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Nutraceuticals in American Horseracing: Removing the Substantive Blinkers From National Racing Legislation

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NOTE

NUTRACEUTICALS IN AMERICAN HORSERACING: REMOVING THE SUBSTANTIVE BLINKERS FROM NATIONAL RACING LEGISLATION

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American horseracing is governed by thirty-eight independent state racing jurisdictions. The lack of one coordinated rulebook has been especially problematic with respect to controlled substances. Industry leaders and legal scholars ubiquitously decry American racing's "drug addiction." The Horseracing Integrity and Safety Act and Thoroughbred Horseracing Integrity Act of 2015 respond to this charge by purporting to regulate drugs and medication under federal auspices. This Note contends, however, that the bills' blinkered focus on drugs problematically ignores nutraceuticals: a class of pharmaceutical-food supplements that poses a greater existential threat to horseracing.

In a 1996 Federal Register notice, the FDA announced that the Dietary Supplement Health and Education Act, which created the first regulatory guidelines for human supplements, did not apply to animals. Although supplements that are incorporated into animal feeds must be "generally recognized as safe," there is presently no regulatory oversight of the synthesized herbs, powders, and tablets that comprise the market for animal nutraceuticals.

Nutraceuticals are pervasive in horseracing. While some are beneficial, more often, nutraceuticals jeopardize equine safety and the sport's integrity by producing physiological effects similar to drugs. Nutraceuticals also threaten to displace medications, like furosemide, an anti-bleeding agent, that are FDA approved. This Note proposes that national racing legislation be amended to regulate nutraceuticals according to the same testing and efficacy requirements as drugs. Doing so will mark the first attempt to regulate nutraceuticals for any animal and cast the 'Sport of Kings' in a rarified light: as an exemplar for animal welfare.

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I. INTRODUCTION

Horseracing is a major contributor to the U.S. economy, annually producing approximately $25 billion in GDP and generating 380,000 domestic jobs.[1] In 2014, U.S. races distributed over $1.1 billion in purses and garnered $8.7 billion in parimutuel wagering.[2] More than 26,000 foals were bred.[3] Horseracing is also a national sport: horses competing in more than one state comprised approximately 50% of the 317,000 starts made by thoroughbred horses in 2014.[4] With industry success predicated on owners winning the lion's share of purses and handicappers scoring at the betting window, the potential for performance-enhancing drugs to distort the competitive landscape is a natural subject for debate and division.

Unlike other major American sports that are privately administered, horseracing is governed by the laws of thirty-eight independent state racing jurisdictions.[5] The lone exception to this federated struc-

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[1] Thoroughbred Horseracing Integrity Act of 2015 (THIA), H.R. 3084, 114th Cong. § 2(2) (2015).

[2] *Facts and Figures: 2014*, INT'L FED'N OF HORSERACING AUTHS., http://www.horseracingintfed.com/default.asp?section=resources&area=4&FF=11&CK=E&YR=2014&key=56 [https://perma.cc/EB96-4P8Q] (accessed Dec. 22, 2016).

[3] *Id.*

[4] H.R. 3084 § 2(2).

[5] Edited Press Release, *'Common Sense Legislation': Barr, Tonko Introduce Thoroughbred Horseracing Integrity Act of 2015*, PAULICK REP. (July 6, 2015, 12:46 PM),

ture is simulcast wagering. The Interstate Horseracing Act of 1978 (IHA) mandated a uniform set of guidelines for interstate wagering.[6] Congress included neither drug nor medication regulations in the IHA. However, in recent years, prominent horse breakdowns and sordid training scandals have driven a surge of voices appealing for a federal entity to unify America's patchwork rules governing medication use in racing.[7] The Horseracing Integrity and Safety Act (HISA) and Thoroughbred Horseracing Integrity Act (THIA) of 2015 are the most recent manifestations of this effort. While the bills are procedurally distinct, they target the same substantive end: achieving uniform drug and medication rules across America's racing jurisdictions.[8]

Although HISA and THIA represent national initiatives to redress American racing's federalist conundrum, their substantive focus is blinkered. Both Congress and thoroughbred industry regulators have targeted drugs and medication to the exclusion of a comparable, if not bigger, long-term threat to equine welfare and the horseracing industry's competitive integrity.[9] Beneath their eyes churns a vibrant mar-

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http://www.paulickreport.com/news/the-biz/common-sense-legislation-barr-tonko-introduce-thoroughbred-horseracing-integrity-act-of-2015/ [https://perma.cc/92RC-SWFP] (accessed Dec. 22, 2016).

[6] *See generally* 15 U.S.C. §§ 3001–3007 (2012) (noting that it is the policy of the Congress to set uniform guidelines for interstate wagering).

[7] *See*, *e.g.*, Walt Bogdanich et al., *Mangled Horses, Maimed Jockeys*, N.Y. TIMES (Mar. 24, 2012), http://www.nytimes.com/2012/03/25/us/death-and-disarray-at-americas-racetracks.html [https://perma.cc/RQC5-XB2H] (accessed Dec. 22, 2016) (discussing, *inter alia*, America's high incidence of drug violations and injury-related breakdowns, particularly in lower-tier claiming races); Joe Drape, *PETA Accuses Two Trainers of Cruelty to Horses*, N.Y. TIMES (Mar. 19, 2014), http://www.nytimes.com/2014/03/20/sports/peta-accuses-two-trainers-of-cruelty-to-horses.html [https://perma.cc/875F-P3VY] (accessed Dec. 22, 2016) (detailing PETA's undercover investigation of trainer Steve Asmussen, who allegedly mistreated his horses and administered drugs for non-therapeutic purposes).

[8] Horseracing Integrity and Safety Act of 2015 (HISA), H.R. 2641, 114th Cong. § 4 (2015); H.R. 3084 § 5(a).

[9] Legal scholarship has similarly blinkered its focus to the issue of performance-enhancing drugs and medications in horseracing. *See* Laurel Benson, *Down the Stretch: Reining in State Approaches Toward a Universal Medication Rule for Racehorses*, 4 KY. J. EQUINE AGRIC. & NAT. RESOURCES L. 155, 155 (2012) ("[T]he most effective way to truly combat the problem of equine medication regulation is through a universal authority or . . . a uniform set of rules."); Luke P. Breslin, *Reclaiming the Glory in the "Sport of Kings"—Uniformity Is the Answer*, 20 SETON HALL J. SPORTS & ENT. L. 297, 299 (2010) ("The influx of money has caused many stakeholders . . . to compromise the health and safety of the racehorse by supplementing the typical hay and oats diet with performance-enhancing drugs and abuse of medications."); Bradley S. Friedman, *Oats, Water, Hay, and Everything Else: The Regulation of Anabolic Steroids in Thoroughbred Horse Racing*, 16 ANIMAL L. 123, 123 (2009) ("[A] pervasive federal law might be the most effective way of ending the use of anabolic steroids in horse racing."); Kimberli Gasparon, *The Dark Horse of Drug Abuse: Legal Issues of Administering Performance-Enhancing Drugs to Racehorses*, 16 VILL. SPORTS & ENT. L.J. 199, 222–23 (2009) ("The horseracing industry has had its share of performance-enhancing drug problems . . . [and] fears an outright ban on steroids . . . ."); Amy L. (Williams) Kluesner, *And They're Off: Eliminating Drug Use in Thoroughbred Racing*, 3 HARV. J. SPORTS & ENT. L. 297, 300 (2012) ("[T]he best way to restore the integrity of thoroughbred racing is for leaders

ket in nutraceuticals—a class of pharmaceutical-food supplements that are not regulated by the Food and Drug Administration (FDA) and today are used in racing with scant oversight.

This Note contends that national legislation to regulate controlled substances in American horseracing should explicitly regulate the use of nutraceuticals. Although the FDA regulates supplements that are incorporated into animal feeds, there is no pre-market requirement that nutraceutical minerals, herbs, and chemical compounds stored in powders and tablets be deemed safe and effective. American racing jurisdictions do not address equine nutraceuticals in their rulebooks, nor are nutraceuticals incorporated into the provisions of HISA or THIA. Although nutraceuticals can be beneficial, most products brand themselves as achieving drug-like effects when administered to racehorses. Performance-enhancing nutraceuticals threaten the competitive integrity of American horseracing; ineffective nutraceuticals threaten equine welfare and subject thoroughbred owners to thousands of dollars in needless veterinary expenses. The tendency for nutraceuticals to fall into one of these latter two categories—performance-enhancing or dangerous, rather than safe and therapeutic—makes it essential that they be regulated on equal terms with drugs and medication.

Section II of this Note surveys the history of drug and medication use in American horseracing, as well as the federated legal landscape that led lawmakers to introduce HISA and THIA. The Note next illustrates how HISA and THIA problematically blinker their focus on drugs and medication. Section III assesses the historical evolution of supplement regulation in the United States, which has produced a legal loophole for animal nutraceuticals. The Note then considers the science and merit of various equine nutraceuticals that purport to achieve drug-like results. Particular consideration is given to the issue of race-day furosemide—a drug that HISA aspires to phase out, yet that many veterinarians believe to be beneficial to the performance horse—and the unregulated nutraceuticals that would otherwise fill

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and organizations within the industry to adopt a nationwide ban on all medications used in racing."); Kjirsten Lee, *Transgressing Trainers and Enhanced Equines: Drug Use in Racehorses, Difficulty Assigning Responsibility and the Need for a National Racing Commission*, 11 J. ANIMAL & NAT. RESOURCE L. 23, 23 (2015) ("Tragically, the sport has been tainted by the use of steroids and painkilling drugs . . . ."); Alexandra D. Logsdon, *Unbridled "Spirits": An Integrated Analysis of the Law, the Science, and the Future of Thoroughbred Medication*, 6 KY. J. EQUINE, AGRIC. & NAT. RESOURCES L. 141, 144 (2014) ("[C]ountries dominating the international racing industry . . . have been successful in policing race day medication use in thoroughbreds."); Alexander M. Waldrop et al., *Horse Racing Regulatory Reform Through Constructive Engagement by Industry Stakeholders with State Regulators*, 4 KY. J. EQUINE, AGRIC. & NAT. RESOURCES L. 389, 407 (2012) ("Without proper pre- and post-race drug and medication testing . . . the integrity of the sport itself cannot be guaranteed."); John T. Wendt, *Horse Racing in the United States: A Call for a Harmonized Approach to Anti-Doping Regulation*, 25 J. LEGAL ASPECTS SPORT 176, 176 (2015) ("The pervasive use of injury-masking and performance-enhancing drugs in United States horse racing has created a crisis in the industry and is destroying the reputation of a once vibrant sport.").

the void. Section IV offers a three-pronged amendment to national racing legislation: first, expressly grant anti-doping agencies the authority to regulate animal nutraceuticals; second, require that nutraceutical manufacturers demonstrate their products' safety and efficacy; and third, eliminate furosemide transition rules.

II. THE ROAD TO NATIONAL REFORM

A. Historical Use of Drugs and Medication in American Horseracing

Drug use has been a phenomenon in American horseracing for a little over a century.[10] In the 1800s, European trainers purified cocaine and morphine and put these substances to use stimulating their racehorses.[11] At the turn of the twentieth century, a group of American trainers called "Yankee Alchemists" imported these stimulants from Europe to the United States.[12] Sir Barton, the first winner of America's Triple Crown, infamously became known as a "hop horse" after it was discovered that he raced on some combination of cocaine, strychnine, mercury, and morphine.[13] Acclaimed American trainer Jack Keene dominated the Russian racing circuit until a saliva sample taken from one of his horses yielded a "positive" when force-fed to a basket of frogs.[14] The irony was that these psychoactive drugs were just as often deleterious as they were performance-enhancing.[15] In one embarrassing episode, trainer William Howell's horse, Dr. Riddle, so completely lost his nerve after receiving an injection of twelve grains of cocaine that he was unable to break from the starting gate.[16]

Harry Anslinger, the first Commissioner of the Federal Bureau of Narcotics, attempted to suppress racing's nascent drug movement.[17] In 1933, Anslinger cracked down on 200 separate incidents of doping throughout the United States by arresting dozens of owners, trainers, and stable hands for trafficking drugs in violation of federal laws.[18] Florida instituted a stimulant ban and implemented mandatory saliva

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[10] Thomas Tobin et al., *Equine Drugs, Medications, and Performance Altering Substances: Their Performance Effects, Detection, and Regulation*, THOMASTOBIN (Dec. 2010), http://www.thomastobin.com/drugsmeds/drugsmeds.htm [https://perma.cc/RLH5-5DQU] (accessed Dec. 22, 2016).

[11] *Id.*

[12] *Id.*

[13] Ryan Goldberg, *A History of Drugs in Racing—Part I of A Painful Truth: A Six-Part Series on Medication and the Reform Movement in U.S. Racing*, THOROUGHBRED DAILY NEWS, May 2, 2013, at 1, http://www.thoroughbreddailynews.com/pdf/magazine/Magazine-Drugs%20in%20Racing-Part%20I.pdf [https://perma.cc/JEN5-M4AU] (accessed Dec. 22, 2016).

[14] Tobin et al., *supra* note 10 ("Some saliva was taken from Mr. Keene's horse, and presumably force-fed to the frog, which then reportedly behaved in a most un-frog-like way.").

[15] Goldberg, *supra* note 13, at 1–2.

[16] *Id.* at 2.

[17] *Id.*

[18] *Id.*

tests for horses, in which veterinarians crystallized and examined specimens under a microscope for the presence of psychoactive drugs.[19] The sentiment among regulators was clear: performance-enhancing drugs had no place in racing.

Regulators were more receptive to therapeutic medications. Dr. Alex Harthill pioneered the use of human medications on horses to relieve the stresses of racing and enable them to achieve their maximum potential.[20] Dr. Harthill treated more than twenty-five Kentucky Derby winners, including Northern Dancer, with furosemide, a controversial diuretic that reduces exercise-induced pulmonary hemorrhage (EIPH) in horses.[21] Trainers imported other therapeutic medications from Europe. In 1946, a Swiss lab synthesized Butazolidin, a precursor to Phenylbutazone (Bute), the most frequently used non-steroidal anti-inflammatory drug (NSAID) in racing.[22] American manufacturing of Bute commenced in 1957, and within three years Colorado became the first state to permit its use.[23] Richard Hite, then-state racing commissioner, justified Bute's legalization on the grounds that Colorado's horses "were sore-legged and they had races to fill."[24]

Therapeutic medications became more controversial with their overuse and abuse in the 1970s. Maryland became the first state to allow Bute and furosemide on race day; facing competitive pressures, a majority of jurisdictions followed suit.[25] As therapeutic medications gained popularity, narcotic drugs that posed as therapeutic medications surfaced on the market. One commentator noted that Sublimaze, a narcotic painkiller, gave horses "such a feeling of euphoria that they felt like they didn't have legs."[26] In the 1980s, Dr. Harthill introduced clenbuterol, a bronchodilator, which regulators soon permitted with minor restrictions.[27] Corticosteroids proliferated on the backside, prompting Dr. Greg Ferraro, Director of the University of California-Davis's Center for Equine Health, to state that "treatments designed to repair a horse's injuries and to alleviate its suffering are now often used to get the animal out onto the track to compete."[28]

The abuse of therapeutic medications led to a number of sordid scandals that raised a public outcry over equine welfare and generated considerable momentum toward national reform. The first significant episode occurred when trainer Rick Dutrow casually admitted that he administered monthly injections of the anabolic steroid Winstrol to his

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[19] *Id.*
[20] *Id.* at 3.
[21] *Id.* at 3–4.
[22] *Id.* at 4.
[23] *Id.*
[24] *Id.*
[25] *Id.*
[26] *Id.* at 5.
[27] *Id.*
[28] *Id.* at 6.

2008 Triple Crown contender, Big Brown.[29] Dutrow's comments provoked racing critics, ones who were already animated following the well-publicized breakdown of the filly Eight Belles in that year's Kentucky Derby.[30] In its provocatively titled 2012 series, *Breakdown: Death and Disarray at America's Racetracks*, the *New York Times* reported that over a three-year period, regulators caught trainers at U.S. racetracks illegally drugging horses on 3,800 separate occasions.[31] The *Times* paid particular consideration to Aqueduct Racetrack in New York, where "the prevalence of drugs" provided a "graphic illustration of how the flood of casino cash has created powerful . . . incentives to run sore, tired or otherwise unfit horses."[32] In 2013, People for the Ethical Treatment of Animals (PETA) embarked on its first significant campaign against horseracing by conducting an undercover investigation of renowned American trainer Steve Asmussen's racing stable.[33] PETA's Senior Vice President, Kathy Guillermo, alleged that Asmussen's horses were "sore, exhausted, [and] drugged . . . every single day . . . in so much pain it hurt them . . . to stand, yet they were trained and run anyway."[34]

The states tightened their regulatory regimes considerably in the wake of these scandals. Following the Dutrow episode, U.S. jurisdictions ubiquitously outlawed the administration of anabolic steroids to horses in training.[35] Another state-driven initiative was the 2013 formation of a mid-Atlantic consortium of eight jurisdictions, which uniformly agreed to winnow their rulebooks to just twenty-four permissible medications and conduct testing in accordance with the Racing Medication and Testing Consortium's most rigorous laboratory standards.[36] However, more sweeping reforms have proven difficult—just four states have adopted in full a 2011 proposal by the National Thoroughbred Racing Association (NTRA), a trade association of American horsemen, to unite all thirty-eight jurisdictions behind one "National Uniform Medication Program."[37] Part of the delay is attribu-

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[29] William C. Rhoden, *Wondering if Big Brown Steroids Use Fueled a Run at Glory*, N.Y. TIMES (June 8, 2008), http://www.nytimes.com/2008/06/08/sports/08iht-horsebig8.13554203.html [https://perma.cc/B2W9-EYQU] (accessed Dec. 22, 2016).

[30] *Eight Belles' Death Sparks Controversy*, CBS NEWS (May 5, 2008, 7:26 AM), http://www.cbsnews.com/news/eight-belles-death-sparks-controversy/ [https://perma.cc/3EU7-HMME] (accessed Dec. 22, 2016).

[31] Bogdanich et al., *supra* note 7.

[32] Joe Drape et al., *Big Purses, Sore Horses, and Death*, N.Y TIMES (Apr. 30, 2012), http://www.nytimes.com/2012/04/30/us/casino-cash-fuels-use-of-injured-horses-at-race tracks.html [https://perma.cc/A7CX-K5GJ] (accessed Dec. 22, 2016).

[33] Drape, *supra* note 7.

[34] *Id.*

[35] Bogdanich et al., *supra* note 7.

[36] Joe Drape, *Eight States Approve Medication Standard*, N.Y. TIMES (Mar. 12, 2013), http://www.nytimes.com/2013/03/13/sports/eight-states-approve-horse-racing-medication-standard.html [https://perma.cc/RG8V-TKQP] (accessed Dec. 22, 2016).

[37] Blood-Horse Staff, *Phipps: Clock Ticking on Adoption of Reforms*, BLOODHORSE (Mar. 28, 2014, 10:04 AM), http://www.bloodhorse.com/horse-racing/articles/84054/

table to slow-moving state bureaucracies.[38] In other instances, states hold out to reap the business that comes from trainers seeking a safe harbor from stringent rules.[39] Whatever the bottom-line reason, idiosyncratic guidelines persist among America's thirty-eight racing jurisdictions in what remains a divided regulatory landscape.

B. Contemporary Medication Guidelines: America's Divided Industry

The history of U.S. horseracing is pockmarked with efforts to achieve national unity. In the 1850s, initial attempts to form a national organization responsible for racing's governance foundered on the inability of northern and southern clubs to agree on a proper headquarters.[40] From 1890 to 1903, illegal gaming, race fixing, and doping at every major racecourse led to the establishment of both private and public regulatory bodies.[41] Although the Jockey Club began maintaining America's authoritative breed registry in 1866, the 1930s saw the emergence of state racing commissions that proffered idiosyncratic rules and regulations.[42] In the seminal case of *Fink v. Cole*, the New York Court of Appeals held that it was unconstitutional for the state's legislature to delegate licensing power to any private organization.[43] Other racing jurisdictions followed suit, leaving state administrative agencies in charge of the rules of racing.[44] This included the regulation of drugs and medication.

The Association of Racing Commissioners International's (ARCI) *Model Rules of Racing* offers a regulatory template for new racing jurisdictions by assigning drugs to one of five classes.[45] Classes one and two consist of the psychoactive and consciousness-altering drugs that originated in racing's early doping era.[46] The *Model Rules* strictly prohibit them, subject to hefty penalties.[47] The *Model Rules* also ban blood-doping agents, such as erythropoietin (EPO), and carbon dioxide

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phipps-clock-ticking-on-adoption-of-reforms [https://perma.cc/5T3V-J4GL] (accessed Dec. 22, 2016).

[38] *Id.*

[39] *See id.* (discussing how many states are slow to adopt horse medication reform laws often because of the slow bureaucratic process and in other cases because of special interest groups wanting to maintain the status quo).

[40] JOAN S. HOWLAND & MICHAEL J. HANNON, 31 LEGAL RESEARCH GUIDES: A LEGAL RESEARCH GUIDE TO AMERICAN THOROUGHBRED RACING LAW FOR SCHOLARS, PRACTITIONERS, AND PARTICIPANTS 4 (1998).

[41] *Id.* at 7.

[42] *Id.* at 9.

[43] Fink v. Cole, 97 N.E.2d 873, 876 (N.Y. 1951).

[44] Howland & Hannon, *supra* note 40, at 11.

[45] ASS'N OF RACING COMM'RS INT'L, MODEL RULES OF RACING 458–61 (2016) [hereinafter ARCI MODEL RULES]. The *Model Rules* are especially worthy of consideration since THIA's initial list of prohibited substances explicitly encompasses classes 1–4. H.R. 3084 § 7(b)(1)(A).

[46] ARCI MODEL RULES, *supra* note 45, at 458.

[47] *Id.* at 462. The floor penalty for first offenders is a one-year suspension, absent mitigating circumstances.

buffers that diminish lactic acid production.[48] Class three drugs may or may not have therapeutic uses and primarily affect the horse's autonomic nervous system, including their cardiovascular and pulmonary systems.[49] Bronchodilators and anabolic steroids are included among their ranks.[50] Of these, only anabolic steroids can be administered, and only out of competition to assist horses recovering from illness or injury.[51] Classes four and five mostly comprise the sort of therapeutic medications that veterinarians like Dr. Harthill first introduced in the 1970s.[52] Class four includes NSAIDs and corticosteroids, and class five comprises therapeutic medications with strict regulatory limits.[53] Although trace NSAIDs may be present in post-race samples, the permissible thresholds are exacting.[54] Furosemide regulations, while less exacting, are still strict: recipient horses must first appear on a "Bleeder List," dosage is capped at 150–500 milligrams, and official state veterinarians must perform the injections.[55]

As America's four most prominent racing jurisdictions, New York, California, Kentucky, and Florida offer a useful window into state digressions from the *Model Rules*.[56] While New York, California, and Kentucky run tight ships, subtle divisions persist across their rulebooks, and Florida remains a substantial step behind the *Model Rules*.[57] All four states uniformly prohibit class one and two substances.[58] However, whereas New York, California, and Kentucky prohibit total carbon dioxide (TCO_2) in excess of a horse's normal physiological concentration, Florida's published rules do not quantify a

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[48] *Id.* at 285, 477.

[49] *Id.* at 458.

[50] *Id.* at 459.

[51] *See id.* at 476 (explaining that where steroids are administered to assist with recovery, the horse may be placed on a "Veterinarian's List" to be monitored and, once drug concentrations in the horse's blood drop to acceptable levels, can be cleared from the list and is again eligible to race).

[52] Steve Haskin, *The History of Drugs in America*, BLOODHORSE (July 1, 2012, 7:34 PM), http://cs.bloodhorse.com/blogs/horse-racing-steve-haskin/archive/2012/07/01/the-history-of-drugs-in-america.aspx [https://perma.cc/4ESK-L74H] (accessed Dec. 22, 2016); Jim Squires, *The Doc's Legacy at the Derby*, N.Y. TIMES: THE RAIL (Apr. 30, 2009, 8:50 AM), http://therail.blogs.nytimes.com/2009/04/30/the-docs-legacy-at-the-derby/?_r=0 [https://perma.cc/6XSP-XPFE] (accessed Dec. 22, 2016).

[53] ARCI MODEL RULES, *supra* note 45, at 459–60.

[54] *Id.* at 470–72. The penalty floor commences with a combination of at least two of the following three NSAIDs appearing in a post-race sample: Flunixin (3 nanograms), Ketoprofen (1 nanogram), and Phenylbutazone (0.3 micrograms).

[55] *Id.* at 472–74.

[56] *The Greatest Horse Racecourses in the USA*, BET O'CLOCK, http://betoclock.com/prestigious-horse-racecourses-guide/ [https://perma.cc/E2XM-K6EH] (accessed Dec. 22, 2016).

[57] N.Y. COMP. CODES R. & REGS. tit. 9, § 4043.12(a)(1) (2015); CAL. BUS. & PROF. CODE § 19413.1 (West 2015); 810 KY. ADMIN. REGS. 1:018 § 20 (2015); FLA. STAT. § 550.235(2) (2015).

[58] *Id.*

regulatory threshold.[59] Class three substances also reflect divisions. As with TCO_2, and unlike the other three states, Florida does not quantify a regulatory threshold for the bronchodilator clenbuterol.[60] Further, the states diverge with respect to their out-of-competition testing of anabolic steroids: only New York and Florida set acceptable regulatory thresholds for Stanozolol; all but New York regulate Boldenone only for intact males;[61] and only Kentucky sets testosterone thresholds for fillies, mares, and geldings.[62] With respect to NSAIDs, all four states restrict Bute concentration to 2 micrograms per milliliter in post-race samples.[63] However, whereas California and Kentucky prohibit multiple NSAIDs, New York and Florida rules do not regulate acceptable thresholds in instances of NSAID "stacking."[64] With state rules divided on dosages, permissible drug combinations, and equine sex-type eligibility for treatment, it is hardly surprising that industry regulators deem national legislation the only practical alternative.[65]

In contrast to this morass of conflicting drug and medication rules, the four jurisdictions are uniformly lax with their regulation of oral supplements. The term "nutraceuticals" is not once mentioned in the states' rulebooks, either positively or negatively. New York expressly permits the use of "antibiotics, vitamins, electrolytes, and other food supplements" until post time,[66] "so long as they are administered orally and so long as they do not contain any other drug."[67] California provides that "feed supplements that do not contain prohibited drugs may be provided to the horse up until post time."[68] Kentucky's rules do not explicitly cover animal supplements, and only drug and medication administration must be recorded on veterinary reports that are sub-

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[59] *State by State Comparison of Medication and Safety Initiative Rules*, HORSE RACING REFORM, http://horseracingreform.com/default.asp?section=2&area=1 [https://perma.cc/K8T3-8WHS] (accessed Dec. 22, 2016) (displaying use of: TCO_2 and alkalizing substances).

[60] *Id.* (displaying use of: clenbuterol).

[61] *Id.* (displaying use of: anabolic steroids). "Intact" refers to horses that have not been gelded, or castrated. *The Horse*, http://www.usask.ca/wcvm/kelsey/part2/horseinfo.pdf [https://perma.cc/2JE6-JJU9] (accessed Dec. 22, 2016).

[62] HORSE RACING REFORM, *supra* note 59 (displaying use of: anabolic steroids). Respectively, fillies are female horses aged three or younger, mares are older female horses, and geldings are castrated horses. *The Horse*, *supra* note 61.

[63] HORSE RACING REFORM, *supra* note 59 (displaying use of: Phenylbutazone).

[64] *Id.* (displaying use of: multiple NSAID rule).

[65] *See* Blood-Horse Staff, *supra* note 37 (At the Jockey Club Round Table Conference in August 2013, former Jockey Club Chairman Ogden Mills Phipps stated, "[I]f the state-by-state approach failed to produce the needed changes, [the Jockey Club] would look to alternative means to implement these reforms.").

[66] "Post time" refers to the time when a horse and rider must be at the starting gate ready to race. *Glossary of Racing Terms*, SARATOGA RACETRACK, http://www.saratogaracetrack.com/about-horse-racing/glossary-terms/p.cfm [https://perma.cc/529K-8QL8] (accessed Dec. 22, 2016).

[67] N.Y. COMP. CODES R. & REGS. tit. 9, § 4043.2(a)(2) (2015).

[68] CAL. CODE REGS. tit. 4, § 1843.5(b) (2015). California does prohibit *injectable* vitamins, electrolytes, and amino acid solutions within twenty-four hours of race day. *Id.* § 1843.5(e)(1)–(3).

mitted to the state's racing commission.[69] Florida's guidelines provide that "[n]othing in this rule shall be interpreted to prohibit the use of vitamins, minerals or naturally occurring substances so long as none exceeds the normal physiological concentration in a race day specimen."[70] This last provision is especially perplexing, as its terms define *normal* with respect to the typical thoroughbred entrant and not an independent scientific standard (if there can even be a scientific norm for vitamin and mineral concentration in a race-day thoroughbred).

C. Shared Blinkers: HISA and THIA Approaches to Drug Regulation

The two contesting legislative initiatives to bring uniformity to American horseracing, HISA and THIA, serve as an ironic reflection of the sport's divided landscape. Yet, while procedurally distinct, the two share the same substantive focus.[71] A review of the bills' terms, findings, and sponsor commentary reveals that legislators, like state regulators, have blinkered their focus on drugs and medication to the exclusion of nutraceuticals.

HISA purports to deliver the rules of racing into the hands of the U.S. Anti-Doping Agency (USADA), which governs the Olympic games.[72] The USADA would serve as the "independent anti-doping organization . . . responsib[le] for ensuring the integrity and safety of horseraces that are the subject of interstate off-track wagers."[73] The USADA would maintain rules with respect to "substances, methods, and treatments" that may or may not be "administered to a horse participating in such a horserace."[74] By contrast, THIA purports to establish a separate "Thoroughbred Horseracing Anti-Doping Authority" (THADA) responsible for "developing and administering an anti-dop-

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[69] 810 KY. ADMIN. REGS. 1:018 § 17 (2015). I write "explicitly" because Kentucky's rules do provide that "[w]ithout the prior permission of the commission . . . a drug, medication, or substance that has never been approved by the United States Food and Drug Administrative for use in humans or animals shall not be possessed or used." *Id.* § 20(2). At surface level, this could be interpreted as a progressive measure that regulates nutraceuticals and other supplements. In practice, the provision carries a more limited effect. As is discussed *infra* with respect to HISA and THIA, racing statutes sometimes juxtapose the open-ended term *substances* next to drugs and medication with the intention of encompassing unorthodox substances that manufacturers market as drugs. As Section III establishes, animal nutraceuticals that purport to benefit an animal's physiological structure or function are not subject to an up-or-down FDA approval decision; only products that carry disease prevention claims are subject to premarket approval. So Kentucky's focus is really on 'substances' that manufacturers brand as drugs and not oral nutraceuticals.

[70] FLA. STAT. § 550.2415(7)(f) (2015).

[71] *See* H.R. 3084 § 2(7) (explaining the need for "the establishment of an independent anti-doping organization . . . to deter the commission of anti-doping rule violations"); H.R. 2641 § 2(6) (explaining that the "use of performance-enhancing drugs in horseracing is widespread").

[72] H.R. 2641 § 4(g).

[73] *Id.* § 4(a).

[74] *Id.* § 4(b)(1)(A)–(B).

ing program."[75] However, in practice, the newly created THADA would operate as a USADA adjunct, governed by both USADA board members and representatives from horseracing's different constituencies.[76] Both bills require the respective anti-doping authorities to obtain feedback from industry representatives as new rules are developed.[77]

On the surface, "substances, methods, and treatments" and "anti-doping program" seem vague enough to equip the prospective racing authorities with regulatory flexibility. However, when read in conjunction with the Acts' terms and findings, it becomes clear that their central legislative focus is drugs and not nutraceuticals.[78] HISA's findings stress that "[t]he use of performance-enhancing drugs in horseracing is widespread in the United States, where no uniform regulations exist with respect to the use of, and testing for, performance-enhancing drugs in interstate horseracing."[79] The bill calls attention to the fact that "nearly every horse . . . is injected shortly before racing with furosemide," an anti-bleeding drug.[80] Beyond regulating specific drugs, two of HISA's motivating forces are the 2012 *New York Times* investigation, which the bill concludes established a link between fatalities and "the misuse of permitted medication and abuse of illegal drugs," as well as a 2013 study which found that "a large majority of parimutuel wagering participants avoid wagering at certain tracks . . . because they assume illegal drug use affects race results."[81]

THIA goes a step further than HISA by providing that THADA's initial list of prohibited substances will include the ARCI *Model Rules*' "class 1, 2, 3, and 4 drugs, medications and substances."[82] THIA finds similarly to HISA that "[b]ecause the various States have been unable to adopt a national uniform anti-doping program, national uniform regulations with respect to the use of, and testing for, drugs . . . and therapeutic medications . . . should be implemented."[83] Also noteworthy is that both bills rely heavily on USADA, an organization whose mission is to keep human athletic events "clean and free from the use of performance-enhancing drugs."[84]

The bills' sponsors echo these drug-focused findings and provisions.[85] Congressman Andy Barr, co-chairman of the Congressional

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[75] H.R. 3084 § 5(a).

[76] *Id.* § 5(b).

[77] H.R. 3084 § 6(a) (requiring a notice-and-comment protocol with industry representatives); H.R. 2641 § 4(e) (requiring consultation with industry representatives).

[78] H.R. 3084 § 2; H.R. 2641 § 2.

[79] H.R. 2641 § 2(6).

[80] *Id.* § 2(4).

[81] *Id.* § 2(7)–(8).

[82] H.R. 3084 § 7(b)(1)(A).

[83] *Id.* § 2(4).

[84] U.S. ANTI-DOPING AGENCY, 2014 ANNUAL REPORT 2 (2015).

[85] Prominent thoroughbred industry leaders also perceive the bills as drug-focused. *See* Edited Press Release, *supra* note 5 (quoting Arthur B. Hancock III, co-founder of the 1,200-member Water Hay Oats Alliance and reform lobbyist: "[T]he horse industry has finally come together to work for meaningful drug reform and uniformity across its

Horse Caucus and THIA sponsor, stated upon the bill's introduction that "we must tear down the silos that divide the industry and replace the existing state-by-state system of conflicting and inconsistent rules with a national uniform medication program."[86] Fellow THIA sponsor and Congressional Horse Caucus co-chairman, Paul Tonko, noted that "[t]he racing industry has taken significant steps toward medication reform in the past several years, and this legislation will build on that progress by providing a uniform, national solution."[87] Congressman Joe Pitts, HISA sponsor, focused his commentary more on the issue of race-day medication than general drug use: "The American horse racing industry needs to align its standards with the international rules that prohibit drug use on race day."[88]

In attempting to discern the meaning of "substances, methods, and treatments" and "anti-doping program," the statutory canon *noscitur a sociis* points to drugs and medication. Lest any doubt linger about the meaning of these provisions, the sponsors unambiguously gear their parol commentary to drugs.[89] The bills indicate that the list of prohibited substances can be updated through consultation with industry leaders.[90] But what is the likelihood of industry leaders pushing to regulate nutraceuticals when current state rules either overlook or shield them?

III. OUT OF SIGHT, OUT OF MIND: AMERICAN HORSERACING'S MARKET FOR NUTRACEUTICALS

Both Congress and horseracing's state regulators have blinkered their focus on drugs and medication to the exclusion of nutraceuticals. As a consequence, they are either unaware of, or willfully ignoring, a significant threat to equine welfare and the sport's competitive integrity. The following section sheds light on this threat by first reviewing how Congress and the FDA created a legal loophole for animal nutraceuticals that omitted them from federal regulatory oversight; next considering the impact that nutraceuticals can have on equine physiology; and finally, illustrating the danger of nutraceuticals supplanting the safe and regulated use of race-day furosemide.

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38 racing jurisdictions."); James L. Gagliano, *Restoring Integrity to Horse Racing*, THE HILL (Sept. 14, 2015, 5:00 PM), http://thehill.com/blogs/congress-blog/253426-restoring-integrity-to-horse-racing [https://perma.cc/V2TY-VPG5] (accessed Dec. 22, 2016) (praising the USADA's "[u]nparalleled experience developing regulations for performance-enhancing drugs").

86 Edited Press Release, *supra* note 5.

87 *Id.*

88 Pat Raia, *Proposed Bill Calls for Federal Anti-Doping Racing Rules*, THE HORSE (June 17, 2015), http://www.thehorse.com/articles/35951/proposed-bill-calls-for-federal-anti-doping-racing-rules [https://perma.cc/WZP7-GFMD] (accessed Dec. 22, 2016).

89 Edited Press Release, *supra* note 5.

90 H.R. 3084 § 7(b)(3); H.R. 2641 § 4(e).

A. Historical Regulation of Supplements for Humans and Animals

Since its founding, the FDA has regulated dietary supplements and drugs.[91] A drug is an "article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease."[92] For humans, "[d]rugs are subject to vigorous premarket testing, involving lengthy double-blind studies, to determine both their safety and therapeutic potential."[93] New animal drug applications are even more precise: they must contain reports of scientific investigations showcasing the drug's safety and effectiveness, a full delineation of the drug's components, and a full description of the drug's manufacturing and packaging process.[94] Combination drugs must prove both the drug's effectiveness for use and the contribution of each active ingredient to the drug's claimed effects.[95]

Until 1994, the FDA attempted to impose similar restrictions on dietary supplements.[96] The Federal Food, Drug, and Cosmetic Act of 1938 (FDCA) initially enabled the FDA to "establish[ ] 'detailed labeling requirements' for foods marketed for 'special dietary uses.'"[97] Congress furthered its regulation of food products with passage of the Food Additives Amendment of 1958 (FAA), an amendment to the FDCA. The FAA required additives, or "any substance the intended use of which results . . . in its becoming a component or otherwise affecting the characteristics of any food," to be generally recognized as safe before entering the market.[98] Although Congress had limited intentions, the FDA used the amendment to more aggressively target food-fortifying supplements for humans and animals, both before and after these supplements entered the market.[99] In 1991, after fatal side effects were linked to dietary supplements containing the amino acid L-tryptophan, an FDA taskforce recommended further regulatory action

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91 Rahi Azizi, *"Supplementing" the DSHEA: Congress Must Invest the FDA with Greater Regulatory Authority over Nutraceutical Manufacturers by Amending the Dietary Supplement Health and Education Act*, 98 CAL. L. REV. 439, 439 (2010).

92 21 U.S.C. § 321(g)(1)(B) (2012).

93 Azizi, *supra* note 91, at 440.

94 21 U.S.C. § 360b(b)(1)(A)–(D) (2012).

95 *See id.* § 360b(d)(4)(A) (requiring "animal drugs contain[ing] more than one active ingredient . . . to establish that . . . each of the active ingredients . . . used in the combination provides appropriate concurrent use . . . [and] substantial evidence that . . . [the] animal drugs make a contribution to the labeled effectiveness").

96 *See* Azizi, *supra* note 91, at 443 (noting that in 1994, Congress halted the FDA's efforts by codifying its "desire for reduced regulation of dietary supplements").

97 *Id.* at 442 (quoting Laura A. Khatcheressian, *Regulation of Dietary Supplements: Five Years of DSHEA*, 54 FOOD & DRUG L.J. 623, 624 (1999)).

98 H.R. 13254, 85th Cong. § 2(s) (1958).

99 *Id.* § 409(a)–(c) (outlining the FAA's watershed pre-market requirements for food additives); Robert E. Nowak, *DSHEA's Failure: Why a Proactive Approach to Dietary Supplement Regulation Is Needed to Effectively Protect Consumers*, 2010 U. ILL. L. REV. 1045, 1054–55 (2010).

to classify dietary supplements as drugs and not food and thereby achieve stronger oversight.[100]

The dietary supplement industry spearheaded a lobbying campaign to block this effort, which culminated with passage of the Dietary Supplement Health and Education Act of 1994 (DSHEA).[101] The DSHEA reflected Congress's desire to impose a "rational Federal framework" that did not hoist "unreasonable regulatory barriers limiting or slowing the flow" of supplements to consumers.[102] The DSHEA amended the FDCA by defining supplements as products "intended to supplement the diet" that contained one or more of vitamins, minerals, herbs, botanicals, amino acids, or dietary substances to increase total dietary intake.[103] The DSHEA placed supplements under a distinct regulatory regime, which allowed manufacturers to make qualified "health claims" that could not otherwise be made for foods, and also to imply drug-like effects through "structure/function claims" describing the products' benefits on a physiological function or system.[104] Dietary supplement manufacturers were no longer obligated to demonstrate the safety or efficacy of their products through clinical testing.[105] The FDA could prevent the release of a human dietary supplement if it posed "a significant or unreasonable risk" of harm to the consumer.[106] The burden rested with the FDA to prove that a supplement was unsafe before the agency removed it from the market.[107] As a consequence, supplement manufacturers marketed their products to consumers without FDA review or approval.[108]

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[100] *See* Azizi, *supra* note 91, at 443 ("In response to the [L-tryptophan outbreak], the FDA [sought] to implement a new regime that would allow it to evaluate uniformly the safety profile of dietary supplements.").

[101] *See id.* ("[T]he dietary supplement industry [advocated for] the adoption of new legislation that would expressly limit the FDA's ability to require premarket testing for dietary supplements. Congress [subsequently] passed the Dietary Supplement Act, which forced the FDA to 'promulgate rules . . . reiterating that the FDA would treat dietary supplements as conventional food.'").

[102] Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, §§ 2(13), 2(15)(B), 108 Stat. 4325, 4326 (1994).

[103] 21 U.S.C. § 321(ff)(1)(A)–(E) (2012).

[104] Kristen N. Nichols, *Nutraceuticals: In the Realm of Consumer Protection, Is the United States' Regulation Too Much or Not Enough?*, 9 MICH. ST. U. J. MED. & L. 369, 373–74 (2005).

[105] Azizi, *supra* note 91, at 444. Supplements containing "new dietary ingredients" must be accompanied by information provided to the Secretary "which is the basis on which the manufacturer . . . has concluded that [the supplement] . . . will reasonably be expected to be safe." 21 U.S.C. § 350b(a)(2) (2012).

[106] 21 U.S.C. § 342(f)(1)(A) (2012).

[107] *Id.* § 342(f)(1).

[108] Azizi, *supra* note 91, at 444. The DSHEA opened the consumer floodgates to the U.S. dietary supplement industry. Over 1,000 manufacturers market approximately 29,000 supplements to some 150 million American consumers in what is today a $20 billion industry. Richard Potomac, Note, *Are You Sure You Want to Eat That?: U.S. Government and Private Regulation of Domestically Produced and Marketed Dietary Supplements*, 23 LOY. CONSUMER L. REV. 54, 57 (2010). The FDA has attempted to circumvent the DSHEA with little success. Since the DSHEA's enactment, only ephedra

Fearing that food animals would be contaminated as a result of lax oversight of supplements, in 1996, the FDA issued a Federal Register notice announcing that the DSHEA did not apply to "products intended for use in animals."[109] The FDA reasoned that Congress intended "that the [DSHEA] apply only to humans" and that "public health will be better protected if ingredients in animal supplements are not subject to the special treatment."[110] The notice flagged the disconcerting potential for such products to leave "harmful residues in food."[111] Animal welfare was also a concern: "[V]ery few substances that meet the criteria of [a 'dietary supplement'] have any established history of safe use in any animal."[112] The 1996 notice's upshot was that the Food Additives Amendment would still regulate dietary supplements incorporated into animal feeds.[113]

The FDA "cooperates with the Association of American Feed Control Officials (AAFCO) and the states for the implementation of uniform policies for regulating the use of animal feed products,"[114] which includes uniformly defining feed ingredients and ensuring safe use through proper labeling.[115] However, enforcement is often lacking—particularly for animals, like horses, that are not an American consumer delicacy. The FDA concedes that "the ultimate responsibility for the production of safe and effective animal feed products lies with the manufacturers and distributors of the products."[116] The FDA primarily concerns itself with "monitoring for contaminants, establishing a list of safe additives, and regulating medicated feeds."[117] Marketed equine feed additives include "antioxidant mixtures [and] direct-fed microbials."[118] Other feed additives address deficiencies by providing

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has been banned from the market—a victory won only after the supplement was linked to numerous deaths and 16,000 adverse events during the years that it was legally sold to U.S. consumers. *Id.* at 60. In *Pearson v. Shalala*, the D.C. Circuit Court of Appeals significantly curtailed the FDA's oversight authority by holding that the First Amendment protects potentially misleading health claims that are curable through disclaimers. 164 F.3d 650, 657 (D.C. Cir. 1999). As a result, the FDA relies on frequent public warnings about the dangers of certain dietary supplements as the only way to protect consumers. Nowak, *supra* note 99, at 1074.

109 Inapplicability of the Dietary Supplement Health and Education Act to Animal Products, 61 Fed. Reg. 17,706, 17,706 (Apr. 22, 1996).

110 *Id.* at 17,707.

111 *Id.*

112 *Id.*; 21 U.S.C. § 321(ff)(1)–(2).

113 *Animal Food & Feeds: Product Regulation*, FDA, http://www.fda.gov/AnimalVeterinary/Products/AnimalFoodFeeds/ucm050223.htm [https://perma.cc/N47E-QYDB] (updated Feb. 23, 2015) (accessed Dec. 22, 2016).

114 *Id.*

115 *Id.*

116 *Id.*

117 ELEANOR M. KELLON, HORSE JOURNAL: GUIDE TO EQUINE SUPPLEMENTS AND NUTRACEUTICALS, at x (2008).

118 Lynn M. Tiffany, *Establishing Nutraceutical Safety and Efficacy*, VETERINARY PRACTICE NEWS (Jan. 24, 2013, 5:39 PM), http://www.veterinarypracticenews.com/January-2013/Establishing-Nutraceutical-Safety-And-Efficacy/ [https://perma.cc/4AV3-EWT4] (accessed Dec. 23, 2016).

essential nutrients such as calcium, phosphorus, magnesium, iron, and other basic vitamins.[119]

Confronting a transformed regulatory landscape for human supplements, the FDA successfully preserved its regulatory regime for animal feed additives. However, the FDA's 1996 notice failed to address a class of supplements that straddles the line between food and drug. There is currently no federal regulatory oversight of animal nutraceuticals.[120] Nutraceuticals, generally, are orally administered substances supposed to have pharmaceutical properties.[121] "Some nutraceuticals are vitamins and minerals that are normally [found in horse feeds] at some minor level, but when fed at a higher dosage are reputed to confer some specific benefit."[122] Other nutraceuticals are herbal substances that are believed to have helpful effects based on their use in humans.[123] Still others are chemical compounds.[124]

The DSHEA, however lax, at least regulates human supplements that are not intended for use in food.[125] The FDA's effort to shield food animals from this weak regulatory regime paradoxically opened a legal loophole for supplements that are not incorporated into animal feeds. Animal nutraceuticals are not subject to the FDA's pre-market testing requirements.[126] At best, the FDA and AAFCO may investigate nutraceuticals whose labels carry drug claims—"express or implied claims that establish the intended use to cure, treat, prevent or mitigate disease."[127] But such oversight is easy to evade through strategic labeling.[128] For example, glucosamine nutraceuticals brand themselves as substances that "'support[ ]' proper joint cartilage development" (a structure/function claim that need not be substantiated for animals) rather than "prevent or alleviate joint pain, swelling, arthritis, or improve joint function" (a disease prevention claim that would re-characterize the nutraceutical as a drug, and thus, require substan-

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119 KELLON, *supra* note 117, at ix.

120 *See id.* at x (stating that animal nutraceuticals not listed as basic nutrients required for life are not regulated in their method of manufacture, potency, safety, or efficacy).

121 Karen Briggs, *Nutraceutical Supplements*, THE HORSE (Feb. 1, 2000), http://www.thehorse.com/articles/10219/nutraceutical-supplements [https://perma.cc/495N-9DS6] (accessed Dec. 23 2016).

122 *Id.*

123 *Id.*

124 *Id.*

125 Nowak, *supra* note 99, at 1054.

126 *See* FDA, *supra* note 113 ("[A]ny article that is intended to be used as an animal feed ingredient, to become part of an ingredient or feed, or added to an animal's drinking water is considered a 'food' and thus, is subject to regulation.").

127 *Id.*

128 *See* Briggs, *supra* note 121 ("[T]he labels and the advertising for nutraceutical supplements often aren't much help in accurately describing the purpose and the action of the supplement, or guaranteeing you that A) the claimed dosage is what's in there, or B) an effective dosage for horses has really been determined in the first place!").

tiation).[129] Most nutraceuticals have limited-to-no research validating their effects.[130] Today, far more animal supplements fall into the category of unregulated nutraceuticals than regulated feed additives.[131]

B. Nutraceuticals and the Performance Horse

The animal nutraceutical industry's growth has profoundly influenced American horseracing. In a 2000 article in *The Horse*, equine nutritionist Karen Briggs described the nutraceutical phenomenon:

> Every tack shop, every feed store, every veterinarian's mobile dispensing van is virtually bulging with them these days—the buckets, tubs, and bottles of nutritional supplements available for your horse. Every horse magazine, including this one, is splashed with eye-catching ads claiming miracle results when you feed Supplement X. One promises improved hoof growth, another explosive performance benefits, and still another better lubricated joints. Some are composed of "all-natural" ingredients with soothing names like meadowsweet and fennel; others have high-tech components you can't pronounce, like polysulfated glycosaminoglycans. It's no wonder we poor owners are a bit bewildered.[132]

Many of these nutraceuticals may be good for horses. Yet, because they are not subject to pre-market testing, owners have no way of knowing whether they are safe or effective. More problematically, nutraceuticals that may be beneficial to the horse in small doses jeopardize equine welfare when overused.

Horseracing's incentives drive the overuse and abuse of nutraceuticals, much as they do with drugs. Improvements in thoroughbred performance are subtle, and "only a fraction of a second in a final race time can make a tremendous difference in earning potential."[133] Many trainers line up to pay for supplements that may or may not have even a small effect.[134] Dr. Brian Nielsen reported being told by one trainer, "I don't know if it works, but if it does, I want to have the same advantage other trainers have."[135] Training is a difficult lifestyle between the obvious fact that not all horses can compete at the highest

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[129] Jeannie Perron & Eugene I. Lambert, *DSHEA and Structure/Function Claims for Animal Feed*, 55 FOOD & DRUG L.J. 151, 159 (2000) (quoting Dr. Stephen F. Sundlof, Director, CVM, FDA, speech presented at the Pet Food Institute's 41st Annual Industry Meeting, Chicago, IL (Oct. 26, 1998) (available through FOI request to FDA)).

[130] Tiffany, *supra* note 118. Several third-party entities, such as the National Animal Supplement Council and the Nutraceutical Alliance, research the merit of equine nutraceuticals and endorse products that are proven safe and effective. However, these entities have no regulatory authority to foreclose the sale of products that are unsafe or make false claims. *Id.*

[131] *Id.*

[132] Briggs, *supra* note 121.

[133] Brian D. Nielsen, *Nutraceuticals: Their Emerging Role in Equine Nutrition*, ENGORMIX (Oct. 25, 2006), http://en.engormix.com/MA-equines/nutrition/articles/nutraceuticals-their-emerging-role-t220/p0.htm [https://perma.cc/9R58-462H] (accessed Dec. 23, 2016).

[134] *Id.*

[135] *Id.*

level and owners' demands for a return on their investments. Drugs can only enter the market once their safety and efficacy have been demonstrated; staunch, if disparate, regulations at the state level diminish the incentive to abuse them. Between the gap in FDA oversight and the complete inattention of industry regulators who blinker their focus on drugs and medication, there is presently no entity overseeing American horseracing's market for nutraceuticals.

Although many veterinarians write off nutraceuticals as black magic, one scientific study has shown that they are capable of improving performance. Seeking to overcome the "little scientific data about the effects of continuous supplementation with nutraceuticals over [a] horse's health and performance," a team of Brazilian molecular biologists researched the effects of nutraceuticals in 2010.[136] The researchers divided nineteen gelded horses into nutraceutical and placebo groups that received equivalent feeding regimens and completed similar exercise programs.[137] The lone difference in care was that the first group received its pellets with a compound nutraceutical.[138] The nutraceutical purported to increase muscle mass; however, the twelve-week program produced no demonstrable change in body composition between the two groups.[139] Instead, the test group saw statistically significant changes in blood parameters, including a larger red blood cell count, hematocrit, and blood glutamine concentration.[140] This uptick in red blood indexes and plasma amino acid concentration facilitated oxygen and nutrient transport through tissues, "leading to improvement in . . . horse performance."[141] The study concluded with the caveat that despite the nutraceutical producing a statistically significant improvement in performance, "[t]he absence of information about quality and efficacy . . . may contribute to mistakes in [a] horse's nutrition program."[142]

The Brazilian study showcased a cross-section of the nutraceutical phenomenon's most troubling aspects: nutraceuticals can be effective, though not always as advertised, they are potentially performance-enhancing, and they can compromise equine welfare if administered without considering overall nutrition.[143] Although scientific studies substantiating the effectiveness of nutraceuticals are lacking in the United States, countless nutraceuticals get marketed as alternatives

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136 Hélio Cordeiro Manso Filho et al., *Supplementation with Nutraceuticals Produces Changes in Working Horse's Blood Parameters but Not in Their Body Composition*, 38 ACTA SCIENTIAE VETERINARIAE 299, 299 (2010) (discussing how, just as U.S. law enables nutraceuticals to have nearly unfettered market access, so in Brazil, "[it] is possible to buy hundreds of different products, but there is no[ ] private or state regulation over production and quality of these products[ ]").

137 *Id.* at 300.

138 *Id.*

139 *Id.* at 303.

140 *Id.* at 302–03.

141 *Id.* at 303.

142 *Id.* at 299.

143 *Id.* at 209, 302–03.

to drugs.[144] Four of the most prominent categories are joint, anti-inflammatory, muscle, and blood-building nutraceuticals.[145]

1. "Natural" Joint Health Without the Cortisone Injection

A prominent line of nutraceuticals addresses degenerative joint disease (DJD), a term referring to cartilage breakdown in the horse's joints that leads to arthritis and eventual lameness.[146] Joint nutraceutical manufacturers report benefits, including all of decreased stiffness, improved lameness scores, reduced joint heat and swelling, and reduced need for injectable joint products.[147] Advocates also assert that these nutraceuticals effectively combat degenerative arthritis and back problems.[148]

"Chondro-protective" joint nutraceuticals brand themselves with the structure/function claim of providing "components that make up healthy cartilage."[149] Many purport to be organic sources of glycosaminoglycans (GAGs), the collagen fibers that form a lattice within cartilage and contribute to elasticity.[150] Chondroitin sulfate is an organic source of GAGs and is reputed to improve joints by inhibiting enzymes that escalate cartilage breakdown.[151] The substance is commonly synthesized through shark cartilage and bovine tracheal cartilage (perhaps, unsettlingly, turning a natural herbivore into an omnivore).[152] One product called EquuSea, which derives from sea cucumber extract, showcased in human trials an anti-inflammatory effect equivalent or superior to corticosteroids.[153] Glucosamine, an amino

144 *See* Briggs, *supra* note 121 ("The trouble is that for the vast majority of these products, little or no independent equine research has been done, or is likely to be done[.]"); *see, e.g.*, *Bute-Less Pellets*, VALLEYVET.COM, https://www.valleyvet.com/ct_detail.html?pgguid=4e405705-eb5c-4fe9-bfa5-554e5ec9ea2f [https://perma.cc/EYY6-BETX] (accessed Dec. 23, 2016) (selling a product called "Bute-Less Pellets").

145 KELLON, *supra* note 117, at x–xi.

146 Briggs, *supra* note 121.

147 KELLON, *supra* note 117, at 177. While this section considers oral joint nutraceuticals, most of the same ingredients are contained in injectable joint products. Two prominent drugs, Adequan and Legend, are FDA approved and more effective in scientific testing than their oral counterparts. Grant Miller, *Adequan vs. Legend vs. Pentosan*, HORSE J. (Apr. 4, 2014), http://horse-journal.com/article/adequan-legend-pentosan-16151 [https://perma.cc/ZM8K-QRGV] (accessed Sept. 5, 2016). A phenomenon called "bioavailability" limits the ability of oral nutraceuticals to disperse throughout the horse's body. *Id.* Through intramuscular and intravenous injections respectively, Adequan and Legend bypass digestion and are directly absorbed. *Id.* However, because the products are transparently effective 'drugs,' state regulators restrict Adequan and Legend from use in competition, while oral nutraceuticals avoid regulatory scrutiny. *See, e.g.*, N.Y. COMP. CODES R. & REGS. tit. 9, § 4043.2(a)(2) (2016) (providing that supplements are permitted for use until race time, "so long as they do not contain any other drug or by their nature, exhibit drug-like properties.").

148 KELLON, *supra* note 117, at 168.

149 Briggs, *supra* note 121.

150 *Id.*

151 *Id.*

152 *Id.*

153 KELLON, *supra* note 117, at 179.

sugar found naturally in articular cartilage, can stimulate matrix synthesis through the regulation of arthritic cartilage cells.[154]

Nutraceuticals that combine chondroitin and glucosamine are both fast acting and effective in blocking or reversing cartilage breakdown.[155] Glucosamine accumulates in cartilage and is detectable in synovial fluid at least twelve hours after dosing.[156] Higher levels accumulate in inflamed joints, and low dosages inhibit cartilage degradation.[157] In one study, researchers that administered glucosamine-chondroitin sulfate nutraceuticals to horses suffering from DJD reported improvements in lameness grade, flexion test, and stride length.[158] However, when fed to clinically normal horses, benefits were minimal.[159]

Nutraceuticals that add hyaluronic acid (HA) to chondroitin-glucosamine compounds can yield an even better response.[160] HA primarily serves as a barrier to fibronectin, a substance that triggers the breakdown of cartilage cells.[161] Dr. Eleanor Kellon, an equine nutraceutical specialist, discovered in field trials that Chondrogen EQ, a product combining glucosamine, chondroitin, HA, and manganese, yielded significant improvement in lameness grades.[162] Other high-potency HA products, such as Conquer and Celadrin, redressed acutely inflamed joints and produced improvements of 1.5 to 2 lameness grades in just two weeks.[163] Dr. Kellon tested Conquer on a 9-year-old racehorse with chronic arthritis problems and a 2-year-old in race training with synovitis in multiple joints. After five weeks of consistent treatment, the 2-year-old had no further problems.[164] Double-dosing Conquer on the 9-year-old the day before and day of speed work eliminated the

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154 Nielsen, *supra* note 133.

155 *See* KELLON, *supra* note 117, at 167 (discussing hyaluronic acid and the combination of glucosamine and chondroitin); Kathleen Crandell, *Nutraceuticals and the Horse*, EQUINEWS (Apr. 30, 2014), http://www.equinews.com/article/nutraceuticals-and-horse [https://perma.cc/SP6Q-BXAR] (accessed Dec. 23, 2016) (discussing various nutraceuticals available for horses and their effectiveness).

156 Crandell, *supra* note 155.

157 *Id.*

158 Nielsen, *supra* note 133.

159 *Id.*; KELLON, *supra* note 117, at 172.

160 KELLON, *supra* note 117, at 168, 172.

161 *Id.* at 167.

162 *Id.* at 168. This Note relies heavily on Dr. Kellon's field trials, which are invaluable given the dearth of source materials that assess the merits of equine nutraceuticals. However, it should be noted that Dr. Kellon's work is more anecdotal than scientific. Dr. Kellon's aim is to provide a fast and ready guide for horsemen who "buy based on advertising claims." *Id.* at xi. Although she does not back up each and every product assessment with validating data, Dr. Kellon tested nutraceuticals "under real-life conditions" with participating horses "carefully screened to make sure they are appropriate for use in the field trial." *Id.* Further, Dr. Kellon did not accept advertising dollars from supplement companies whose products she deemed effective. *See id.* at xii ("*Horse Journal* does not accept advertising [and] so is not catering to advertising clients[.]").

163 *Id.* at 177, 181–82.

164 *Id.* at 176.

heat and filling problem.[165] However, the older horse regressed to her original condition once removed from treatment.[166]

2. "Natural" Anti-Inflammatories Without the Bute

The wear and tear of racing inevitably leads to pain and inflammation.[167] While drugs like Bute are effective at controlling pain, common sense dictates that trainers will investigate alternatives that are not subject to regulatory thresholds.[168] Many plant-based nutraceuticals purport to serve as anti-inflammatory agents.[169] Devil's claw, a genus of plants in the sesame family, has demonstrated NSAID-like effectiveness in equine laboratory studies.[170] Other popular ingredients in Bute substitutes are plants with naturally occurring salicylates (of the aspirin family), such as meadowsweet and white willow; herbs that influence clotting, such as yucca; and bio-flavonoids (plant-based antioxidants).[171]

Several attractively named compound nutraceuticals demonstrate pain reduction comparable to Bute.[172] These include "B-L Solution" (combining vitamin B12, devil's claw, and yucca), "Free Bute" (combining devil's claw, plant-based antioxidants, and even chondroitin), and "Pain X" (a nutraceutical incorporating the amino acid phenylalanine, which is believed to trigger endorphins).[173] Dr. Kellon's field trials found that these three products reduced pain and swelling at levels comparable to 1–2 grams of Bute, achieved rapid onset (taking full effect within twenty-four to forty-eight hours of administration), and improved lameness grades in chronically lame horses.[174] Another product, "Herbal Bute" (combining devil's claw, white willow, and meadowsweet), produced little effect even at double dosage.[175] The

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165 *Id.*

166 *Id.*

167 *See* Patricia Dowling, *Myths and Truths About Controlling Pain and Inflammation in Horses*, GOV'T OF ALBERTA, AGRIC. AND FORESTRY (Mar. 13, 2002), http://www1.agric.gov.ab.ca/$department/deptdocs.nsf/all/hrs3708 [https://perma.cc/3WBZ-YB3J] (accessed Dec. 23, 2016) ("The modern uses and common diseases of horses predispose them to conditions of pain and inflammation.").

168 U.S. PHARMACOPEIAL CONVENTION, PHENYLBUTAZONE 1 (2004); *see, e.g.*, Briggs, *supra* note 121 (advising trainers to "[r]esearch [nutraceuticals] as best [they] can").

169 KELLON, *supra* note 117, at 18.

170 *Id.* at 19–21 ("In our trial, devil's claw products once again emerged as the most potent and reliable in terms of reduction of pain in both acute and chronic problems, as well as control of swelling."); *see also* Briggs, *supra* note 121 ("[Devil's claw] has anti-inflammatory and pain-killing properties that make it a common ingredient in supplements designed to assist arthritic horses.").

171 KELLON, *supra* note 117, at 18–19; *see also* Briggs, *supra* note 121 ("Often used as a 'bute substitute,' yucca is believed to have anti-inflammatory and pain-killing properties[.]").

172 KELLON, *supra* note 117, at 20–21.

173 *Id.* at 20.

174 *Id.*

175 *Id.*

price for natural pain relief can be steep, running as high as $28.45 for 8 ounces.[176]

3. "Natural" Muscle Building Without the Anabolic Steroids

Muscle-building nutraceuticals run a wide gamut of effectiveness. Nutraceuticals containing branched-chain amino acids (BCAAs) can significantly bolster muscle growth and improve performance.[177] Nutraceuticals containing plant steroids can normalize muscle mass and body condition but do not necessarily improve performance.[178] Creatine, a product that human athletes use to build muscle, is singularly ineffective in horses.[179] Even impactful muscle builders cannot be effective without a racehorse maintaining adequate nutrition, including fresh water and sufficient calories.[180]

Beta-hydroxy beta-methylbutyrate (HMB), a product generated in muscle tissue through the amino acid leucine, serves as a building block for intramuscular cholesterol synthesis.[181] Scientists first developed HMB boosters on the theory that heavy training and exercise prevented muscle cells from making enough cholesterol for maximal growth or function.[182] Treadmill studies have shown that HMB-supplemented horses suffer less muscle tissue breakdown and condition faster.[183] Dr. Kellon considers HMB one of the best nutraceutical generators of muscle bulk and improved performance.[184] One remarkably effective nutraceutical, Su-Per HMB, improved the forearm circumference of two older racing geldings by 1.5 centimeters in two weeks and enhanced muscle definition through the neck and shoulders.[185] One of the geldings had his first win in twenty starts within that same two-week trial period.[186] BCAA Complex, another nutraceutical combining leucine with two other branched-chain amino acids, increased a 3-year-old filly's forearm circumference by 1 centimeter, relieved muscle stiffness, and enabled the filly to work more comfortably for her trainer—again, after just two weeks of treatment.[187]

Nutraceuticals containing gamma oryzanol, a plant steroid extracted from rice bran, purport to increase lean muscle mass and improve strength and endurance.[188] Gamma oryzanol is structurally

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176 *Id.*

177 *Id.* at 202; Crandell, *supra* note 155.

178 *See* KELLON, *supra* note 117, at 201, 218 (finding muscle growth in the horses studied, but no improvements in performance).

179 *See id.* at 205 (finding no change in blood or muscle levels in horses studied that were given creatine); Crandell, *supra* note 155.

180 KELLON, *supra* note 117, at 198–200.

181 Crandell, *supra* note 155.

182 *Id.*

183 *Id.*

184 KELLON, *supra* note 117, at 202.

185 *Id.* at 219.

186 *Id.*

187 *Id.* at 218.

188 Briggs, *supra* note 121.

similar to animal steroid hormones.[189] Although its anabolic (muscle building) effects remain unclear, Body Builder is a commonly used gamma oryzanol-containing nutraceutical for improving muscle definition and body condition.[190] However, racehorses supplemented with Body Builder do not see corresponding improvements in competition.[191]

Creatine nutraceutical manufacturers claim that supplementing with creatine increases muscles' creatine phosphate (PCr) concentration, which generates the muscle cells' first and fastest source of energy.[192] However, studies have failed to show either increased muscle mass or improved performance after supplementation.[193] Dr. Kellon's field trials revealed that supplementing 60 grams of pure creatine daily merely results in muscle tension, stiffness, and cramping.[194] One specific nutraceutical, Creatine XL, demonstrated no change in muscling, forearm circumference, or body condition after thirty days of low-dose feeding.[195] Any noteworthy gains only came after quadrupling the dosage.[196] Trainers that aggressively supplement their horses with creatine pay a high price for paltry gains, as these nutraceuticals cost in excess of $21 per pound.[197]

4. "Natural" Blood Building Without the EPO

Despite blood doping bans, horse trainers still look for ways to increase work capacity and reduce fatigue symptoms.[198] One category of nutraceuticals purports to mimic the effects of substances like EPO by boosting red blood cell counts.[199] More red cells mean more oxygen-carrying capacity, and consequently, more stamina.[200]

Common blood building nutraceuticals comprise relatively simple syntheses of traditional vitamins and minerals.[201] Vitamins B6 and B12 stimulate hemoglobin and red blood cell production.[202] Many contain cobalt, an essential mineral for the synthesis of vitamin B12.[203] Another common mineral is copper, which strengthens red blood cells'

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189 KELLON, *supra* note 117, at 201.
190 *Id.* at 201, 218.
191 *Id.*
192 Crandell, *supra* note 155.
193 KELLON, *supra* note 117, at 205; Crandell, *supra* note 155. Practically, it is difficult to put horses on a creatine booster, since the nutraceutical must be taken four-to-six times per day. *Id.*
194 KELLON, *supra* note 117, at 205, 232.
195 *Id.* at 218.
196 *Id.*
197 *Id.*
198 *See* Briggs, *supra* note 121 (discussing the prevalent demand for nutraceuticals that produce these effects).
199 KELLON, *supra* note 117, at 37.
200 *Id.*
201 *See id.* at 39 (listing various vitamins and minerals found in these nutraceuticals).
202 *Id.*
203 *Id.* at 37.

use of iron.[204] While in isolation these vitamins and minerals show great promise for boosting red blood cell count, Dr. Kellon's field trials have shown that combination nutraceuticals often miss the mark.[205] And there is no evidence that conclusively shows mega dosing vitamins or minerals will make a horse perform better.[206] Cobalt, while exceedingly effective, has come under scrutiny from horseracing regulators who recognize that the mineral produces effects tantamount to blood doping.[207]

Other blood-building nutraceuticals are chemical compounds that aim to facilitate cell respiration, or the exchange of gases across cell membranes, and reduce lactic acid build-up.[208] Like red blood cell boosters, most have proven ineffective.[209] In the human body, naturally occurring quantities of N-dimethylglycine (DMG) play an important role in cellular respiration.[210] Manufacturers market DMG boosters to horse owners and trainers as a means of reducing lactic acid accumulation, increasing oxygen utilization, and consequently bolstering a horse's overall tolerance to physical activity.[211] One study that assessed a DMG nutraceutical found no beneficial effects on cardiovascular function or lactate accumulation in the exercising horse.[212] Another study reported less lactate build-up in DMG-supplemented horses than among horses training in a control group, but the effects wore off in the long term.[213] That same study reported that trainers imagined results entirely disassociated from DMG's physiological effects, including subjective claims that their horses were "more aggressive," had "better appetites and attitudes," and could "recover faster from racing and training than the controls."[214]

Nutraceuticals containing carnitine also purport to reduce lactic acid production.[215] Carnitine is an essential cofactor that oxidizes

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[204] *Id.* at 39.

[205] *See id.* at 40 (noting poor results from several combinations of vitamins and minerals).

[206] *Id.* at 230.

[207] T.D. Thornton, *Cobalt: How Big a Problem in the U.S.?*, THOROUGHBRED DAILY NEWS, http://www.thoroughbreddailynews.com/cobalt-how-big-a-problem-in-us-shared-archive [https://perma.cc/PTA4-EJNR] (accessed Dec. 23, 2016). In January 2015, three prominent Australian trainers had thoroughbreds test positive for cobalt overages. *Id.* In that same month, one standardbred trainer based at New Jersey's Meadowlands racetrack had a horse test positive at five times the threshold limit for cobalt in out-of-competition testing. *Id.*

[208] Briggs, *supra* note 121; Crandell, *supra* note 155.

[209] *See* KELLON, *supra* note 117, at 232 (advising against use of N-dimethylglycine (DMG)).

[210] Briggs, *supra* note 121.

[211] Crandell, *supra* note 155. Many thoroughbred medications derive from products first used by human athletes; Russian athletes first used DMG as a "super drug" in Olympic competition. *Id.*; Briggs, *supra* note 121.

[212] Nielsen, *supra* note 133.

[213] *Id.*

[214] *Id.*

[215] Crandell, *supra* note 155.

BCAAs and facilitates oxygen transport across the red blood cells' inner mitochondrial membranes.[216] However, studies have shown that for conditioned horses, carnitine-boosting nutraceuticals are poorly absorbed after oral administration, fail to increase muscle carnitine content, and consequently improve neither muscle function nor endurance.[217]

5. The Bottom Line

While many nutraceuticals are ineffective, some demonstrably improve performance.[218] Even for nutraceuticals that have proven effective, research is minimal—and certainly, a far cry from the exacting FDA standards for new animal drugs.[219] While some nutraceuticals can balance a horse's diet in the same way as feed additives, too often the burgeoning and unregulated nutraceutical industry puts U.S. horseracing between Scylla and Charybdis: either effective nutraceuticals compromise the integrity of competition by enhancing a horse's performance in such a way that imitates the effects of prohibited drugs, or ineffective nutraceuticals jeopardize equine welfare and cost owners thousands of dollars.[220] Neither HISA nor THIA would stop a desperate trainer, struggling to find a competitive edge, from turning his thoroughbred into a kitchen sink of nutraceuticals.

While some nutraceuticals, such as cobalt supplements, have sparked regulatory interest among the states, the creation of new folios for testing is expensive.[221] Dr. Dionne Benson, executive director of the Racing Medication and Testing Consortium, remarked in January 2015 that, "when we start to regulate one area we will start to see problems in another . . . . [The process] takes time and it takes money. We've probably spent $50,000 on cobalt so far and we don't have a regulation yet."[222] Beyond the expense of creating tests for known performance-enhancing nutraceuticals, a more ominous threat comes from the unknown products that are marketed to trainers. Dr. Benson concedes, "Honestly, we will never be ahead of people who want to put different substances into horses . . . . I can't even dream up these things that people put into horses."[223]

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216 Nielsen, *supra* note 133.

217 *Id.*; Crandell, *supra* note 155.

218 *See* KELLON, *supra* note 117, at 218–19 (reporting the results of a study showing the varying success of different nutraceuticals).

219 *See* Nielsen, *supra* note 133 (noting the lack of research in the area).

220 *See* KELLON, *supra* note 117, at 218–19 (reporting the results of a study showing the varying success of different nutraceuticals).

221 *See generally* Thornton, *supra* note 207 (explaining that many states are interested in regulating cobalt).

222 *Id.*

223 *Id.*

C. When Drugs Do Better: The Problem with Phasing Out Race-Day Furosemide

Although unregulated nutraceuticals already jeopardize horseracing, in the worst-case scenario, they threaten to displace safe, regulated, and accessible drugs. HISA advances a "Transition Rule" with respect to the use of race-day furosemide (commonly known as Lasix).[224] HISA's findings condescend the drug's rampant use, noting that "[c]urrently, nearly every horse participating in interstate horseracing is injected shortly before racing with furosemide, a drug that is approved by the Food and Drug Administration for use in horses only for the treatment of edema."[225] The Act provides that "[d]uring the 2-year period beginning on the date of the enactment of this Act, the independent anti-doping organization . . . shall permit the use of furosemide . . . if the horse is 3 years old or older," with the drug eliminated for 2-year-old horses.[226] The furosemide Transition Rule is a signal part of HISA as it represents an attempt by the drafters to commandeer USADA, which would otherwise have full regulatory discretion over the "substances, methods, and treatments" permitted in racing.[227] While THIA does not expressly advance a furosemide transition rule, its findings acknowledge that the newly formed THADA should strive to achieve "consistency with the uses permitted in major international Thoroughbred horseracing jurisdictions, including the use of race-day medication."[228]

Although furosemide is a diuretic that can treat edema, veterinarians have primarily used the drug for decades in American racing to combat exercise-induced pulmonary hemorrhage (EIPH).[229] EIPH is bleeding that occurs during strenuous exercise—either occult (bleeding within the lungs) or epistaxis (nasal bleeding).[230] Most veterinarians contend that the combination of dilating and constricting small veins and arteries leads to "pulmonary capillary stress failure," and consequently, bleeding.[231] Dr. Dave Marlin of the University of Bristol writes that, "EIPH is a pervasive and important problem of athletic

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224 H.R. 2641 § 4(f).

225 *Id.* § 2(4).

226 *Id.* § 4(f)(1).

227 *Id.* § 4(b)(1).

228 H.R. 3084 § 2(4). Race-day medication is prohibited almost uniformly in international jurisdictions. Daniel Ross, *Lasix: The Drug Debate Which Is Bleeding U.S. Horse Racing Dry*, THE GUARDIAN (Aug. 31, 2014), https://www.theguardian.com/sport/2014/aug/31/lasix-drug-debate-bleeding-horse-racing [https://perma.cc/G2JK-EGVP] (accessed Dec. 23, 2016).

229 Ray Geor, *EIPH: Exercise-Induced Pulmonary Hemorrhag*e, THE HORSE (Nov. 1, 2001), http://www.thehorse.com/articles/12529/eiph-exercise-induced-pulmonary-hemorrhage [https://perma.cc/JUE5-AGAR] (accessed Dec. 23, 2016).

230 *Id.*

231 *Id.*

horses, in particular, racehorses."[232] The condition occurs in 55–80% of racehorses, with medical costs ranging from $115–225 million annually, not including the cost of missed training.[233] And EIPH is debilitating to thoroughbred performance.[234] Dr. Kenneth W. Hinchcliff assessed the correlation between bleeding and racehorse performance by scoring EIPH from zero (no bleeding) to four (nasal bleeding).[235] The results were stark: among other findings, horses with EIPH grades less than or equal to one were four times as likely to win and three times as likely to be in the ninetieth percentile or higher for race earnings as were horses with grades greater than or equal to two.[236] Worse, 60% of sudden deaths during races are attributable to pulmonary hemorrhage.[237]

Furosemide is the only drug that has scientifically proven effective at combating EIPH.[238] In a pioneering 2009 study conducted by Dr. Hinchcliff and a team of researchers, 167 South African racehorses received both furosemide and a saline placebo on race-day.[239] EIPH scores ranged from one to four in 55% of horses racing on furosemide and 80% of horses racing on the placebo.[240] None of the horses given furosemide developed severe EIPH (i.e., a score of three or four).[241] Overall, 67.5% of the horses that suffered EIPH after receiving the saline solution saw a reduced EIPH score of at least one when subsequently administered furosemide.[242] The study's authors reasoned that furosemide's efficacy stems from its diuretic effect, since "furosemide-induced reductions in body water and intravascular fluid volume . . . attenuate the exercise-induced increase in pulmonary arterial blood pressure typically associated with exercise, with a consequent reduction in the incidence of alveolar capillary rupture and decreased hemorrhage."[243]

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232 David J. Marlin & Kenneth W. Hinchcliff, *Editors' Foreword* to EXERCISE-INDUCED PULMONARY HAEMORRHAGE: STATE OF CURRENT KNOWLEDGE at v, v (D.J. Marlin et al. eds., 2008).

233 *Id.*

234 *See* Kenneth W. Hinchcliff, *EIPH and Performance*, *in* EXERCISE-INDUCED PULMONARY HAEMORRHAGE: STATE OF CURRENT KNOWLEDGE, *supra* note 232, at 8, 8–9 (explaining that EIPH is an important cause of impaired performance in thoroughbred racehorses).

235 *Id.* at 8.

236 *Id.* at 9.

237 Kenneth W. Hinchcliff et al., *Efficacy of Furosemide for Prevention of Exercise-Induced Pulmonary Hemorrhage in Thoroughbred Racehorses*, 235 J. AM. VETERINARY MED. ASS'N 76, 76 (2009).

238 *Id.* at 76–82 (discussing the scientific study of furosemide for the prevention of EIPH).

239 *Id.* at 77, 79.

240 *Id.* at 80.

241 *Id.*

242 *Id.*

243 *Id.* at 81.

Despite reducing the incidence of EIPH, critics contend that furosemide leads to improved performance.[244] A first theory suggests that less water weight means a faster racehorse.[245] Furosemide is a powerful diuretic, with urine production persisting for approximately three hours after administration.[246] However, to limit furosemide's diuretic effect, jurisdictions uniformly limit the permissible dose and prohibit its administration within four hours of post time.[247] And while applying weight to a horse's saddle is the internationally recognized means of handicapping races, one might reasonably distinguish a horse losing weight in the build-up to a race from a horse having weight removed from its back.[248] Perhaps the weight loss makes it more strenuous for a horse to support the combined weight of jockey and saddle—much as a lighter offensive lineman in football can have a harder time repelling his defensive counterpart. More concerning, in the absence of furosemide, a common way to replicate the diuretic effect is to withhold food and water from the horse for several days preceding the race.[249]

Critics also contend that furosemide improves performance by masking the simultaneous injection of undetectable performance-enhancing agents.[250] This seems unlikely. A study conducted by Dr. Richard Sams revealed that limiting the injection threshold to 250 milligrams—a figure near the middle of the *Model Rules*' acceptable range—results in "no appreciable effect on the detection of [drug] analytes."[251]

Critics finally contend that furosemide improves performance by serving as a carbon dioxide buffer that significantly delays oxygen debt in aerobic metabolism.[252] This theory holds more water; studies have shown that furosemide tends to increase TCO_2.[253] As with the use of

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244 Geor, *supra* note 229.

245 *Id.*

246 Richard Sams, *Regulatory Issues Regarding Drug Treatment of EIPH*, *in* EXERCISE-INDUCED PULMONARY HAEMORRHAGE: STATE OF CURRENT KNOWLEDGE, *supra* note 232, at 44, 44.

247 *Id.*

248 *See Theory of Handicapping*, HORSE RACING, http://www.horseracing.com/handicapping/theory/ (accessed Dec. 23, 2016) (describing the common practice of handicapping racehorses by adding weight to their saddles).

249 Letter from John S. Mitchell, President, Am. Ass'n of Equine Practitioners, to John Sabini, Chairman, N.Y. State Racing & Wagering Bd. (May 14, 2012) [hereinafter AAEP Letter] (on file with Animal Law Review).

250 Ross, *supra* note 228; *Diuretics and Other Masking Agents*, TECHNISCHE UNIVERSITÄT MÜNCHEN, http://www.doping-prevention.com/substances-and-methods/diuretics-and-other-masking-agents/diuretics-and-other-masking-agents.html [https://perma.cc/462B-RZ62] (accessed Dec. 23, 2016).

251 Sams, *supra* note 246, at 44.

252 Byron Rogers, *A New Study on EIPH and Salix*, EXERCISE PHYSIOLOGY (May 20, 2013), http://www.performancegenetics.com/single-post/2013/05/20/A-new-study-on-EIPH-and-Salix [https://perma.cc/A5JH-JTBG] (accessed Dec. 23, 2016).

253 *E.g.*, N.D. Cohen et al., *Factors Influencing Pre-Race Serum Concentration of Total Carbon Dioxide in Thoroughbred Horses Racing in California*, 38 EQUINE VETERI-

any drug in competitive sports, furosemide is not without its unwanted side effects,[254] but that is precisely why the drug is uniformly permitted in every American racing jurisdiction. HISA correctly states that nearly all horses race on furosemide.[255] In 2005, there were 66,692 unique starters in North American thoroughbred races, and 62,017 started at least once on furosemide.[256] A regulated drug that is both inexpensive (Lasix costs $20–$25 per injection[257]) and readily accessible mitigates competitive advantage. It seems reasonable to further contend that furosemide actually normalizes competition, given the inconsistent performances that would otherwise result from horses suffering a more severe grade of EIPH. And most importantly, furosemide benefits equine welfare by reducing the incidences of sudden death and bleeding caused by EIPH during races.

By purporting to eliminate furosemide simply because of its being labeled a "drug," HISA opens the door for nutraceuticals to more deeply infiltrate horseracing. In the absence of a regulated and accessible drug like furosemide, trainers will pursue suspect alternatives. Cottage industries have formed around anti-bleeder nutraceuticals, most of which are unproven.[258] The American Association of Equine Practitioners (AAEP) highlighted nutraceuticals as a chief concern in opposing the New York State Racing and Wagering Board's 2012 initiative to ban furosemide:

> The racing industries should expect that unproven and perhaps undetectable products will be used in an attempt to alleviate EIPH on race day. Some of these products may include, but are not limited to, *herbal remedies, nutraceuticals, and compound medications* that are not approved for use in the horse and have no scientific merit of efficacy in treating EIPH. The potential harmful side effects of some of these products to the horse are a serious concern.[259]

Dr. Scot Waterman, former Executive Director of the Racing Medication and Testing Consortium, describes one such colorfully named nutraceutical, "Black Ice," as typical of black market substances "in which the active ingredient is a true unknown."[260] According to Dr.

NARY J. 543, 546 (2006) ("The factor most strongly associated with TCO_2concentration was [furosemide] administration.").

254 Natalie Voss, *New Furosemide Research Reveals Unexpected Impacts of the Medication*, PAULICK REP. (June 29, 2015, 4:04 PM), http://www.paulickreport.com/horsecare-category/vet-topics/new-furosemide-research-reveals-unexpected-impacts-of-the-medication/ [https://perma.cc/3WAY-8RFQ] (accessed Dec. 23, 2016).

255 H.R. 2641 § 2(4).

256 Scot A. Waterman, *EIPH and Horseracing in the USA—Scale of the Problem, Management, Regulation and Unique Aspects*, *in* EXERCISE-INDUCED PULMONARY HAEMORRHAGE: STATE OF CURRENT KNOWLEDGE, *supra* note 232, at 48, 48.

257 Steve Zorn, *NYTHA Report on Lasix*, BUS. OF RACING (May 14, 2012), http://businessofracing.blogspot.com/2012/07/dear-readers-view-of-escalating-debate.html [https://perma.cc/RF84-9VKJ] (accessed Dec. 23, 2016).

258 Waterman, *supra* note 256, at 48.

259 AAEP Letter, *supra* note 249 (emphasis added).

260 Waterman, *supra* note 256, at 48–49.

Waterman, even with furosemide legal, there are pages of online forums attesting to the effectiveness of supplemental diuretics, reflecting the "general desperation level to keep horses in training . . . and the reliance on combinations of drugs and 'voodoo science'" for those trainers unable to use furosemide.[261]

Even Dr. Kellon, a supplement advocate, concedes that most antibleeder nutraceuticals "don't disclose their ingredients," despite claiming to be "'natural' alternatives to diuretics or furosemide."[262] Dr. Kellon's lone recommendation is furosemide, a prescription drug.[263] Although combination nutraceuticals containing Chinese herbs purport to loosen mucus and clear airways,[264] no scientific study has linked these products to a reduced incidence of EIPH. More concerning, these nutraceuticals boast attractive names such as "Breathe Ease" and "Jet Breathe,"[265] which could easily deceive trainers into thinking that their use will curtail bleeding. Closely resembling herbal strains that have no medicinal value and are potentially toxic can easily contaminate these combinations.[266]

Legislative opposition to race-day furosemide illustrates the extent to which regulators have blinkered their focus on drugs and medication. By either endorsing (THIA) or explicitly legislating (HISA) the elimination of race-day furosemide, Congress aspires to implement a new horseracing order that would jeopardize equine welfare, undermine fair competition, and further exacerbate trainer reliance on untested and unsafe nutraceuticals.[267]

IV. REMOVING THE BLINKERS: A SUBSTANTIVE REDIRECTION TO NATIONAL RACING LEGISLATION

Federal legislation to regulate permissible substances in horseracing is a worthwhile cause. As Section II establishes, state-driven initiatives to achieve uniform rules and regulations on "substances, methods, and treatments" have not succeeded.[268] Horseracing's federated structure incentivizes jurisdictions to be safe havens for trainers who want to cut corners. Other states that have taken the initiative to impose tougher guidelines splinter on idiosyncratic regulations. This

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[261] *Id.* at 49.

[262] KELLON, *supra* note 117, at 257.

[263] *Id.* at 256.

[264] *Id.* at 252.

[265] *Id.*

[266] *Id.* at 257; Briggs, *supra* note 121.

[267] For a demonstration of the prevalence of herbal combinations used in racing and the resulting risks, see Wendy Pearson, *Concurrent Use of Veterinary Drugs and Herbal Medicines in Racing Standardbreds*, CAN. VETERINARY J. (2009), http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2777294/ [https://perma.cc/924H-FTRN] (accessed Dec. 23, 2016) (discussing the issue with respect to standardbred racing).

[268] *See Breeding, Drugs, and Breakdowns: The State of Thoroughbred Horseracing and the Welfare of the Thoroughbred Racehorse: Subcomm. on Commerce, Trade, and Consumer Protection of the Comm. on Energy and Commerce H. of Reps.*, 110th Cong. 10 (2008) (statements of Richard B. Shapiro, Chairman, Cal. Horse Racing Board).

federalist dilemma has led thoroughbred racing's biggest constituencies to support congressional intervention. But as Section III establishes, without accounting for nutraceuticals, national racing legislation bypasses a more significant threat to the sport's competitive integrity and equine welfare.[269] HISA, THIA, or any other bill purporting to regulate substances in thoroughbred racing must incorporate the following three amendments:

- ***Expressly grant federal regulatory authorities oversight over nutraceuticals as regulated "substances."*** This will, at least for racehorses, close the outstanding loophole in FDA law.
- ***Require nutraceutical manufacturers to present scientific research attesting to the safety and efficacy of new products before they are marketed to horsemen.*** Nutraceuticals that are currently on the market will be given a grace period of two years to present substantiating research. If they fail to do so, their products will be banned from competitive racing.
- ***Eliminate provisions purporting to phase out race-day furosemide.*** Most medications are safer than nutraceuticals, given that they must undergo rigorous testing before entering the market. Trainers are less likely to feed their horses suspect nutraceuticals when they can legally use a cheap and effective "controlled substance" on race day.

Regulating nutraceuticals in horseracing will mark the first invasion of a congressionally created safe harbor for manufacturers of animal nutraceuticals. This initiative, in turn, could pave a path toward regulating nutraceuticals that are manufactured for other animals. And if regulating nutraceuticals in horseracing proves too daunting and expensive, the experiment will have failed without the greater waste that would otherwise come through the FDA's imposing blanket regulations on all animal nutraceuticals.

V. CONCLUSION

Thoroughbred racing has come a long way since Sir Barton won the 1919 Triple Crown on cocaine.[270] Medications have become more sophisticated, simultaneously alleviating the discomfort of racehorses and creating a regulatory conundrum.[271] Lax enforcement has led to a number of training scandals that have severely compromised racing's image.[272] Idiosyncratic state guidelines on permissible substances have hindered the efficiency of interstate horseracing and further pro-

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[269] *See* AAEP Letter, *supra* note 249 (stating the dangers of unproven nutraceuticals within the horseracing industry).

[270] Goldberg, *supra* note 13, at 1.

[271] Sid Gustafson, *Drugs and Racehorses*, N.Y. TIMES: THE RAIL (June 4, 2008, 3:42 PM), http://therail.blogs.nytimes.com/2008/06/04/drugs-and-racehorses [https://perma.cc/U5BG-TMF6] (accessed Sept. 3, 2016).

[272] *E.g.*, Bogdanich et al., *supra* note 7; Rhoden, *supra* note 29.

voked calls for one uniform set of rules across America's thirty-eight racing jurisdictions.

Although commendable for their initiative, HISA and THIA are substantively blinkered. The bills fetishize "performance-enhancing drugs." They fail to grasp the basic precept of FDA law that the "drug" label connotes efficacy and oversight. There is no more salient illustration than HISA's attempt to phase out race-day furosemide.[273] Conversely, nutraceuticals are free from FDA oversight and absent from state rulebooks. Because of their demonstrated potential to enhance performance and jeopardize equine welfare, nutraceuticals represent the most pressing existential threat to the integrity of American horseracing.

The prevailing lesson to be learned from Dr. Harthill's revolution is that horseracing must be forward-looking. With a legislative protocol that demands scientific substantiation, safety, and efficacy, nutraceuticals can do best by the equine athlete and become a force for good in racing. More remarkably, after years of scandal, such legislation would make American horseracing an exemplar for animal welfare in other industries by commencing the first invasion of a safe harbor that has for too long protected the manufacturers of potentially dangerous animal nutraceuticals.

[273] *See* H.R. 2641 § 4(f) (proposing a "Transition Rule" with respect to the use of race-day furosemide).