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AHA/ACC SCIENTIFIC STATEMENT

# Eligibility and Disqualification Recommendations for Competitive Athletes With Cardiovascular Abnormalities: Task Force 11: Drugs and Performance-Enhancing Substances

A Scientific Statement From the American Heart Association and American College of Cardiology

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The use of performance-enhancing drugs and substances, or doping, is one of the most important and difficult challenges in contemporary sports. Doping occurs when a prohibited substance or its metabolite is documented in a bodily specimen or when a prohibited method is used to increase athletic performance (1). Most commonly, the substances or methods used for doping have not been evaluated for therapeutic use. The abuse of counterfeit or designer drugs that are not regulated is a particular threat to the athlete's health. Doping also threatens the integrity of sport. The use of artificial enhancements to gain an advantage over others in competition is fundamentally unfair to athletes who train and compete by the rules.

Athletic governing organizations maintain updated lists of prohibited substances (2). The prohibition of these agents is based on preventing an unfair athletic advantage and eliminating the health risks of doping. Generally, these drugs fall into categories that include anabolic agents, hormones and related substances, $\beta_2$-adrenergic agonists, stimulants, and

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diuretic agents (1,2). Multiple masking agents are also prohibited because they are used to hide or prevent detection of a banned substance (1,2). Drugs used for enhancement of oxygen transfer, such as erythropoietin, or techniques of autotransfusion are also prohibited (1,2). Many drugs and substances considered "recreational" rather than performance enhancing, including narcotics, cannabinoids, and alcohol, are also prohibited (1,2).

Of the many adverse effects of performance-enhancing substances, those that affect the cardiovascular system are among the most serious and will be the focus of this document (3). This section also summarizes the best available, albeit limited, data on the adverse cardiovascular effects of prohibited substances in athletes. In addition, strategies for effective implementation of antidoping programs will be discussed, and specific recommendations for healthcare professionals will be made. To ensure harmonized, coordinated, and effective antidoping programs at the international and national level with regard to detection, deterrence, and prevention of doping, a World Anti-Doping Code has been accepted by almost all international athletic organizations (4). Ultimately, all stakeholders, including athletic governing organizations, athletes, trainers, and physicians, have a shared responsibility to discourage the use of doping in sports.

The evidence base for performance-enhancing drugs and substances is subject to limitations not usually encountered in the assessment of risk and benefit for cardiovascular drugs approved by the U.S. Food and Drug Administration (FDA). Scientifically designed studies of efficacy are lacking, and many reports or opinions are subjective and often specific to an individual sport. The application of randomized clinical trials has not been feasible and in many cases may be considered unethical because of the listing of the drug or substance on lists of banned substances (5). Searches of the medical literature for randomized trials demonstrate very few clinical trials that evaluated the efficacy and safety of performance-enhancing drugs or substances. One prospective randomized trial of supraphysiological doses of testosterone combined with strength training demonstrated an increased fat-free mass and muscle size and strength in normal men with this steroid (6). The ClinicalTrials.gov Web site does not list any currently enrolling trials when searched under the terms of *sports* or *performance* (7). Because many of the substances in question are regulated by the FDA as food supplements, claims of efficacy are not substantiated by randomized clinical trials.

The evidence base for safety is somewhat more extensive but is also limited by its observational nature and the absence of randomized trials with placebo controls in most cases. Excellent summaries of the detrimental cardiovascular effects of performance-enhancing substances have been published (5,8). FDA efforts are largely directed at individual product recalls and warning letters for unwarranted claims rather than published trial data. However, in its ban of ephedra-containing dietary supplements in the United States in 2004, the FDA based its decision on the principle of "unreasonable risk," a risk-benefit analytical method based on even a small potential for harm in the absence of any scientifically reliable support for benefit (9). The FDA avoided the principle of "significant risk," which would have required a higher level of scientific reliability of specific risk than was available (9). Gaps in the evidence base may continue to expand. The number of performance-enhancing substances available to athletes continues to increase, and the substances are readily available via the Internet. Large numbers of youth are being prescribed stimulant drugs to treat attention-deficit hyperactivity disorder, with a prevalence estimated to be as high as 10% of the relevant age group (10). Participation of these patients in competitive sports will require assessment of the risk and benefit. Finally, athletes will continue to explore new substances to enhance performance, without the benefit of adequate trials of efficacy or measures of safety published in the medical literature.

The term *antidoping program* refers to any organized system designed to prevent the use of banned substances in sport. Such programs have been designed and implemented with the dual objectives of ensuring fair sport competition and protecting the health of athletes. There are numerous key stakeholders in an effective antidoping program, including athletic governing bodies, athletic league directors and administrators, healthcare professionals, athletic trainers, coaches, and athletes themselves. Collectively, this group should work to promote awareness about the consequences of the use of performance-enhancing drugs and substances (education), design and implement transparent and evidence-based drug testing protocols (detection), impart and uphold fair sanctions for athletes who abuse performance-enhancing drugs and substances (enforcement), and provide resources for athletes who develop medical or psychiatric complications (treatment).

Athletic governing organizations play a crucial role in the effort to curb abuse of performance-enhancing drugs and substances among athletes. Historically, these organizations were created to generate and maintain lists of prohibited substances and to develop policies for the detection and punishment of users (1,2). These fundamental objectives remain their primary focus. The antidoping organization community now includes members at the international, regional, national, and local levels. Over the past decade, their role has expanded to include development of widespread