

Make Sport Great Again: The Use and Abuse of the Therapeutic Use Exemptions Process

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History Will Judge 2016 as an *Annus Horribilis* for Olympic Sport The Main Events

January 2016: The World Anti-Doping Agency (WADA) adds meldonium to the S4 list of banned substances, citing evidence that this metabolic modulator was used by athletes with the intention of enhancing performance (8,11). Meldonium had been on WADA's 2015 monitoring list. Numerous athletes sanctioned early in 2016 for meldonium use claimed their innocence, stating that they had stopped its use immediately upon receiving information that meldonium was to be included in WADA's 2016 prohibited list. WADA subsequently issues updated guidelines, allowing less than 1 $\mu\text{g}\cdot\text{mL}^{-1}$ of meldonium for tests done before March 1, 2016, as preliminary tests showed that it could take weeks or even months for the drug to leave the body given the high but therapeutic doses of meldonium (6). It is unclear whether and if so, how meldonium increases performance in athletes (5). Since January 1, there have been 178 positive tests for meldonium including a number of high-profile athletes. Given the controversy, most athletes found "positive" for meldonium eventually avoided prolonged suspension (7).

May 2016: The International Olympic Committee (IOC) announces its intent to step up the fight against doping by retesting samples from Beijing 2008, London 2012, and Sochi 2014. Retest results of 1053 samples from Beijing and

403 samples from London have been announced to date. From these 1456 retest results, the IOC has sanctioned 93 athletes (6.4%), representing 16 National Olympic Committees (NOC) and six sports and international federations (IF). Retesting samples from Beijing and London is having a major impact on the final medal tally of these games (see Figure) and therefore on the integrity and reputation of these games and Olympic sport in general.

May 12, 2016: The *New York Times* publishes allegations by Dr. Grigory Rodchenkov, former director of the Russian antidoping laboratory, that a conspiracy of corrupt antidoping officials and Federal Security Services Intelligence Agents, aided complicit Russian athletes to use banned substances to gain an unfair advantage during the Sochi Games (4). Dr. Rodchenkov alleged that agents from the Federal Security Services tampered with more than 100 urine samples as part of a cover-up, and that a third of the Russian medals at Sochi were won by doping athletes. The IOC had announced they conducted 2667 tests, 477 blood tests and 2190 urine tests, during Sochi 2014 and declared "Thanks to the most stringent antidoping programme in Olympic Winter Games history, never has it been so difficult for cheats to prosper" (2).

July 18, 2016: Richard McLaren, appointed by WADA to conduct an independent investigation of the allegations, presented the first report of his assessment, concluding that there was systematic state-sponsored subversion of the drug testing processes by the Russian government during and subsequent to the 2014 Winter Games in Sochi.

July 24, 2016: The IOC rejects WADA's recommendation to ban Russia from the Summer Olympics and announces that each sports federation would make a decision. In contrast, the International Paralympic Committee (IPC) unanimously votes to ban Russian athletes from the 2016 Summer Paralympics, citing the exposure of the state-sponsored doping program.

September 2016: WADA confirms a serious cyber attack by a Russian cyber espionage group operating under the name of Tsar Team (APT28), also known as "Fancy Bears," that gained access to WADA's Anti-Doping Administration and Management System (ADAMS) database through an IOC-created account for the Rio 2016 Games (12). This breach was made possible by spear-phishing of ADAMS users' email to gain passwords. The group accessed athlete data, including confidential medical data, such as Therapeutic Use Exemptions

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Figure: The impact (gold, silver, bronze, and diploma) of the final medal tally of the updated retesting of samples from Beijing ($n = 1053$) and London ($n = 403$).

(TUE) delivered by IF and national antidoping organizations (NADO) related to the Rio Games. Fancy Bears subsequently released these data into the public domain on several occasions. In total, 127 athletes, involving 25 IF, and 27 countries were affected. The expectation is that there will be further leaks of confidential data by this Russian cyber espionage group. While the full extent of the fallout from the events that marred Olympic sport in 2016, during an Olympic year, remains to be determined, it is clear that Olympic sport is in crisis and needs a serious paradigm shift.

December 2016: McLaren published the second part of his report on doping in Russia, revealing that from 2011 to 2015, more than 1000 Russian competitors in various sports (including summer, winter, and Paralympic sports) benefited from the cover-up described by Rodchenkov (10).

An Evolution Is Needed in the TUE Process

The International Federation of Sports Medicine (FIMS) in solidarity with the Olympic movement and the global sporting community as a whole, strongly and unequivocally condemn the indefensible criminal activity leading to the publication of personal medical information, that seriously undermines the three fundamental pillars of sports medicine: 1) respect of medical and sports ethics, 2) protection of the health of the clean athlete, and 3) fair competition and equal opportunities for all competitors. The 2016 events have, however, highlighted serious shortcomings in the current International Standard for TUE. The TUE process was introduced to ensure that any athlete with a diagnosed medical condition that requires the use of a prohibited substance or method is not denied access to competition. The TUE process is carefully described in one of five WADA International Standards (9). Briefly, the TUE process requires the antidoping organizations to establish “Therapeutic Use Exemption Committees” (TUECs) whose membership includes at least three physicians

with experience in the care and treatment of athletes and a sound knowledge of sports and exercise medicine. In order to ensure impartiality, a majority of the TUEC members should have no political responsibility in the antidoping organization that is responsible for appointing them. All members of the TUEC also are required to sign a conflict of interest and confidentiality declaration. The responsibility of the TUEC panel is to review each application before granting permission for a course of treatment, or prohibiting its use. Applications are normally forwarded to a NADO for consideration by their appointed TUEC, or by a TUEC of an IF or major event organization if the TUE application is from an athlete planning to participate in a major competition (*e.g.*, IOC, International Association of Athletics Federations).

On the face of it, the International Standard for TUE seems to be well developed with good attention to necessary detail. However, scratch below the surface and significant problems emerge with how the TUE process is actually carried out and enforced. For example, there may be general lack of global consensus on best evidence-based practice in sports medicine. Problems can occur because of the nonstandardized criteria for disease/injury diagnosis and treatment, such as the nonstandardized use of corticosteroids to treat musculoskeletal injuries (3), or the use of thyroid hormones to treat training-induced hypothyroidism in athletes (1). There is a need to fully embed in the TUE process the fact that medical conditions are not static but dynamic, so the TUE process should require any athlete seeking a TUE to undergo frequent medical assessments by an independent medical commission and protect against open-ended provision of treatment(s) for months on end when unjustified on medical grounds.

The retroactive use of TUE should only be permitted in real emergency situations when it can be demonstrated beyond reasonable doubt that the clinical situation did not exist 24 hours before the need. As currently practiced, the TUE process can

be misused as a “permissive” doping passport alongside the current antidoping methods, such as the Athlete Biological Passport (ABP).

Therefore, to restore credibility in the TUE system, a truly independent TUE process is needed. A single independent authority should oversee TUE for a particular disorder (*e.g.*, an independent commission mandated to ensure pathology and treatment of a medical entity such as asthma), made up of newly appointed and well-trained medical practitioners. A significant research fund also should be created exclusively to support and encourage the evolution of the TUE process. Most importantly, however, there needs to be a paradigm shift in the TUE process and practices, away from primarily political and legal processes. The TUE process should instead focus on protecting the health of the clean athlete at all costs, while the antidoping process focuses on stopping cheating. This shift will require enormous commitment by sports and exercise medicine practitioners worldwide to ensure the scientific integrity and clinical credibility of the TUE processes, while simultaneously adhering to a universally high standard of care for athletes.

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