit that spilling water for fish passage was a "cornerstone of protection and mitigation programs" in the area and that there was "regional agreement that spill is the safest passage route through mainstream hydroelectric projects." He testified that "recent information indicates that transportation [of fish] is not providing the benefits previously assumed," citing the 2004 BiOp statement that "it is uncertain whether transport provides a benefit or a detriment for Snake River fall Chinook." Olney concluded that the plaintiffs' request for summer spills would pose less risk for migrating fish than the proposed operations.

The plaintiffs also tendered the opinion of Stephen Pettit, a former fisheries research biologist for the Idaho Department of Fish and Game, who similarly concluded that the plaintiffs' proposed spills would "reduce significantly, even substantially, the harmful effects ESA-listed salmon **[**33]** and steelhead would otherwise experience under the 2004 BiOp."

In addition to the opinions of these experts, and others, the district court considered the previous positive results of the prior use of spills for assisting salmon migrating during the summer months. The 2000 BiOp concluded that "relative to other passage routes currently available, direct juvenile survival is highest through spillbays." In reaching this conclusion, the agency took into consideration the possibility of gas bubble trauma and elevated temperatures. The agency also concluded that spillway passage "should be the baseline against which other passage methods are measured." Because "juvenile survival is generally highest through this passage route," the 2000 BiOp recommended that "measures that increase juvenile fish passage over FCRPS project spillways are the highest priority unless it can be shown that alternative passage improvements would provide comparable survival." The district court's action was in accord with the consulting agency's findings and recommendations in its 2000 BiOp, which was the only operative document at the time, and was in conformance with the historical belief that spillway passage **[**34]** produced the highest survival of the species. This historical assumption was not contested in the 2004 BiOp; rather, it asserted that alternative transportation could provide comparable, but not necessarily better, survival rates.

In short, without summarizing all of the voluminous evidence in the record, the district court had a more than sufficient basis upon which to conclude that summer spills would provide the best and safest alternative to the planned operations contemplated **[*798]** in the 2004 BiOp that was rejected by the court.

The federal appellants and other defendants vigorously contest the conclusions of the experts tendered by the plaintiffs. The defendants offered substantial expert counter-testimony in opposition to the proposed spills, with experts opining that:

> . Because the migratory patterns and river conditions are so different, it is inappropriate to extrapolate the experience from previous spills involving adult salmon at different locations and times to the summer spills proposed by the plaintiffs to assist juvenile migrating salmon.
>
> . Although passage over a spillway may result in higher survival, the falling water over the dam increases **[**35]** the amount of atmospheric gases that are dissolved in the water, which may cause "gas bubble trauma" and damage fish. In addition, spills may expose the fish to potentially dangerous high water temperatures.
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> . Research indicates that there is no apparent

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[10] The district court also appointed a technical advisor, Dr. Howard Horton, to aid it in understanding the various reports, studies and opinions regarding the status of the listed species and effects of FCRPS.

difference in adult return rates between fish that are transported and those that remain in the river. New research also indicates that a significant number of salmon hold over in freshwater and migrate to the ocean during their second year of life, which may mean that hastening the transportation of salmon downstream may not necessarily be beneficial.

. The total number of adult Snake River Chinook Salmon that migrated upriver has increased significantly.

. It is highly imprudent and highly risky to try an untested operation in a critically low water year. Transportation rather than spillage is the safest means of passage in a low water year.

. Ordering spills at certain locations will adversely affect other endangered species.

These are significant and serious concerns. However, it is not our task to weigh the evidence presented to the district court; rather we must decide whether the district court abused **[**36]** its discretion. An abuse of discretion is "a plain error, discretion exercised to an end not justified by the evidence, a judgment that is clearly against the logic and effect of the facts as are found." *Wing v. Asarco, Inc., 114 F.3d 986, 988 (9th Cir. 1997)* (quoting*Int'l Jensen, Inc. v. Metrosound U.S.A., Inc., 4 F.3d 819, 822 (9th Cir. 1993))* (internal quotation marks omitted). The abuse of discretion standard requires that we "not reverse a district court's exercise of its discretion unless we have a definite and firm conviction that the district court committed a clear error of judgment in the conclusion it reached. " *SEC v. Coldicutt, 258 F.3d 939, 941 (9th Cir. 2001)*.

The federal appellants argue that the district court was required to defer to agency expertise. ***HN15*** Courts, as a general matter, ought to defer to an agency's scientific or technical expertise. "Deference to the informed discretion of the responsible federal agencies is especially important, where, as here, the agency's decision involves a high level of technical expertise." *R-CALF, 2005 U.S. App. LEXIS 15148 at *32*. However, "the deference accorded **[**37]** an agency's scientific or technical expertise is not unlimited." *Brower v. Evans, 257 F.3d 1058, 1067 (9th Cir. 2001)* (citing *Defenders of Wildlife v. Babbitt, 958 F. Supp. 670, 679 (D.D.C. 1997))*. Deference is not owed when '"the agency has completely failed to address some factor consideration of which was essential to [making an] informed decision.'" *Id.* (quoting *Inland Empire Pub. Lands Council v. Schultz, 992 F.2d 977, 981 (9th Cir. 1993)* (internal **[*799]** citations omitted)). Here, the district court had already invalidated the agency biological opinion upon which the operations were based, in large part because it omitted factors essential to the analysis. As the district court noted, NMFS had completely reversed course in its 2004 BiOp, particularly in its statutory interpretation of the environmental baseline. ***HN16*** "An agency interpretation of a relevant provision which conflicts with the agency's earlier interpretation is 'entitled to considerably less deference,' than a consistently held agency view." *INS v. Cardoza-Fonseca, 480 U.S. 421, 446, n. 30, 94 L. Ed. 2d 434, 107 S. Ct. 1207 (1987)* **[**38]** (quoting *Watt v. Alaska, 451 U.S. 259, 273, 68 L. Ed. 2d 80, 101 S. Ct. 1673 (1981))*. The district court had rejected the underlying premise of the agency's methodology and the 2004 BiOp. Therefore, there was no formal agency finding to which deference might arguably be owed. Rather, the government chose to present its case through expert affidavit.

Throughout the course of these proceedings, the government has adhered to its position that it would not alter its planned summer dam operations which the district court had determined could cause irreparable harm. Indeed, the government's own 2000 BiOp had concluded that the present operations of the Columbia River System would jeopardize eight of the listed species. In its summary judgment order, the district court had made the factual finding that the listed species were "in serious decline and not evidencing signs of recovery." Therefore, in the absence of an approved, final biological opinion, the district court did not abuse its discretion in considering the record evidence. We conclude that the district court did not abuse its discretion in ordering preliminary injunctive relief.

C

The federal appellants also **[**39]** suggest that, even if preliminary injunctive relief were appropriate, the district court's order must be vacated because it is not narrowly tailored. The appellants did not present this argument to the district court, nor have they sought modification of the injunction. On appeal, the appellants have declined to identify how the injunction should be narrowly tailored, even under questioning. There is also some tension between appellants' argument on appeal that the district court is micromanaging the Columbia River System and its argument that the district court was not specific or detailed enough in its order. The gist of the federal appellants' argument seems to be that the

purported lack of narrow tailoring should result in a vacation of the entire injunction, rather than any modification designed to achieve narrow tailoring.

That being said, all sides agree that modifications to the district court's order have been required. Indeed, the district court anticipated this by encouraging the parties "to engage in discussions to reach a consensus on issues of spill." The federal appellants have requested that we allow them to supplement the appellate record with declarations identifying **[**40]** specific problems with the district court's injunction. The plaintiffs have opposed the motion; however, in the alternative, they have tendered supplemental declarations.

Without reviewing the tendered evidence or outlining the evidence in the record indicating that specific issues at certain sites may require modification of the preliminary injunction, we conclude that there are issues that have arisen after the issuance of the preliminary injunction that may require modification of the district court order. It is inappropriate for us to decide those questions for the first time on **[*800]** appeal, and we therefore deny the parties' motions to supplement the record. Although we conclude that the district court did not abuse its discretion in granting the preliminary injunction, we remand the question of whether modification or "narrow tailoring" of the order is required to the district court for its consideration in the first instance.

The BPA Customer Group has also argued that the district court's order should be vacated as not narrowly tailored. The basis of the BPA Customer Group's argument is different. It argues that the order insufficiently relates the remedy to the alleged **[**41]** ESA violation. Although the BPA Customer Group raised this issue in their memorandum in opposition to the preliminary injunction, the district court did not explicitly address this issue in its preliminary injunction order. In light of our decision to remand for consideration of modifications to the preliminary injunction, we also remand this question to the district court for its consideration in the first instance. We urge the parties and the district court to resolve these remanded issues as expeditiously as possible.

IV

In sum, we affirm the district court's issuance of a preliminary injunction, but remand to the district court the question of whether the injunction should be more narrowly tailored or modified.

AFFIRMED AND REMANDED.

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TAB 7

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

In the Matter of	)	
Luis Jorge Perez,	)	Docket No. 9420
Appellant.	)	

ADMINISTRATIVE LAW JUDGE DECISION ON APPLICATION FOR REVIEW

Pursuant to 15 U.S.C. § 3058(b) and 16 C.F.R. § 1.146(a), Luis Jorge Perez ("Perez" or "Appellant") appeals the final civil sanctions imposed against him by the Horseracing Integrity and Safety Authority, Inc. ("the Authority") based on a finding by an arbitrator that Appellant violated section 3214(a) of the Anti-Doping and Medication Control Program ("ADMC" or the "ADMC Program"). As set forth below, Appellant's liability under section 3214(a) and the imposed final civil sanctions are AFFIRMED.

I. BACKGROUND

A. The ADMC Program

The Horseracing Integrity and Safety Act ("HISA"), 15 U.S.C. §§ 3051-3060, empowered the Authority to develop and enforce rules and sanctions on a variety of subjects, including anti-doping and medication for horses, subject to oversight by the Federal Trade Commission ("FTC"). 15 U.S.C. §§ 3053, 3055, 3057. Implementing regulations, effective May 22, 2023, established the specific rules of the ADMC Program, including persons and animals covered by the ADMC Program, banned substances, and sanctions for violations. *See generally* 88 Fed. Reg. 5070-5201 (Jan. 26, 2023) (FTC Notice of HISA Proposed Rule and Request for Comment); Order Approving the ADMC Rule Proposed by the Authority (Mar. 27, 2023) (available at https://www.ftc.gov/system/files/ftc_gov/pdf/P222100CommissionOrder AntiDopingMedication.pdf); 88 Fed. Reg. 27894 (May 3, 2023) (FTC Notice of Final Rule,

effective May 22, 2023) (available at https://hisaus.org/regulations?modal-shown=true#equine-anti-doping-and-controlled-medication-protocol-rules) (hereafter, "ADMC Rules"). Rules for FTC oversight of the Authority, including the Authority's imposition of civil sanctions, are set forth in 16 C.F.R. § 1.145 *et. seq.*; *see* 87 Fed. Reg. 60077 (Oct. 4, 2022) (Final Rule) (hereafter, "FTC Rules").

ADMC Rule 3010(e)(1) established the Horseracing Integrity and Welfare Unit ("HIWU") to enforce the ADMC Program for the Authority. HIWU charges under the ADMC Program are adjudicated by an arbitrator. ADMC Rule 7020. Liability found and civil sanctions imposed by the Authority, including those imposed for violations of the ADMC Program, are reviewable by an FTC Administrative Law Judge. 15 U.S.C. § 3058(b); FTC Rule 1.146.

B. Procedural History

On June 13, 2023, HIWU issued Appellant an Equine Anti-Doping Notice of Alleged Anti-Doping Rule Violation based upon Appellant's alleged possession of a banned substance ("Notice Letter"). The Notice Letter imposed a provisional suspension effective as of June 14, 2023. On June 17, 2023, Appellant submitted a written response to the Notice Letter. On June 26, 2023, HIWU charged Appellant with violating the ADMC Program by possessing levothyroxine, a banned substance known as "Thyro-L." On October 9, 2023, after an evidentiary hearing held on September 18, 2023, the arbitrator appointed to adjudicate the charge against Appellant (the "Arbitrator") issued a final decision finding that Perez violated ADMC Rule 3214(a) by possessing Thyro-L (the "Decision"). The Decision determined that the appropriate sanctions for the violation should be a 14-month period of ineligibility[1] and a $5,000 fine. On October 10, 2023, HIWU sent Perez a Notice of Final Civil Sanctions under the ADMC Program, imposing the sanctions recommended by the Arbitrator, and on October 11, 2023, pursuant to FTC Rule 1.145, the Authority filed a Civil Sanction Notice with the FTC (hereafter, the "Sanctions").

[1] Ineligibility means the "Covered Person is barred for a specified period of time from participating in specified activities," "involving Covered Horses, or in any other activity . . . taking place at a Racetrack or Training Facility . . . ." ADMC Rules 1020, 3229(a)(2).

On November 9, 2023, Appellant filed a notice of appeal and application for review ("Application for Review") requesting an evidentiary hearing to contest the facts found by the Arbitrator. Appellant asserted that the Sanctions imposed upon him were arbitrary, capricious, an abuse of discretion, prejudicial, or otherwise not in accordance with law.[2] On December 11, 2023, Appellant withdrew his request for an evidentiary hearing to contest facts.[3]

On December 14, 2023, an order was issued directing each party to submit briefing limited to the legal issues raised by Appellant in connection with the civil sanctions.

On January 9, 2024, pursuant to the December 14, 2023 order, the parties each filed proposed conclusions of law, a proposed order, and supporting legal briefs. On January 19 and January 20, 2024, the Authority and Appellant, respectively, filed responses to each other's January 9, 2024 filings.

C. Summary of Applicable Law

ADMC Rule 3214(a) provides that:

> The following acts and omissions constitute Anti-Doping Rule Violations by the Covered Person(s) in question: . . . Possession of a Banned Substance or a Banned Method, unless there is compelling justification for such Possession.

As a veterinarian who treats racehorses, Appellant is a "Covered Person," and Thyro-L is a "banned substance" under the ADMC Program. ADMC Rule 1020; ADMC Rule 3020(a)(3); ADMC Rule 4310 (Prohibited Substances List). As sanctions for a first 3214(a) possession offense, ADMC Rule 3223(b) provides for a two-year period of ineligibility, a fine of "up to"

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[2] Appellant's Application for Review included a request to stay the Sanctions pending the disposition of this appeal, pursuant to 16 C.F.R. § 1.148, which the Authority opposed. FTC Rule 1.148(c) requires that an application for a stay address the factors outlined in FTC Rule 1.148(d), which are: (1) The likelihood of the applicant's success on review; (2) Whether the applicant will suffer irreparable harm if a stay is not granted; (3) The degree of injury to other parties or third parties if a stay is granted; and (4) Whether the stay is in the public interest. 16 C.F.R. § 1.148(d). By order dated November 28, 2023, Appellant's stay request was denied for failure to address all of the foregoing factors.

[3] The Authority's response to the Application for Review, filed November 17, 2023, had asserted, among other things, that Appellant failed to identify any facts that he seeks to contest and urged that Appellant's request for an evidentiary hearing be denied. On November 30, 2023, based on the Application for Review and the Authority's response, the Administrative Law Judge issued an order directing Appellant to specifically identify the material facts he was contesting. In response to that order, Appellant withdrew his request for an evidentiary hearing.

$25,000, and payment of "some or all of the adjudication costs and [HIWU's] legal costs." ADMC Rules 3224 and 3225 authorize consideration of factors that mitigate the degree of fault, where the Covered Person establishes that he or she bears no fault or negligence, or no significant fault or negligence, for the anti-doping rule violation in question.

Based on issues presented in the Application for Review, this appeal requires a determination of whether Appellant violated ADMC Rule 3214(a) and whether the Sanctions imposed by the Authority are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 15 U.S.C. § 3058(b)(2)(A)(i)-(iii); 16 C.F.R. § 1.146(b)(1)-(3). The Administrative Law Judge makes these determinations *de novo*. 5 U.S.C. § 3058(b)(1); 16 C.F.R. § 1.146(b)(1)-(3). Thus, the Administrative Law Judge must review the record and sanctions "anew," as though the issue had not been heard before, and no decision had previously been rendered. *See Freeman v. DirecTV, Inc.*, 457 F.3d 1001, 1004 (9th Cir. 2006) (describing *de novo* review by appellate court of district court dismissal of complaint under Federal Rule of Civil Procedure 12(b)(6)). *De novo* review requires an independent examination of the record. *See Agyeman v. INS*, 296 F.3d 871, 876 (9th Cir. 2002) (describing scope of *de novo* review of agency's interpretations of statute). With *de novo* review, there is no deference owed to the determinations made below. *See Barrientos v. Wells Fargo Bank, N.A.*, 633 F.3d 1186, 1188 (9th Cir. 2011) (holding that, on *de novo* review by an appellate court, there is no deference to district court).

"[T]o pass muster under the arbitrary and capricious standard," a court must only find a "rational connection between facts and judgment." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43, 56 (1983). "To make this finding the court must consider whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment." *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971). Judicial review under the arbitrary and capricious standard looks to ensure that "the agency has acted within a zone of reasonableness and, in particular, has reasonably considered the relevant issues and reasonably explained the decision." *FCC v. Prometheus Radio Project*, 141 S. Ct. 1150, 1158 (2021). Similarly, to find an abuse of discretion, the record must reveal a clear error of judgment. *Nat'l Wildlife Fed'n v. Nat'l Marine Fisheries Serv.*, 422 F.3d 782, 798 (9th Cir. 2005). An abuse of discretion is defined as "a plain error, discretion exercised to an end

not justified by the evidence, a judgment that is clearly against the logic and effect of the facts as are found." *Id.* Finally, whether the Sanctions are in accordance with the law is determined with reference to the substantive law of HISA and the implementing regulations, summarized above.

After conducting the required review, the Administrative Law Judge "(ii) may affirm, reverse, modify, set aside, or remand for further proceedings, in whole or in part, the final civil sanction of the Authority; and (iii) may make any finding or conclusion that, in the judgment of the administrative law judge, is proper and based on the record." 15 U.S.C. § 3058(b)(3)(A)(ii), (iii).

II. PROCEEDINGS BELOW

A. Summary of Material Facts

Based on the arbitration record and the briefs of the parties, the material facts are summarized as follows. Appellant is a Covered Person who provides veterinary services to both racehorses, that are covered by HISA, and other horses that are not covered by HISA. Decision ¶¶ 1.5, 2.29(1), 4.3. On June 9, 2023, after the May 22, 2023 implementation of the ADMC Program, investigators from the New York Racing Association and HIWU found two one-pound tubs of Thyro-L inside Appellant's trailer. Decision ¶¶ 2.29 (3)-(4), 7.2. Appellant had purchased the Thyro-L prior to it becoming a banned substance under the ADMC Program. Decision ¶ 7.3.

Based on training provided by HIWU prior to the effective date of the ADMC Program, Appellant knew that Thyro-L would become a banned substance upon implementation of the ADMC Program on May 22, 2023. Decision ¶¶ 2.29(2), 7.8. On March 24, 2023, HIWU's Chief of Science, Dr. Mary Scollay, conducted a seminar on the ADMC Program, its rules and regulations, and the expectations for Covered Persons. Decision ¶ 2.29(2). It was stipulated below that during her presentation, Dr. Scollay made the following comments:

> . . . [I]f the veterinarians are practicing also on a population of [N]on-Covered horses, they're taking care of quarter horses or they've got a country practice part-time they are able to possess a Banned Substance because we don't have control over those horses, and so to the extent that they want to use bisphosphonates on a Non-Covered horse, we can't ban them from possessing them . . . [W]e can't penalize people for something that we don't have control over so, you know, let's just say because we have the ability to investigate, if the story starts to get a little

> weird or a little extreme, you're going to get more than a raised eyebrow. But at the end of the day if someone is practicing out in the country, we don't have the authority to control the medications they administer or carry for Non-Covered Horses . . . [T]he regulation addresses if there is a justification for them to be in Possession of a Banned Substance and certainly a practice that incorporates Non-Covered horses.

Decision ¶ 2.29(2). There was no evidence presented at the Arbitration hearing that the Thyro-L product was used by Appellant on any horse after the implementation of the ADMC Program. Decision ¶ 7.27.

In his June 17, 2023 response to HIWU's Notice Letter, Appellant asserted that he accepted responsibility for possessing the substance and that his offense was not intentional, but rather was due to having forgotten that the Thyro-L was in his trailer. Decision ¶ 2.29(7); *see also* June 17, 2023 response ("The truth is I completely forgot it was there as it had not been touched in almost 6 months.").

B. Arbitrator's Decision

In determining Appellant's liability for possession under ADMC Rule 3214(a), the Arbitrator noted that ADMC Rule 3214(a) unequivocally provides that possession of a banned substance is an anti-doping rule violation "unless there is *compelling* justification for such possession." Decision ¶ 7.13 (emphasis in original). The Arbitrator noted that neither Dr. Scollay nor anyone at HIWU cautioned veterinarians that ADMC Rule 3214(a) required a "compelling justification" to avoid liability, or what a compelling justification meant for the possession of banned substances by covered veterinarians whose practice included non-covered horses. Decision ¶ 7.14. However, the Arbitrator determined that Appellant's asserted justification for possessing the substance – that his practice included non-covered as well as covered horses – was a "theoretical justification raised by his counsel, after the fact" because Appellant did not submit evidence that he was administering, or intending to administer, the substance to non-covered horses, and because Appellant had initially attributed his possession to mere oversight. Decision ¶ 7.15.

Having determined that Appellant violated ADMC Rule 3214(a) by possessing Thyro-L, the Arbitrator proceeded to consider whether the maximum 24-month period of ineligibility

provided under ADMC Rule 3223(b) should be eliminated or reduced due to "No Fault or Negligence" or "No Significant Fault or Negligence" pursuant to ADMC Rules 3224 and 3225. Decision ¶ 7.19. In light of Appellant's admission that he did not clean out his trailer following the HIWU seminar, the Arbitrator found sufficient negligence was established to preclude a finding of "no fault or negligence" under ADMC Rule 3224. Decision ¶ 7.22.

In determining the sanctions for Appellant's unlawful possession of Thyro-L, the Arbitrator considered several mitigating factors, including: Appellant having originally obtained Thyro-L before it became a banned substance; the absence of evidence that Appellant intended to use Thyro-L on covered horses or that he had done so; the ADMC Program was new and no veterinarians had experience under it; only one education session had been provided at Belmont Park as of June 9, 2023; and how a reasonable person may have interpreted Dr. Scollay's March 2023 comments regarding ADMC Rule 3214. Decision ¶¶ 7.26-7.29.

The Arbitrator broke down the twenty-one months of possible periods of ineligibility into three seven-month ranges, beginning with the minimum ineligibility period of 3 months,[4] as follows: slight or insignificant (3-10 months); moderate (10-17 months); and significant: (17-24 months). Decision ¶ 7.25. The Arbitrator found that Appellant's level of objective fault fell in the moderate category because: Appellant was aware Thyro-L would become a banned substance before the ADMC Program went into effect; Appellant failed to clean out his trailer as HIWU recommended; and Appellant's controlled substances were not properly stored and his trailer was disorganized, unsafe, and unsanitary. Decision ¶¶ 7.26-7.29. However, in determining sanctions, the Arbitrator applied a lower level of subjective fault and reduced the maximum allowable 24-month period of ineligibility under ADMC Rule 3223 to 14 months, given the mitigating factors discussed above. Decision ¶ 7.29. In addition, the Arbitrator reduced the fine under ADMC Rule 3223 from the allowed maximum of $25,000 to $5,000, "considering the inexperience of Dr. Perez with the ADMC Program, the limited training he received, the Agency's lack of clarity, and the absence of any impermissible use of the substance in question or any violation other than

[4] ADMC Rule 3225 provides that even "[w]here the Covered Person establishes that he or she bears No Significant Fault or Negligence for the Anti-Doping Rule Violation in question, then (unless Rule 3225(b) or 3225(c) applies) the period of Ineligibility shall be fixed between 3 months and 2 years, depending on the Covered Person's degree of Fault."

the Possession itself." Decision ¶ 7.32. Furthermore, the Arbitrator in her discretion declined to require Appellant to contribute to the adjudication costs, as requested by the Authority. Decision ¶ 7.33.

III. ANALYSIS

A. Contentions on Appeal

Appellant argues that he should not be sanctioned for possessing a banned substance under ADMC Rule 3214 because he is a veterinarian who treats both covered and non-covered horses. Appellant frames his claims as jurisdictional and "due process" ones. Specifically, Appellant argues that the Authority lacks jurisdiction over non-covered horses; therefore, Appellant cannot be held liable for possessing a banned substance because his practice includes non-covered horses. In support of his due process claim, Appellant contends that ADMC Rule 3214(a) is vague, arbitrary and capricious because covered veterinarians who also treat non-covered horses could not know whether possession of a banned substance was permitted or not, and that the Authority and HIWU did not properly inform covered veterinarians that providing a "compelling justification" would be required to avoid liability, nor how the "compelling justification" evidentiary standard would be interpreted. Accordingly, Appellant argues that the finding of liability and imposed sanctions should be reversed.

The Authority responds that a covered veterinarian who also treats non-covered horses is not automatically exempt from ADMC Rule 3214, but rather must establish a "compelling justification" to avoid liability. The Authority argues that while the administration of a banned substance to a non-covered horse *may* satisfy the "compelling justification" evidentiary standard, to meet this evidentiary standard the Appellant must put forth specific evidence that the banned substance was used for or intended to be used for non-covered horses, which Perez did not. The Authority alleges that Appellant has only put forth a "theoretical justification" for possessing Thyro-L, and that the mere statement that a covered veterinarian also treats non-covered horses is insufficient to prove "compelling justification" for possession. Moreover, the Authority argues that allowing covered veterinarians who also treat non-covered horses to be exempt from ADMC Rule 3214 through bald assertions would create a blanket exception for covered veterinarians who also treat non-covered horses that would undermine the integrity of the ADMC Program.

Accordingly, the Authority urges that the finding of liability and the imposed sanctions be affirmed.

B. Discussion

1. Liability under ADMC Rule 3214

As an initial matter, it is undisputed that Appellant is a Covered Person treating racehorses; accordingly, the Authority and HIWU have jurisdiction over Appellant and he is subject to ADMC Rule 3214. With regard to Appellant's "due process" claims, ADMC Rule 3214 clearly lays out an exception to liability for possession of banned substance where such possession has a "compelling justification." This is an evidentiary standard. Appellant has failed to support his assertion that due process requires ADMC Rule 3214 to identify factual scenarios that may meet the standard. The fact that during the educational seminar HIWU's Chief of Science did not explicitly mention the "compelling justification" standard or describe in detail how this standard would be interpreted similarly does not support a finding of a due process violation. Moreover, the mechanisms for enforcing ADMC Rule 3214 provide ample opportunities to defend against the charge of unlawful possession; first before a neutral arbitrator and now through the present appeal. For this reason as well, Appellant has failed to demonstrate he has been deprived of due process.

To the extent that Appellant's jurisdiction and/or due process claims can be construed as asserting that a covered veterinarian can establish a "compelling justification" for possession solely by demonstrating that the veterinarian's practice includes non-covered horses, without any further evidentiary inquiry, this contention is rejected. Appellant's proposal to create a blanket exemption to ADMC Rule 3214 for covered veterinarians by virtue of their treating non-covered horses contradicts the "compelling justification" evidentiary standard requirement, which by nature of the inclusion of the word "compelling," suggests the need to put forth evidence beyond an unsupported, theoretical allegation, and to analyze such evidence on a case-by-case basis. Appellant's statement that his veterinary practice includes non-covered horses, is thus not by itself a compelling justification for the possession. Accordingly, a *de novo* review of the record supports a finding of liability under ADMC Rule 3214.

2. Sanctions for violating ADMC Rule 3214

Although the Arbitrator found that Appellant's level of objective fault fell in the moderate category because of Appellant's awareness Thyro-L would become a banned substance and Appellant's failure to clean out his trailer as HIWU recommended, the Arbitrator applied a lower level of subjective fault and reduced both the maximum allowable period of ineligibility and fine under ADMC Rule 3223 to 14 months and $5,000, respectively. In making this determination, the Arbitrator considered various mitigating factors discussed above, including that Appellant initially obtained Thyro-L before it became banned; the lack of evidence that Appellant intended to or did use Thyro-L on covered horses after the ADMC Program went into effect; that the ADMC Program was new and only one education session had been provided at Belmont Park as of June 9, 2023; and that Dr. Scollay's March 2023 comments regarding ADMC Rule 3214 may have been misinterpreted. Decision ¶ 7.29. In summary, Appellant has failed to demonstrate that the Arbitrator's sanctions determination was arbitrary, capricious, an abuse of discretion, or not in accordance with applicable law. Rather, the Arbitrator appropriately applied the ADMC rules; the Decision does not reveal any "plain error," *Nat'l Wildlife Fed'n*, 422 F.3d at 798; and the Arbitrator "acted within a zone of reasonableness . . . , reasonably considered the relevant issues and reasonably explained the decision." *Prometheus Radio Project*, 141 S. Ct. at 1158.

Furthermore, an independent, *de novo* review of the record supports the Sanctions imposed by the Authority as in accordance with ADMC Rules, reasonable, and rationally related to Appellant's degree of fault. Appellant's degree of objective fault in possessing the Thyro-L after implementation of the ADMC Program was at the very least moderate. Despite having been aware through training that Thyro-L would be banned for racehorses upon implementation of the ADMC Program and having received recommendations concerning his responsibilities as a Covered Person under the ADMC Program, Appellant did not take any steps to ensure that the Thyro-L was disposed of after the ban went into effect. Further, Appellant's failure to act was not due to his belief that he lawfully possessed the Thyro-L, but rather because he forgot he had it.

Notwithstanding the foregoing, the lack of wrongful intent on Appellant's part supports a reduction in the maximum allowable period of ineligibility and fine, as demonstrated by the facts that Appellant initially acquired the Thyro-L when it was lawful to do so; the ADMC Program imposed new rules as to which there was limited training; and the lack of evidence that Appellant used the Thyro-L on a covered horse after the ban went into effect. The reduced sanctions imposed by the Authority fairly and reasonably reflect the application of the mitigating facts in the record.

IV. CONCLUSION

Having conducted the review required under 15 U.S.C. § 3058(b)(2)(A)(i)-(iii), for the reasons stated above, the finding of liability and the imposed Sanctions are AFFIRMED.

ORDERED:

D. Michael Chappell
Chief Administrative Law Judge

Date: February 7, 2024

From: TrackingUpdates@fedex.com
To: Thomas, Anita CTR
Subject: FedEx Shipment 775118468823: Your package has been delivered
Date: Monday, February 12, 2024 1:12:55 PM

FedEx

Hi. Your package was delivered Mon, 02/12/2024 at 1:05pm.

Delivered to 114 OLD COUNTRY RD 600, MINEOLA, NY 11501
Received by R.DLGROSSO

OBTAIN PROOF OF DELIVERY

How was your delivery ?

TRACKING NUMBER 775118468823

FROM Federal Trade Commission
400 7th Street SW

	Drop 5422 Washington, DC, US, 20024
TO	Robert G. Del Grosso 114 Old Country Road, Suite 600 MINEOLA, NY, US, 11501
PURCHASE ORDER NUMBER	0616
REFERENCE	D09420/609612
SHIPPER REFERENCE	D09420/609612
SHIP DATE	Thu 2/08/2024 05:36 PM
DELIVERED TO	Receptionist/Front Desk
PACKAGING TYPE	FedEx Envelope
ORIGIN	Washington, DC, US, 20024
DESTINATION	MINEOLA, NY, US, 11501
SPECIAL HANDLING	Deliver Weekday Direct Signature Required
NUMBER OF PIECES	1
TOTAL SHIPMENT WEIGHT	0.50 LB
SERVICE TYPE	FedEx International Economy®

From: TrackingUpdates@fedex.com
To: Thomas, Anita CTR
Subject: FedEx Shipment 775118579764: Your package has been delivered
Date: Monday, February 12, 2024 1:20:21 PM

FedEx

Hi. Your package was delivered Mon, 02/12/2024 at 1:13pm.

Delivered to 333 W VINE ST, LEXINGTON, KY 40507
Received by S.THOMAS

OBTAIN PROOF OF DELIVERY

How was your delivery ?

TRACKING NUMBER 775118579764

FROM Federal Trade Commission
400 7th Street SW

	Drop 5422 Washington, DC, US, 20024
TO	Bryan Beauman 333 W. Vine Street, Suite 1500 LEXINGTON, KY, US, 40507
PURCHASE ORDER NUMBER	0616
REFERENCE	D09420/609612
SHIPPER REFERENCE	D09420/609612
SHIP DATE	Thu 2/08/2024 05:36 PM
DELIVERED TO	Receptionist/Front Desk
PACKAGING TYPE	FedEx Envelope
ORIGIN	Washington, DC, US, 20024
DESTINATION	LEXINGTON, KY, US, 40507
SPECIAL HANDLING	Deliver Weekday Direct Signature Required
NUMBER OF PIECES	1
TOTAL SHIPMENT WEIGHT	0.50 LB
SERVICE TYPE	FedEx International Economy®

From: TrackingUpdates@fedex.com
To: Thomas, Anita CTR
Subject: FedEx Shipment 775118617210: Your package has been delivered
Date: Monday, February 12, 2024 11:37:25 AM

FedEx

Hi. Your package was delivered Mon, 02/12/2024 at 10:30am.

Delivered to 4801 MAIN ST 350, KANSAS CITY, MO 64112
Received by K.GILBANE

OBTAIN PROOF OF DELIVERY

How was your delivery ?

TRACKING NUMBER 775118617210

FROM Federal Trade Commission
400 7th Street SW

	Drop 5422 Washington, DC, US, 20024
TO	Michelle C. Pujals 4801 Main St, Suite 350 KANSAS CITY, MO, US, 64112
PURCHASE ORDER NUMBER	0616
REFERENCE	D09420/609612
SHIPPER REFERENCE	D09420/609612
SHIP DATE	Thu 2/08/2024 05:36 PM
DELIVERED TO	Receptionist/Front Desk
PACKAGING TYPE	FedEx Envelope
ORIGIN	Washington, DC, US, 20024
DESTINATION	KANSAS CITY, MO, US, 64112
SPECIAL HANDLING	Deliver Weekday Direct Signature Required
NUMBER OF PIECES	1
TOTAL SHIPMENT WEIGHT	0.50 LB
SERVICE TYPE	FedEx International Economy®