

WADA ST. PETERSBURG DECLARATION - June 11-2008

SUMMARY. The participants of the St. Petersburg WADA workshop underscore the principles and conclusions presented in the declarations from the previous WADA meetings at the Banbury Center in New York in 2002 and in Stockholm in 2005, which included:

1. acknowledgement of the techniques of gene transfer for the purpose of therapy and an awareness that the same methods may be applied to gene-based doping. The techniques are still immature and filled with known and unknown risks to participants that are justified in the attempt to ameliorate suffering and treat illness but not in normal, healthy athletes in an attempt to enhance athletic performance.

2. a commitment by WADA to catalyze public and scientific awareness and public discussion of the potential side effects and dangers of gene-based doping and to enhance a research effort for the detection of gene-based doping.

3. recognition that participation of physicians and other trained professionals in illicit gene transfer for the purpose of enhancing athletic performance should be considered malpractice and/or professional misconduct.

4. to increase awareness of the potential for gene-based doping among scientific, clinical research and professional licensing agencies, and to encourage development of appropriate sanction mechanisms for illegal and illicit application of gene transfer in sport.

5. a commitment by WADA to continue its vigorous research program and to coordinate anti-doping research efforts with other academic and private organizations.

6. to encourage a discussion of sport as a paradigm for the potential social implications of broad applications of enhancement.

The St. Petersburg workshop identified additional areas of concern, including;

1. the importance of an effective public discussion and understanding of the role of the marketplace in non-therapeutic application of gene transfer concepts and methods.

2. the need to define the role of sport in the broad societal issue of genetic enhancement and to better delineate the boundary between therapy and doping.

1. PROGRESS AND PROBLEMS IN GENE THERAPY. Gene therapy is a reality, albeit an imperfect one, and the tools of gene transfer have proven to be therapeutically effective in a number of clinical studies, including especially the severe combined immunodeficiency diseases (SCID), several forms of cancer, genetic forms of retinal degeneration and blindness, and other diseases. Nevertheless, serious conceptual and technical problems continue to produce severe and unanticipated setbacks and adverse events, including death and the induction of leukemia in some patients. These developments and the evolution of this new form of medicine are similar to the time required to apply basic scientific advances to effective clinical application for several other major new forms of therapy such as bone marrow and other tissue transplantation, cancer

chemotherapy and therapeutic use of monoclonal antibodies, all of which required three to four decades for wide-spread and efficient clinical application.

2. THE WADA RESEARCH PROGRAM. WADA currently supports various research programs in several leading laboratories around the world aimed at, for example, identifying the molecular changes induced by exposure to drugs and genetic elements and identifying those changes that could constitute signatures for detection procedures. To help with the difficult task of analyzing such large and complicated databases, WADA has established a central informatics unit that will coordinate the work of many WADA-supported laboratories and apply the most modern informatics methods to identify such signature molecular changes.

A new area of concern involves the role of naturally occurring genetic variations in genes that affect physical traits and athletic performance. A number of such variants have already been identified, including mutations of the myostatin gene that produces muscle hypertrophy, variants in the gene for expression of alpha actinin 3 in fast skeletal muscle fibers, genetic variants of the erythropoietin (EPO) receptor that causes permanent activation of the EPO signalling pathway and erythrocyte production. As the human genome characterization matures, many more such polymorphisms will be identified, and WADA is aware of the need to remain informed on such discoveries to be able to assess the role that polymorphisms would play in interpreting markers or analytes used in anti-doping testing. WADA will interact with the leading sport authorities to propose that such considerations are addressed as part of sport rules.

3. GENE-BASED ENHANCEMENT – SPORT AS A PARADIGM. Many forms of enhancement of normal human traits are an accepted and growing practice in our societies. Drugs and surgical methods are commonly used for physical modification and enhancement and mood modification. Sport is an area of human activity that is already suffused with drug-based enhancement, and the financial and personal rewards for enhanced performance in sport indicate that sport will be one of the areas in which gene-based enhancement is first likely to arise. The world of sport therefore serves as a very effective setting in which to examine broad societal issues of enhancement and the unclear boundary between treatment and enhancement.

4. REGULATORY ISSUES – COMMERCIALIZATION OF GENE DOPING IN SPORT.

In a setting in which modern communication technologies, unencumbered by geographical boundaries, facilitate the dissemination of information and goods for both legitimate and illicit purposes, it is important for sports authorities to interact with academic, private economic and professional scientific and medical organizations to monitor further developments in genetic enhancement technologies and in their production, promotion and use in the global marketplace. Governmental, commercial and sports organizations must function in the context of conflicting pressures regarding gene technology - how best to nurture and develop the gene technology industry, how to regulate and exploit scientific advances profitably for the public good, but also to prevent ill-advised

applications being developed for economic gain without proper consideration for health, societal or ethical values. To promote awareness of these complexities and provide support to the sport community, it is important for WADA to have a clear view of the regulatory framework that would best serve the interests of sport and be an active participant in the societal discussion of these issues.

5. POLICY PERSPECTIVES, LEGAL FRAMEWORK AND LAW ENFORCEMENT.

In addition to its traditional activities with governments, WADA is intensively developing relationships with international police and anti-criminal organizations to ensure that national and international laws penalize uncontrolled or illegal possession, commercialization and trafficking of prohibited substances and methods, including reagents for genetic manipulation. To ensure safety and compliance with international ethical standards of human experimentation, all genetic manipulations in human subjects and patients in most countries currently require extensive regulation and oversight at institutional, local and national levels. Illicit application of gene transfer technology in sport is unlikely to comply with such standards, and, therefore, procedures are required to identify the legal and ethical safeguards and responses available to deter and to counter such uses of genetic technology. In addition, advances in genetic science are revealing the existence of an increasing number of naturally occurring genetic variants and polymorphisms. The existence of such normal human genetic differences is likely to be increasingly used in arbitration and appeals in sport to challenge anti-doping results. It will also become increasingly important to define the role of these variants on performance, on testing programs in sport, and on eligibility to participate in competition.

CONCLUSIONS AND RECOMMENDATIONS.

1. The use of genetic technology should continue to be applied to the task of developing improved detection methods for doping in sport. The WADA research program should continue to be the central component of that effort and there should be increasing emphasis on expanding such research to additional academic, private and commercial institutions.

2. Gene transfer is becoming an established and increasingly effective method of therapy for human disease. WADA should be cognizant of the application of the very same techniques for illicit purposes to enhance athletic performance.

3. WADA is committed to intensifying discussion and strengthening interactions with governmental authorities, law enforcement, policy agencies and licensing authorities to define participation of licensed professionals in gene transfer manipulations outside the accepted oversight and approval procedure as constituting professional misconduct and to devise suitable sanctions.

4. The commercialization of genetic science and the worldwide market are affecting the development and accessibility by sport figures to materials and methods of potential use in genetic doping. WADA should facilitate interactions with public and commercial authorities to identify emergence of future doping agents or methods, and to stimulate governments, sports authorities, private economic and scientific and medical sectors to regulate the promotion and dissemination of genetic enhancement technologies in a global marketplace. Anti-Doping Organizations should be prepared to provide objective and reliable information to

athletes, trainers and physicians, to enable them to assess critically the claims made on the Internet and elsewhere regarding the “power of genetics” to enhance athletic performance.