Michael Best

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Drug Reform for Horseracing Crosses the Finish Line

The Horseracing Integrity and Safety Act of 2020 (HISA) became law as part of the year-end funding bill and COVID-19 relief package, increasing racetrack safety for the sport of horseracing by establishing long-awaited, uniform national standards for anti-doping, medication control. Though it will take effect in 2022, the time to start planning is now. The FDA and Policy Teams at Michael Best have the depth of experience to ensure you are compliant with HISA.

HISA's new rules will replace the current patchwork of regulations that govern horseracing's 38 racing jurisdictions by creating an independent Horseracing Integrity and Safety Authority (the Authority) to develop and implement a horseracing medication control program and a racetrack safety program. A separate anti-doping and medication control committee composed of industry experts will provide guidance to the Authority on the development and maintenance of the medication control program.

The anti-doping rules must include a list of prohibited substances, methods and protocols for the administration of permitted substances, and laboratory testing accreditation and protocols. In developing the permitted and prohibited substances and practices, the Authority is required to consider international anti-doping standards, veterinarian ethical standards, as well as feedback from racing industry representatives and the public. The regulations put in place by HISA are to promote fair competition, restore confidence in all industry stakeholders, and provide protections and safety to horses and athletes.

The Federal Trade Commission (FTC) will have oversight over the Authority, and the U.S. Anti-Doping Agency (USADA) will be responsible for enforcement of the program. HISA goes into effect no later than July 1, 2022 but could be effective earlier following the creation of the Authority and approval of an anti-doping and medication control program by the FTC.

The U.S. Food and Drug Administration's Center for Veterinary Medicine (CVM) and the U.S. Department of

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Agriculture's Animal and Plant Inspection Service (APHIS) will continue to have regulatory authority over the approval of new animal drugs and the licensing of veterinary biologics, respectively. As they do now, both will be responsible for ensuring the safety and effectiveness of substances used in animals including in sports such as racing.

Once HISA takes effect, the Authority could become a vehicle for power. With the responsibility to regulate on matters of medication and safety, the Authority will have a large hand in the operations of the industry. There are nine positions to be filled on the Authority board of directors. Four positions must be filled by industry representatives, which could include owners, breeders, jockeys, racetracks, trainers, state racing commissions, and veterinarians. Once nominated to the board, these four board members along with members of the Authority's standing committees will represent their section of the industry and could govern the sport with their group's interest in mind.

Although there may be a shift in power to the Authority, state racing commissions will still have important responsibilities. Commissions will still oversee licensing, racing rules, and other operations, and may be able to work with the Authority and USADA to enforce anti-doping regulations at the state level.

For veterinary drug companies who plan to continue selling horseracing products, now is the time to prepare for HISA by reviewing your products to see how they will be impacted and develop a strategy if you are in a precarious category where your FDA approved therapeutic drugs or USDA licensed biologics may be banned from the sport. It is highly likely that pursuing FDA new animal drug approval or USDA biologic licensing will be required, if your company has not already done so, to ensure that your therapeutic products are included on the HISA's list of permitted substances. The HISA may also present an opportunity for existing laboratory service to expand business by becoming one of the certified testing facilities relied on by the sport.

The FDA and Policy Teams at Michael Best have experience advising clients on FDA regulatory matters. If you have any questions or concerns about how HISA may impact you, please contact your Michael Best attorney or the author listed below.

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