

THE THERAPEUTIC USE EXEMPTION UNDER THE WADA CODE: BALANCING MEDICAL NECESSITY AGAINST THE RIGHT TO CLEAN SPORT

MERINDA GREENWOOD*

ABSTRACT

The World Anti-Doping Agency ('WADA') is responsible for promoting, coordinating and monitoring anti-doping in elite sport. While it is necessary for WADA to protect athletes' right to participate in doping-free sport, the health of all athletes must not be compromised by prohibiting medical treatment entirely. WADA's Therapeutic Use Exemption ('TUE') recognises an athlete's legitimate therapeutic need for treatment which would otherwise be banned. Following the September 2016 hacking of WADA's databases containing confidential athlete medical data, WADA's TUE regime was widely criticised for the high number of elite athletes requiring TUEs. In light of such concerns, this paper evaluates the WADA's TUE regime. While the TUE regime largely balances competing interests of clean sport with athlete wellbeing, there is room for improvement. The author recommends changes to the current TUE application process to increase fairness to applicants and promote transparency, stringent regulation and training of sporting physicians, greater supervision and education of athletes granted TUEs, and greater transparency surrounding TUE disclosure. With the 2021 World Anti-Doping Code Review well underway, the current TUE regime must be carefully considered by sporting stakeholders to ensure positive changes can be made to WADA's TUE regime.

I INTRODUCTION

Through the *World Anti-Doping Program* ('WADP'),¹ The World Anti-Doping Agency ('WADA') aims to protect the fundamental rights of athletes to participate in doping-free sport.²

However, the effectiveness of the WADP has been the topic of recent debate. Just one month after the Rio De Janeiro Games of the XXXI Olympiad ('*the Games*'), WADA's Anti-Doping Administration and Management System ('*ADAMS*') was illegally hacked

* LLB (Hons) (JCU), GDLT (College of Law).

¹ According to the World Anti-Doping Agency, The World Anti-Doping Program consists of three levels:

Level 1: The Code

Level 2: International Standards and Technical Documents

Level 3: Models of Best Practice and Guidelines

World Anti-Doping Agency, *World Anti-Doping Code* 2021 (25 November 2019) <https://www.wada-ama.org/sites/default/files/resources/files/2021_code.pdf> 11 ('*WADA Code*') 8.

² *Ibid.*

by a Russian cyber espionage group known as ‘Fancy Bear’.³ On six occasions from 13 to 30 September 2016, the group released confidential athlete medical data, disclosing TUEs granted to athletes during the Games.⁴

In total, 127 athletes from over 24 countries were affected, including elite tennis players Serena Williams, Roger Federer and Rafael Nadal, Tour De France winner Christopher Froome, and American Olympic Gymnast Simone Biles. The 2016 hacking raises concern about whether the current TUE regime allows athletes to use drugs or medical processes that are ‘otherwise classified as performance enhancing and banned under the WADA Code’ where no therapeutic need exists.⁵

Although the current TUE regime is a ‘necessary part of elite sport’⁶ it must be evaluated. On one hand, a need exists to protect athletes’ right to ‘compete on a clean and level playing field’,⁷ while on the other, athletes have a right ‘to the best possible treatment for any medical condition’⁸ they may have. This paper assesses the appropriateness and effectiveness of the TUE regime in the global sporting community and comments on its’ ability to balance these competing interests.

II THE WADA CODE AND THE THERAPEUTIC USE EXEMPTION

Throughout their careers, athletes may require Prohibited Substances or Prohibited Methods to treat legitimate medical conditions. For instance, former Team Sky member Bradley Wiggins initially received three TUEs for salbutamol, formoterol and budesonide, administered to treat his asthma.⁹ Subsequent TUEs also permitted Wiggins to receive three 50mg intramuscular injections of the powerful corticosteroid, triamcinolone to treat his hay-fever.¹⁰ The timing of the injections — before the 2011

³ Kate O’ Flaherty, ‘Midterm Election Hacking – Who Is Fancy Bear?’, *Forbes* (online) 23 August 2018 <<https://www.forbes.com/sites/kateoflahertyuk/2018/08/23/midterm-election-hacking-who-is-fancy-bear/#1c3dc48f2325>>.

⁴ World Anti-Doping Agency, ‘WADA confirms attack by Russian cyber espionage group’, *World Anti-Doping Agency* (online) 13 September 2016 <<https://www.wada-ama.org/en/media/news/2016-09/wada-confirms-attack-by-russian-cyber-espionage-group>>; World Anti-Doping Agency, ‘WADA confirms another batch of athlete data leaked by Russian cyber hackers “Fancy Bear”’, *World Anti-Doping Agency* (online) 14 September 2016 <<https://www.wada-ama.org/en/media/news/2016-09/wada-confirms-another-batch-of-athlete-data-leaked-by-russian-cyber-hackers-fancy>>.

⁵ Luke Sayer, ‘Possible ways the Therapeutic Use Exemptions system can be improved to prevent abuse’, *Law in Sport* (online), 18 October 2016 <<https://www.lawinsport.com/topics/articles/item/are-therapeutic-use-exemptions-open-to-abuse-and-how-can-they-be-improved?>>.

⁶ Note, ‘TUE system can be abused by athletes – Dr Richard McLaren’, *BBC Sport* (online) 16 September 2016 <<https://www.bbc.com/sport/37382825>>.

⁷ International Olympic Committee, *Join us and stand up for clean athletes*, International Olympic Committee (2019) <<https://www.olympic.org/athlete365/zh-hans/%E6%96%B0%E9%97%BB/join-us-and-stand-up-for-clean-athletes/>>.

⁸ World Anti-Doping Agency, *Athletes and Medications*, World Anti-Doping Agency (2019) <<https://www.wada-ama.org/en/questions-answers/athletes-and-medications>>.

⁹ Tony Mogan, ‘What drugs have Sir Bradley Wiggins and Chris Froome been permitted to use?’, *International Business Times* (online) 15 September 2016 <<https://www.ibtimes.co.uk/what-drugs-have-sir-bradley-wiggins-chris-froome-been-permitted-use-1581552>>.

¹⁰ Corticoids are used to ‘reduce pain and ... improve endurance capability and to achieve weight loss to improve power to weight ratio’ which allows cyclists to lose weight without sacrificing power, Cycling Independent Reform Commission, *Report to the President of the Union Cycliste Internationale* (February 2015)

The Therapeutic Use Exemption under the WADA Code

and 2012 Tours de France, and before the 2013 Giro d'Italia — was suspect. Wiggins later took out the title for the 2012 Tour de France. Prentice Steffen, the 2009 Garmin team doctor employed when Wiggins made his breakthrough at the Tour de France, stated he was surprised to see Wiggins had received triamcinolone before these events saying:

You do have to think it is coincidental that a big dose of intramuscular long-acting corticosteroids would be needed at that exact time before the most important race of the season ... the decision to apply for that TUE, is questionable.¹¹

Following the scandal, the United Kingdom ('UK') through its damning government report, *Combating Doping in Sport*, found Team Sky had used triamcinolone to prepare Wiggins for the Tour de France.¹² It was further stated that the drug was administered 'not to treat medical need, but to improve his power to weight ratio ahead of the race.'

It is not only WADA's role to prevent athletes such as Bradley Wiggins from gaining a competitive advantage through the use of such substances or methods, but to ensure such prohibitions do not discriminate against athletes with existing medical conditions, impairment, or disabilities.¹³ In balancing these competing interests, the TUE regime under art 4.4 of the *World Anti-Doping Code* ('WADA Code') provides:

The presence of a Prohibited Substance or its Metabolites or Markers, and/or the Use or Attempted Use, Possession or Administration or Attempted Administration of a Prohibited Substance or Prohibited Method shall not be considered an anti-doping rule violation if it is consistent with the provisions of a TUE granted in accordance with the International Standard for Therapeutic Use Exemptions.¹⁴

In determining whether a TUE should be granted or recognised, the onus of proof rests on the athlete and it remains the same regardless of which Therapeutic Use Exemption Committee ('TUEC') hears the application: 'has the Athlete demonstrated by a balance of probability that each of the conditions set out in article 4.1 is met?'¹⁵

Under the current *International Standards for Therapeutic Use* ('ISTUE'), the criteria which must be met by an athlete seeking a TUE are:

<https://www.zora.uzh.ch/id/eprint/113060/1/Marty_Nicholson_Haas_Report_Cycling_Independent_Reform_Commission_2015.pdf> 59; Tom Ough, "What is triamcinolone, the drug at the heart of the Team Sky 'doping' controversy?" *The Telegraph* (online) 6 March 2018 <<https://www.telegraph.co.uk/health-fitness/body/triamcinolone-drug-heart-team-sky-doping-controversy/>>.

¹¹ Note, 'Former Team Doctor Questions Wiggins' TUEs', *The Straits Times* (online) 25 September 2016 <<https://www.straitstimes.com/sport/former-team-doctor-questions-wiggins-tue>>.

¹² UK Parliament, House of Commons Digital, Culture, Media and Sport Committee, *Combating Doping in Sport* (27 February 2018) <<https://publications.parliament.uk/pa/cm201719/cmselect/cmcumeds/366/366.pdf>>.

¹³ John Koukouras, "Does the World Anti-Doping Authority's current Therapeutic Use Exemption regime sufficiently protect against athletes 'cheating the system?'" (2017) 99 *The Commentator* 3.

¹⁴ WADA Code (n 1) art 4.4 31-6.

¹⁵ World Anti-Doping Agency, *International Standard for Therapeutic Use Exemptions* (1 January 2019) <https://www.wada-ama.org/sites/default/files/resources/files/istue_2019_en_new.pdf> art 4.1 11 ('ISTUE').

- (a) The Prohibited Substance or Prohibited Method in question is needed to treat an acute or chronic medical condition, such that the Athlete would experience a significant impairment to health if the Prohibited Substance or Prohibited Method were to be withheld;
- (b) The Therapeutic Use of the Prohibited Substance or Prohibited Method is highly unlikely to produce any additional enhancement of performance beyond what might be anticipated by a return to the Athlete's normal state of health following the treatment of the acute or chronic medical condition;
- (c) There is no reasonable Therapeutic alternative to the Use of the Prohibited Substance or Prohibited Method;
- (d) The necessity for the Use of the Prohibited Substance or Prohibited Method is not a consequence, wholly or in part, of the prior Use (without a TUE) of a substance or method which was prohibited at the time of such Use.¹⁶

Where an Anti-Doping Rule Violation ('*ADRV*') would ordinarily result from the use of the Prohibited Substance or Method, a TUE recognises an athlete's legitimate therapeutic need for the use of Prohibited Substance or Prohibited Method.

To ensure current attitudes in the fight against anti-doping are recognised, WADA regularly reviews the WADA Code.¹⁷ WADA began the 2021 World Anti-Doping Code Review ('*2021 WADA Code Review*') and a simultaneous review of the International Standards on 16 November 2017. It entailed a two-year, three-phase stakeholder consultation process which aimed to eliminate misapplication and misinterpretation of the WADA Code and International Standards in areas where debate previously arose. A final draft of the 2021 WADA Code was presented for consideration and was approved at the fifth World Conference on Doping in Sport, on 7 November 2019, in Katowice, Poland. The 2021 WADA Code and standards come into effect on 1 January 2021.¹⁸ The 2021 *International Standards for Therapeutic Use Exemptions* ('*2021 ISTUE*') is also due to come into effect on that date.¹⁹

The criteria for obtaining a TUE under art 4.2 of the 2021 ISTUE requires an athlete seeking a TUE to establish:

- (a) The Prohibited Substance or Prohibited Method in question is needed to treat a diagnosed medical condition supported by relevant clinical evidence.

¹⁶ ISTUE (n 15) 4.1 11.

¹⁷ World Anti-Doping Agency, *2021 World Anti-Doping Code and International Standard Framework Development and Implementation Guide for Stakeholders*, World Anti-Doping Agency (18 October 2019) <https://www.wada-ama.org/sites/default/files/resources/files/worldconferencebackgrounder_0.pdf>.

¹⁸ World Anti-Doping Agency, *WADA publishes approved 2021 World Anti-Doping Code and International Standards*, World Anti-Doping Agency <<https://www.wada-ama.org/en/media/news/2019-11/wada-publishes-approved-2021-world-anti-doping-code-and-international-standards>>.

¹⁹ World Anti-Doping Agency, *2021 International Standard for Therapeutic Use Exemptions* (25 November 2019) <<https://www.wada-ama.org/en/resources/the-code/2021-international-standard-for-therapeutic-use-exemptions>>.

The Therapeutic Use Exemption under the WADA Code

- (b) The Therapeutic Use of the Prohibited Substance or Prohibited Method will not, on the balance of probabilities, produce any additional enhancement of performance beyond what might be anticipated by a return to the Athlete's normal state of health following the treatment of the medical condition.
- (c) The Prohibited Substance or Prohibited Method is an indicated treatment for the medical condition, and there is no reasonable permitted Therapeutic alternative.
- (d) The necessity for the Use of the Prohibited Substance or Prohibited Method is not a consequence, wholly or in part, of the prior Use (without a TUE) of a substance or method which was prohibited at the time of such Use.

Considering the approved changes to the current TUE regime, the WADA 2021 Code Review presented a valuable opportunity to evaluate the appropriateness and effectiveness of the then current TUE regime.

III EVALUATION OF THE CURRENT THERAPEUTIC USE EXEMPTION REGIME

A *Number of Therapeutic Use Exemptions Granted*

In light of the 2016 'Fancy Bear' hacking, many sporting stakeholders have questioned whether TUEs may enable healthy athletes to 'legally dope'.²⁰ According to WADA's 2018 *Annual Report*, 2,891 TUEs were entered into ADAMS in 2018 compared to 3,563 entered in 2017.²¹

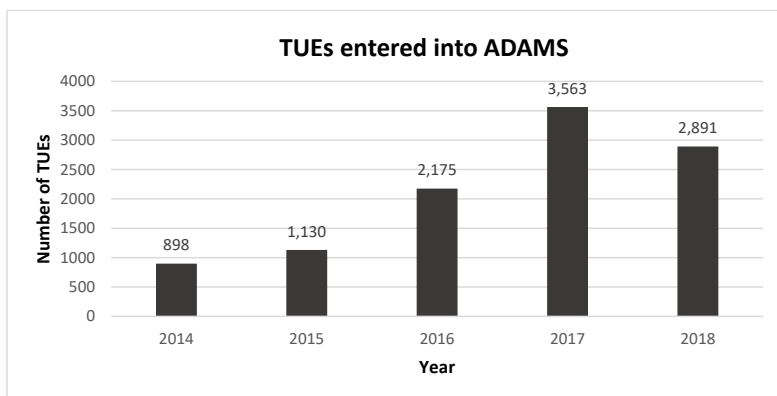


Figure 1: Trend of TUEs entered into ADAMS over five-year period

²⁰ John Koukouras, 'Does the World Anti-Doping Authority's current Therapeutic Use Exemption regime sufficiently protect against athletes 'cheating the system?' (2017) 99 *The Commentator* 4; Jamie Strashin, 'How Olympic athletes (legally) use banned substances', *CBC Sports* (online) 14 October 2016 <<https://www.cbc.ca/sports/olympics/therapeutic-use-exemptions-1.3801960>>.

²¹ World Anti-Doping Agency, *Annual Report* (2018) <https://www.wada-ama.org/sites/default/files/resources/files/ar2018_digital_mq.pdf> 69 ('*WADA 2018 Annual Report*'); World Anti-Doping Agency, *Annual Report* (2017) <https://www.wada-ama.org/sites/default/files/resources/files/ar2017_web.pdf> 58 ('*WADA 2017 Annual Report*').

Despite concerns that TUEs may be easily granted, there are several factors which have led to the increase in TUEs recorded. For one, the decision of the WADA Foundation Board in May 2016 required all Anti-Doping Organisations ('ADO') to enter new TUE decisions into ADAMS. This, coupled with the overwhelming use of ADAMS to record TUEs during the Games, contributed to the 48 percent increase of TUEs recorded between 2014 and 2015.²² According to WADA's 2018 *Annual Report*, the steady increase in TUEs being entered into ADAMS in recent years is due to 'increased compliance efforts by WADA.'²³

According to a 2016 article published by the Sports Integrity Initiative,²⁴ the United States, Australia and France led the world in the number of TUEs granted, with 63 percent of all TUEs granted originating from these countries.²⁵

In Australia, the number of TUE applications received by the Australian Sports Anti-Doping Authority ('ASADA') has reduced significantly since 2009. In ASADA's 2017/18 *Annual Report*, only 169 TUEs were granted, equating to approximately half of the TUEs granted in 2009/10.²⁶

TUE APPLICATIONS	2009-10	2010-11	2011-12	2012-13	2013-14	2014-15	2015-16	2016-17	2017-18
Approved	263	207	202	237	256	234	170	133	169
Closed	2	2	9	15	15	31	10	24	30
Pending	21	20	10	6	17	17	17	4	7
Rejected	17	23	12	12	13	5	3	3	2
Approval not required	282	107	72	67	73	52	45	50	43
Planned retroactive	-	-	-	-	-	30	54	44	39
Total	593	359	305	337	374	369	299	259	291

Figure 2: Trends in TUEs granted by ASADA from 2009/10-2017/18²⁷

²² WADA 2018 Annual Report (n 21) 69. WADA concluded that downturn in TUEs entered from 2017 to 2018 was likely an adjustment to higher administrative efforts for the past years.

²³ World Anti-Doping Agency, *Therapeutic Use Exemption Frequently Asked Questions* (17 November 2016) <https://www.wada-ama.org/sites/default/files/resources/files/tue_qa-eng.pdf> 5.

²⁴ Ibid; Jamie Strashin, 'How Olympic athletes (legally) use banned substances', *CBC Sports* (online) 14 October 2016 <<https://www.cbc.ca/sports/olympics/therapeutic-use-exemptions-1.3801960> (accessed 7 October)>.

²⁵ Andy Brown, 'US & Australia appear to lead world in approved TUEs', *The Sports Integrity Initiative* (online) 26 September 2016 <<http://www.sportsintegrityinitiative.com/us-australia-appear-to-lead-world-in-approved-tues/>>.

²⁶ Australian Sports Anti-Doping Agency, *Annual Report* (2017/18) <https://www.asada.gov.au/sites/default/files/ASADA%20Annual%20Report_2017_18.PDF?v=1549402236> 197.

²⁷ Ibid; Australian Sports Anti-Doping Agency, *Annual Report* (2016/17) <<https://www.asada.gov.au/sites/g/files/net126/f/ASADA%20Annual%20Report%202016-17.pdf>>;

Australian Sports Anti-Doping Agency, *Annual Report* (2015/16) <https://www.asada.gov.au/sites/g/files/net126/f/ASADA%20AR1516%20AccPDF_web.pdf>;

Australian Sports Anti-Doping Agency, *Annual Report* (2014/15) <https://www.asada.gov.au/sites/g/files/net126/f/ASADA_Annual%20Report_2014-15.PDF?v=1446178429>; Australian Sports Anti-Doping Report, *Annual Report* (2013/14)

The Therapeutic Use Exemption under the WADA Code

The decrease in TUE applications and grants can be attributed to the streamlining of information available in relation to the TUE regime. For instance, in 2016, the Australian Sports Drug Medical Advisory Committee ('*ASDMAC*') published criteria that outlined which athletes were required to apply for a TUE depending on their chosen sport. ASADA also attributes the decrease in applications to website improvements which include additional educational components. This enabled athletes to check whether they required a TUE.²⁸

The implementation of ADAMS as a global database for recording TUEs represents a positive step towards better statistics management. While there is concern that excessive TUEs have been granted, such concerns are readily dismissed in light of the above considerations. The data indicates greater reporting compliance to ADAMS.

B Adequacy of the Therapeutic Use Exemption Application Process

A TUEC is required to evaluate the merits of an application by considering the athlete's particular circumstances and applying the stringent TUE rules and regulations of the relevant ADO. With great care and skill, a TUEC must decide whether to grant or refuse an application, or recognise a TUE on the unique facts of before it.

In *International Shooting Sport Federation v World Anti-Doping Agency*,²⁹ ('*ISSF v WADA*') the Court of Arbitration for Sport ('*CAS*') Panel ('*the Panel*') explored the TUE process in an application by professional shooter, Nadine Ungerank, to take the beta-blocker atenolol in order to minimise her risk of cardiac arrest. The 17-year-old athlete suffered from the genetic disorder, Long QT Syndrome ('*LQTS*') Type 1. As beta-blockers act to slow heart rate, their use is prohibited in accuracy sports, having the potential to make firing between heart beats easier.³⁰ As such, the Panel was *inter alia*, required to consider whether the athlete had established the TUE criteria under art 4.1 of the ISTUE.

In doing so, the Panel was faced with the task of balancing competing interests between:

... on the one hand the desire of a young athlete of apparent early promise but adventitiously diagnosed with a potentially fatal heart condition to participate, at the highest level, in her chosen sport, on the other hand the entitlement of her potential

<https://www.asada.gov.au/sites/g/files/net126/f/asada_annual_report_1314.pdf>; Australian Sports Anti-Doping Agency, *Annual Report* (2012/13)

<https://www.asada.gov.au/sites/g/files/net126/f/ASADA_Annual%20Report_2012-13.pdf?v=1446178407>; Australian Sports Anti-Doping Agency, *Annual Report* (2011/12)

<https://www.asada.gov.au/sites/g/files/net126/f/ASADA_Annual%20Report_2011-12.pdf?v=1446178384>; Australian Sports Anti-Doping Agency, *Annual Report* (2010/11)

<<https://www.doping.nl/media/kb/3181/ASADA%20annual%20report%202010-2011.pdf>>; Australian Sports Anti-Doping Agency, *Annual Report* (2009/10)

<https://www.asada.gov.au/sites/g/files/net126/f/ASADA_Annual%20Report_2009-10.pdf?v=1446178315>.

²⁸ Australian Sports Anti-Doping Agency, *Annual Report* (2016/17)

<<https://www.asada.gov.au/sites/g/files/net126/f/ASADA%20Annual%20Report%202016-17.pdf>> 172.

²⁹ CAS 2013/A/3437 ('*ISSF v WADA*').

³⁰ *Ibid* [111] - [113]; NPS Medicinewise, *Atenolol GH Tablets*, NPS Medicinewise <<https://www.nps.org.au/medical-info/medicine-finder/atenolol-gh-tablets>>.

competitors to be confident they are not asked to challenge an athlete with an unfair advantage induced by prohibited substances.³¹

CAS proceedings arose after Ungerank's urine sample collected on 27 February 2013 during an international ISSF competition tested positive to traces of atenelol. While Ungerank had obtained a TUE from her National Anti-Doping Organisation ('*NADO*'), she did not have an international TUE from the ISSF to take atenelol. Therefore, the ISSF Executive Committee instituted disciplinary proceedings against her, expunging her world record and stripping her of her gold medal from the event. Ungerank also received a three-month sanction as a result of the ADRV.

Ungerank's subsequent application for an international TUE was denied. The ISSF held she had only partially established, under art 4.1(a) of the ISTUE, that the drug would significantly impair her health if withheld, being that her risk of suffering a cardiac arrest would increase. The ISSF held Ungerank had failed to establish the drug produced no additional enhancement under art 4.1(b) — she had finished with exceptionally high scores in the competition and failed to counteract the substantial medical evidence surrounding the performance enhancing effect of beta-blockers on athletes in accuracy sports. The ISSF concluded that she had failed to establish the third criterion under art 4.1(c), that no therapeutic alternative was available.³²

Upon review, WADA reversed the decision of the ISSF, granting her permission to use atenolol 35mg twice daily for a period of four years.³³ Under art 4.1(a) of the ISTUE, WADA found she had been 'correctly diagnosed' with LQTS Type 1, a 'life-threatening cardiac arrhythmia syndrome characterised by disturbances of normal electrical activity in the heart'.³⁴ Further, as the natural course of LQTS Type 1 meant patients commonly experienced Sudden Cardiac Death ('*SCD*'), if left untreated, the risk of SCD increased by approximately 12 per cent.³⁵ WADA agreed that the correct therapy to treat LQTS Type 1 was beta-blockers.³⁶ WADA reasoned that, under art 4.1(b), atenolol did not produce a performance enhancing effect as the current literature exploring the effect of beta-blockers in shooting was 'insufficient to constitute any claim of general performance enhancement'.³⁷ In considering art 4.1(c), WADA held there was no reasonable therapeutic alternative to the use of beta-blocker therapy and alternative treatments, such as Implantable Cardioverter Defibrillator ('*ICD*') were 'not medically justifiable or relevant in this instance'.³⁸ Finally, under art 4.1(d), WADA found that that the athlete's medical condition did not result from the use of a Prohibited

³¹ *ISSF v WADA* (n 29) [288].

³² *Ibid* [9] - [18]; art 4.1(d) of the ISTUE was not a contentious issue.

³³ *Ibid* [20].

³⁴ *Ibid* [20].

³⁵ *Ibid* [64].

³⁶ *Ibid* [20]; In its reasons under art 4.1(a), the WADA TUEC held 'Based on current evidence, withholding beta-blockers in a patient with LQTS is unethical and irresponsible as it entails accepting the enhanced risk of Sudden Cardiac Death as a consequence, raising fundamental medico- legal concerns. No physician can be expected to assume responsibility for such a decision.'

³⁷ *Ibid* [20].

³⁸ *ISSF v WADA* (n 29) [20].

The Therapeutic Use Exemption under the WADA Code

Substance or Prohibited Method. As such, WADA found Ungerank had established all criteria under art 4.1 of the ISTUE.

On appeal by the ISSF, the Panel conceded that art 4.1(a) was satisfied — atenolol was needed to treat an acute or chronic medical condition. The Panel further stated that art 4.1(d) was readily satisfied and was not in dispute. The Panel also found art 4.1(c) satisfied on the basis that an informed medical opinion ‘would not recommend as a treatment of first resort something other than beta blockers.’³⁹ Notably, the Panel remarked that the athlete should not compromise treatment as the ‘price to pay’⁴⁰ for competing in such a sport. The Panel lastly considered whether the drug would not enhance the athlete’s performance ‘other than that which might be anticipated by a return to a state of normal health following the treatment of a medical condition’ under art 4.1(b).⁴¹ In turn, the Panel highlighted WADA’s failure to present evidence that atenolol, a beta-blocker, had no performance enhancing effect. Given that the substance was listed on the *Prohibited List*, the Panel held this was:

indicative of the height of the hurdle confronting the Athlete who seeks to satisfy Condition 4.1(b), for even on the premise that atenolol will have beneficial performance enhancing effect on some persons but will not on others, it remains for the Athlete to show that she falls into the category with those who would derive no performance enhancing effect from use of the substance.⁴²

In determining whether the use of atenolol had a performance enhancing effect, the Panel compared the athlete’s shooting scores over the period in which she received beta-blocker treatment.⁴³ While the Panel recognised a trend of improvement in performance once treatment had commenced, it acknowledged the improvement could have been attributed to a ‘multitude of factors’ including coaching, training, competitive experience, and even luck.⁴⁴

In concluding the criteria under 4.1 of the ISTUE was not satisfied, the Panel reinstated the original decision of the ISSF TUEC, refusing the application for an international TUE. WADA subsequently refused the application:

with the regret appropriate in the case of someone, like the Athlete, who has been able to participate in a chosen sport at the highest level while at the same time being the victim of a heart complaint. Nonetheless while all human rights instruments recognise that there is a right to life, none recognise that there is an equivalent right to sport.⁴⁵

With jurisprudence on the TUE regime limited, *ISSF v WADA* greatly impacts athletes seeking TUEs. Of concern, art 4.1(b) of the ISTUE requires an athlete to establish that a Prohibited Substance or Prohibited Method has no performance-enhancing effect.

³⁹ Ibid [302].

⁴⁰ Ibid [302].

⁴¹ ISTUE (n 15) art 4.1(b) 10.

⁴² *ISSF v WADA* (n 29) [313].

⁴³ WADCommentary, *The ISSF v WADA CAS Award: Another Therapeutic Use Exemption Request for Beta Blockers Shot Down*, WADCommentary < http://wadc-commentary.com/issf-v-wada/#_ftn1>; *ISSF v WADA* (n 29) [316].

⁴⁴ *ISSF v WADA* (n 29) [317].

⁴⁵ Ibid [327]; ISTUE (n 15) 6.2(a) 14.

However, under art 4.3.3 of the WADA Code, the classification of substances and methods on the prohibited list is not subject to challenge through reasoning that it does not have the potential to ‘enhance performance, represent a health risk or violate the spirit of sport’. Nevertheless, under art 4.1(b), applicants must establish a lack of performance enhancement.

To advance athletes’ interest and promote fairness in the TUE application process, the criteria under art 4.1 of the ISTUE could be relaxed through the implementation of the ‘*Beweisnotstand doctrine*’⁴⁶ which arises where there is ‘serious difficulty in discharging the burden of proof’.⁴⁷ Where such difficulty arises, the other party is required to ‘substantiate and explain in detail why it deems the facts submitted by the other party to be wrong’.⁴⁸ Applying the *Beweisnotstand doctrine*, a TUEC, if not satisfied that art 4.1(b) could be met, would be required to raise sufficient evidence that the substance or method actually enhances performance in the circumstances. Failure to adduce such evidence would result in satisfaction of art 4.1(b) by default.⁴⁹

To further protect athletes’ interests throughout the TUE application process and promoting greater transparency, independent review of TUEC decisions is recommended. In recognising a need for such review, ASADA’s 2017 *Annual Report* recommended a TUE Committee Peer Review and Audit process be established in Australia.⁵⁰ This recommendation was submitted to WADA by the Australian Government during stage one of the 2021 WADA Code Review. It read:

[T]here is a need for greater monitoring of the application of and adherence to the standard, including TUE committee membership, rigour adopted by such committees in making TUE assessments, and effective audit and central review by the World Anti-Doping Agency. TUE Committee peer review may be one mechanism by which improvements may be realised.⁵¹

Not only could the committee develop protocols for a peer review process of TUEC decisions, but could evaluate the qualifications of TUEC members, and review the current effectiveness of ASDMAC as a decision-maker. If successful, the review system ‘could be used as the standard worldwide and be an important part of ensuring a fair and robust TUE system.’⁵²

⁴⁶ Also referred to as ‘the presumption of fact’. While it does not involve a reversal of an onus, it reduces the effort in discharging the legal burden of proof on the party with whom the burden lies.

⁴⁷ CAS 2011/A/2386, *WADA v Alberto Contador Velasco & RFEC* [255].

⁴⁸ *Ibid* [255].

⁴⁹ WADCommentary, *The ISSF v WADA CAS Award: Another Therapeutic Use Exemption Request for Beta Blockers Shot Down*, WADCommentary < http://wadc-commentary.com/issf-v-wada/#_ftn1>; Marjolaine Viret, *Evidence in Anti-Doping at the Intersection of Science & Law* (ASSER Press/Springer, January 2016) 81.

⁵⁰ The Review Committee would rely on the support of well-established committees such as those of New Zealand, Singapore, and the United States.

⁵¹ World Anti-Doping Agency, *2021 Code Review – First Consultation: Questions to Discuss and Consider* (6 January 2018) <https://www.wada-ama.org/sites/default/files/2018_06_04_stakeholdercomments.pdf>.

⁵² Australian Sports Anti-Doping Agency, *Annual Report* (2016/17) <<https://www.asada.gov.au/sites/g/files/net126/f/ASADA%20Annual%20Report%202016-17.pdf>> 175.

The Therapeutic Use Exemption under the WADA Code

As the 2021 ISTUE no longer requires the TUE be for treatment of an ‘acute’ or ‘chronic’ medical condition, it is likely that athletes will have greater ease in establishing art 4.2(a) of the 2021 ISTUE that, ‘The Prohibited Substance or Prohibited Method in question is needed to treat a diagnosed medical condition supported by relevant clinical evidence’.

While it is reassuring to note TUEs are not readily granted, fairness should remain central to the application, recognition, review, and appeals processes. Such fairness can be advanced through the implementation of the ‘*Beweisnotstand doctrine*’ throughout the TUE application process. In further recognising the need for greater fairness and transparency, a TUE Committee Peer Review and Audit Process would assist by ensuring all decisions reached are in accordance with the WADP. Though the 2021 ISTUE is yet to come into effect, close attention should also be paid to the effect of the reviewed TUE criteria under art 4.2 of the 2021 ISTUE upon athletes seeking to obtain a TUE.

C *Role of Athlete Physicians in the Application Process*

There is no doubt that physicians who treat elite athletes (known as ‘Athlete Support Personnel’)⁵³ play a fundamental role in the sporting community. As the first point of contact, it is crucial that physicians have a sound knowledge of the WADP and *Prohibited list*. It is also important that physicians are externally monitored to ensure their methods are globally consistent and in accordance with the WADP. While art 21.2.1 of the WADA Code mandates that Athlete Support Personnel must be knowledgeable of, and compliant with all anti-doping policies and rules, case studies suggest physicians who act as Athlete Support Personnel lack sufficient knowledge of the WADP.

In 2013, the Australian Crime Commission released its report, *Organised Crime and Drugs in Sport*, which investigated the use of Performance and Image Enhancing Drugs (‘*PIEDs*’) by elite athletes in Australia.⁵⁴ The report found that complacent physicians were ‘key conduits’ through which *PIEDs* were being negligently prescribed to athletes.⁵⁵ Although predating the WADA 2015 amendments, the report highlights concern that members of the medical profession may irresponsibly and/or unlawfully, treat athletes.⁵⁶

The fight against doping is no stranger to intentional, and inadvertent, opposition by physicians. In July 2010, French basketball player, Milos Milinic underwent an in-competition doping test in Zadar, Croatia during the France-Spain semi-final of the International Basketball Federation Europe U-20 Men’s Championship. Milinic’s AAF resulted in an ADRV after his team doctor administered him a mixed treatment of β -

⁵³ WADA Code (n 1) 136.

⁵⁴ Australian Crime Commission, *Organised Crime in and Drugs in Sport* (February 2013) <<http://www.medsafe.govt.nz/consultations/acc-pieds.pdf>>.

⁵⁵ *Ibid* 25.

⁵⁶ David Hughes, ‘Organised crime and drugs in sport’: Did they teach us about that in medical school?’ (2013) (11) *British Journal of Sports Medicine* 661.

agonists - salbutamol and terbutaline to treat his sudden asthma attack. While Milinic had a TUE, his doctor failed to administer the medication in accordance with the exemption. Milinic received a one-month ban as he was held to be of 'no significant fault or negligence'. However, his treating doctor escaped punishment. In 2015, Doctor Stephen Dank, the biochemist responsible for overseeing the supplement program at Essendon in 2012, was found guilty by the Australian Football League ('AFL') tribunal of numerous doping charges, including trafficking illicit substances.⁵⁷ In his defence, for injecting AFL players with thymosin beta 4,⁵⁸ Dank argued he had confused 'thymosin beta 4' with the 'thymomodulin' which was a permitted substance.⁵⁹

The recent 2017 study, *Evaluation of Knowledge on Doping in Sports Among Serbian General Practitioners*,⁶⁰ evaluated the knowledge and attitudes towards doping in sport among general practitioners in Vojvodina, Serbia. The study assessed 276 practitioners, finding only a small number of participants were well-informed about substances on the *Prohibited List* and the WADP (10.5 percent and 8 percent respectively). The study found only 2.5 percent of practitioners believed they were qualified to treat athletes.⁶¹ When asked whether practitioners needed more education in the field of doping, 93.1 percent of participants responded positively. The study found that general practitioners have 'insufficient knowledge on different aspects of doping in sports'.⁶² Dusan Antić argues that, in treating athletes, a need exists to further educate practitioners about doping in sport to prevent accidental doping.⁶³

Physicians who are well informed about the WADP and *Prohibited List* are able to make informed choices about the most suitable form of treatment in the unique sporting context. Well-informed physicians may also implement procedures for consistently treating medical conditions in athletes. In addressing the need to ensure medical practitioners make informed, unbiased decisions, Paul Dimeo and Verner Møller in, *The Anti-Doping Crisis in Sport: Causes, Consequences, Solutions*, suggest WADA-accredited physicians could be appointed to treat athletes. According to Dimeo and Møller:

If WADA-accredited physicians were introduced, the TUE system would undoubtedly be harder to exploit. Independent doctors detached from athletes' and teams' competitive ambitions would be harder to convince that an athlete should be granted a TUE than a

⁵⁷ Michael Warner, 'Stephen Dank cops life ban from AFL anti-doping tribunal', *Herald Sun* (online) 26 June 2015 <<https://www.heraldsun.com.au/sport/afl/more-news/stephen-dank-cops-life-ban-from-afl-antidoping-tribunal/news-story/cff336c38e0512abfd27bbe359a2808a>>.

⁵⁸ World Anti-Doping Agency, *The Prohibited List* (1 January 2018) <https://www.wada-ama.org/sites/default/files/prohibited_list_2018_en.pdf> 27 ('*Prohibited List*'); Thymosin beta 4 is an S2 Prohibited Substance.

⁵⁹ Chip Le Grand, 'Dank swears peptides were permitted', *The Australian* (online) 23 June 2014 <<https://www.theaustralian.com.au/sport/afl/dank-swears-peptides-were-permitted/news-story/2c6c0bc8e016b70c9580bbb3e5ed00da>>.

⁶⁰ Dusan Antić, 'Evaluation of knowledge on doping in sports among Serbian general practitioners' (2017) *LXX Medicinski pregljed* 25-31.

⁶¹ *Ibid* 25-27.

⁶² *Ibid*.

⁶³ *Ibid*.

The Therapeutic Use Exemption under the WADA Code

doctor appointed for good money in the hope that their expertise will make the athletes under their supervision stay competitive and successful.⁶⁴

While Dimeo and Møller's recommendation for the use of WADA accredited physicians is appealing, difficulties exist in its implementation. Practitioners wishing to be accredited would be required to complete rigorous training to ensure they are adequately equipped to diagnose and treat athletes. However, Dimeo and Møller's recommendation should not be disregarded. It would ensure the TUE regime could be strengthened to prevent abuse by physicians acting as Athlete Support Personnel.

D *Retroactive Therapeutic Use Exemptions*

To increase flexibility by recognising athletes' need to receive urgent medical treatment, the 2015 WADA amendments placed broader discretion on TUECs to retroactively grant TUEs under art 4.4.5 of the WADA Code.⁶⁵ A retroactive TUE may be granted where an athlete meets the standard TUE criteria set out under art 4.1, and additionally establishes art 4.3 of the ISTUE. A retroactive TUE may be granted under art 4.3 where:⁶⁶

- (a) Emergency treatment or treatment of an acute medical condition was necessary; or
- (b) Due to other exceptional circumstances, there was insufficient time or opportunity for the Athlete to submit, or for the TUEC to consider, an application for the TUE prior to Sample collection; or
- (c) The applicable rules required the Athlete or permitted the Athlete to apply for a retroactive TUE; or
- (d) It is agreed, by WADA and by the Anti-Doping Organization to whom the application for a retroactive TUE is or would be made, that fairness requires the grant of a retroactive TUE.

The case of *Samir Nasri v Union des Associations Européennes de Football*⁶⁷ ('*Nasri v UEFA*') explored the retroactive TUE criteria and considered the high threshold which athletes must meet in obtaining a retroactive TUE.⁶⁸

In December 2016, French football player Samir Nasri visited Los Angeles for a family holiday. On 26 December 2016, Nasri fell ill. Nasri contacted Dr Sarabjit Anand who visited his hotel room and diagnosed him as being 'in a state of dehydration', having symptoms of 'fever, vomiting, [and] diarrhea.'⁶⁹ Dr Anand prescribed Nasri a 500ml

⁶⁴ Paul Dimeo, Verner Møller, *The Anti-Doping Crisis in Sport: Causes, Consequences, Solutions* (Routledge, 2018).

⁶⁵ World Anti-Doping Agency, *Significant Changes Between the 2009 Code And the 2015 Code Version 4.0*, World Anti-Doping Agency (<<https://www.wada-ama.org/sites/default/files/wadc-2015-draft-version-4.0-significant-changes-to-2009-en.pdf>>).

⁶⁶ ISTUE (n 15) art 4.3 11-2.

⁶⁷ CAS 2017/A/5061 ('*Nasri v UEFA*').

⁶⁸ Rustam Sethna, 'When can athletes obtain a valid retroactive TUE? A review of the Samir Nasri Case' *Law in Sport* (online) 28 March 2018 <<https://www.lawinsport.com/topics/articles/item/when-can-athletes-obtain-a-valid-retroactive-tue-a-review-of-the-samir-nasri-case>>.

⁶⁹ *Nasri v UEFA* (n 67) [113].

intravenous infusion of a sodium chloride solution, stating ‘in general cases treatment would be given per oral.’⁷⁰ As Nasri was required to fly back to Europe to play for Sevilla in the La Liga, Dr Anand regarded his prescription as the ‘fastest and most efficient treatment.’⁷¹ That evening, a company called ‘Drip Doctors’ administered the treatment to Nasri in his hotel room. Nasri quickly recovered and flew back to Europe on 30 December 2016. He informed the Sevilla Football Club of the treatment on the same day and applied for a retroactive TUE on 21 January 2017.⁷²

Considering the above facts,⁷³ the UEFA TUEC rejected Nasri’s original request for a retroactive TUE on the basis that he failed to meet the burden of proof as he had not established all the elements under art 4.1 of the ISTUE, and under art 4.3, had not been suffering from an acute medical condition. The UEFA TUEC concluded no medical emergency existed.⁷⁴

On appeal to CAS, Nasri argued under art 4.1(a) that he was suffering from an acute medical condition as his symptoms made it ‘absolutely impossible for him to travel back to Seville from Los Angeles (a 15-hour flight).’⁷⁵ In the circumstances, Nasri argued, under art 4.1(c), that oral rehydration was not a valid alternative form of treatment as it did not allow him to recover in time to return to Sevilla. With respect to art 4.3(a), Nasri submitted his gastroenteritis and dehydration required emergency medical treatment. Under art 4.3(b), Nasri also argued the treatment was undertaken in exceptional circumstances — Nasri had fallen ill in a foreign country and was required to embark on an international flight in four days’ time.

UEFA argued Nasri had not suffered from an acute medical condition. While Dr Anand diagnosed Nasri with gastroenteritis, he did not consider his symptoms particularly serious. Nasri also failed to provide evidence that he had lost weight as a result of his condition.⁷⁶ In evaluating the application, UEFA’s TUEC member, Dr Gordon, concluded Nasri suffered from ‘mild dehydration that would have been amenable to oral fluids.’⁷⁷ In considering the meaning of ‘acute’ under art 4.1(c), UEFA argued it meant the athlete would experience a significant impairment to health if the Prohibited Method were withheld. UEFA did not regard Nasri’s inability to embark on an international flight as a ‘potential impairment to health.’⁷⁸ Further, UEFA argued that Nasri’s temperature had decreased by the time the Drip Doctors attended him and there was no medical reason why oral rehydration was not possible.⁷⁹ It submitted that no emergency existed under art 4.3(a), and Nasri’s circumstances were not exceptional

⁷⁰ Ibid [114].

⁷¹ Ibid [123].

⁷² Ibid [11].

⁷³ Rustam Sethna, ‘When can athletes obtain a valid retroactive TUE? A review of the Samir Nasri Case’ *Law in Sport* (online) 28 March 2018 <<https://www.lawinsport.com/topics/articles/item/when-can-athletes-obtain-a-valid-retroactive-tue-a-review-of-the-samir-nasri-case>>.

⁷⁴ *Nasri v UEFA* (n 67) [17].

⁷⁵ Ibid [31].

⁷⁶ *Nasri v UEFA*, (n 67) [50].

⁷⁷ Ibid [50].

⁷⁸ Ibid [56].

⁷⁹ Ibid [58] - [59].

under art 4.3(b). UEFA finally argued that Nasri was obligated to contact his team doctor at the time he had fallen ill to discuss adequate alternative treatment instead of following the instructions of a medical practitioner unknown to him.⁸⁰

The Panel ultimately refused Nasri's application for the retroactive TUE. In agreeing with UEFA, the Panel relied upon the Drip Doctors' report, confirming Nasri did not suffer from an acute medical condition. The Panel concluded that, even if Nasri was suffering from an acute medical condition at the time he was visited by Dr Anand, that was no longer the case when the treatment was administered. In relation to art 4.1(c), the Panel found that despite Nasri's condition, he was in a position to question the decision taken by Dr Anand to take the infusion. It said:

he could not simply rely on the decision taken by Dr. Anand to take the infusion. Dr Anand ... was unknown to him and had no doping-related experience ... the Appellant did not even try to contact the medical personnel of his club ... between Dr. Anand's visit and the administration of the infusion. The Appellant was an experienced professional football player who ... checked the Prohibited List every year.⁸¹

Further, the Panel found no 'emergency'⁸² existed for the use of the Prohibited Method. The Panel failed to accept Nasri's obligation to return to Europe as 'exceptional circumstances'. In upholding UEFA's decision to refuse the application for the retroactive TUE, the Panel resolved that while Nasri was in an 'unfortunate situation', considerations concerning intent or the degree of negligence were irrelevant. On the application for the retroactive TUE being refused, Nasri received a six-month sanction for committing an ADRV.⁸³ This decision highlights the stringency of the criteria which must be satisfied in order to obtain a retroactive TUE. Where circumstances arise when an athlete's health is compromised, there is no question that they must tread very carefully by seeking appropriate medical advice and treatment in order to comply with anti-doping laws.

The 2021 ISTUE was approved by WADA's Executive Committee on 7 November 2019 as part of the 2021 WADA Code Review.⁸⁴ The previously-existing criteria under art 4.3 of the ISTUE was amended, and it is now dealt with under art 4.1 of the 2021 ISTUE. Under that article, an athlete may apply retroactively for a TUE if any of the following exceptions apply:⁸⁵

- (a) Emergency or urgent treatment of a medical condition was necessary;

⁸⁰ Ibid [67].

⁸¹ Ibid [125].

⁸² Ibid [128], the Panel stated, 'An emergency situation connotes even more severe circumstances than an acute medical condition in the sense of Article 4.1 a ISTUE'.

⁸³ CAS 2013/A/3327 *Marin Cilic v International Tennis Federation* & CAS 2013/A/3335 *International Tennis Federation v Marin Cilic*; Rustam Sethna, 'When can athletes obtain a valid retroactive TUE? A review of the Samir Nasri Case' *Law in Sport* (online) 28 March 2018 <<https://www.lawinsport.com/topics/articles/item/when-can-athletes-obtain-a-valid-retroactive-tue-a-review-of-the-samir-nasri-case>>.

⁸⁴ 2021 ISTUE (n 19).

⁸⁵ Ibid art 4.1 10.

- (b) There was insufficient time, opportunity or other exceptional circumstances that prevented the Athlete from submitting (or the TUEC to consider) an application for the TUE prior to Sample collection;
- (c) Due to national level prioritization of certain sports, the Athlete's National Anti-Doping Organization did not permit or require the Athlete to apply for a prospective TUE;
- (d) If an Anti-Doping Organization chooses to collect a Sample from an Athlete who is not an International-Level Athlete or National-Level Athlete, and that Athlete is Using a Prohibited Substance or Prohibited Method for Therapeutic reasons, the Anti-Doping Organization must permit the Athlete to apply for a retroactive TUE; or
- (e) The Athlete Used Out-of-Competition, for Therapeutic reasons, a Prohibited Substance that is only prohibited In-Competition.

Notably, it is no longer necessary that the Prohibited Substance or Method be required for treatment of an *acute* medical condition.⁸⁶ Instead, art 4.1(a) be met if emergency or urgent treatment of a medical condition was necessary.⁸⁷ The 2021 ISTUE also includes an exception under art 4.1(e) for situations where a Prohibited Substance or Prohibited Method is used Out-of-Competition for therapeutic reasons, but there is a risk that the substance will remain in the athlete's system In-Competition.⁸⁸

Under the 2021 ISTUE, a stand-alone exemption also exists under art 4.3 where 'it would be manifestly unfair not to grant a retroactive TUE, even if all the criteria in Article 4.2 may not be fulfilled.'⁸⁹ However, the exemption is reserved for 'truly exceptional and rare circumstances'.⁹⁰

Retroactive TUEs add much-needed flexibility to anti-doping laws. While their use is confined to circumstances of absolute necessity, the changes to the retroactive TUE provisions following the 2021 WADA Code Review afford greater fairness to athletes wishing to obtain retroactive TUEs. If the case of *Samir Nasri v Union des Associations Européennes de Football* were to be decided under the 2021 ISTUE, Nasri would have a greater chance of obtaining a retroactive TUE in his unfortunate circumstances.

E *Supervision of Athletes with a Therapeutic Use Exemption*

Once granted a TUE, the athlete must strictly comply with the conditions of use imposed by the relevant TUEC, such as dosage, frequency, route and duration for the use of the medication.⁹¹ Failure to comply may result in the TUE being withdrawn, or

⁸⁶ ISTUE (n 15) art 4.3 11.

⁸⁷ 2021 ISTUE (n 19) art 4.1 10.

⁸⁸ Ibid art 4.1(e) 10; See WADA Code (n 1) 90,92 for definitions of 'In-Competition' and 'Out-of-Competition'

⁸⁹ 2021 *World Anti-Doping Code and International Standard Framework Development and Implementation Guide for Stakeholders* (n 17) 26.

⁹⁰ Ibid 26.

⁹¹ ISTUE (n 15) art 6.8(a) 15.

The Therapeutic Use Exemption under the WADA Code

WADA may reverse it upon review or appeal.⁹² Supervision of athletes with TUEs remains a legitimate concern within the global sporting community.

While literature on the topic of TUE supervision is limited, CAS jurisprudence suggests that an Adverse Analytical Finding ('AAF') may arise in circumstances where an athlete uses an excess of the substance *without* an intention to enhance their performance.

For instance, the case of *Filippo Volandri v International Tennis Federation*,⁹³ ('*Volandri v ITF*') involved the overuse of salbutamol by professional tennis player, Filippo Volandri. In that case, Volandri's A Sample collected on 3 March 2008 after losing his first game in two straight sets, was found to have a higher concentration of salbutamol than permitted under the WADA Code. Volandri's TUE directed he use salbutamol in a dosage of 200mcg by inhalation 'if necessary'. The AAF arose in circumstances where Volandri had experienced 'the most serious asthma attack of his life'⁹⁴ where he took approximately 10 to 20 puffs of insulin over an 8 to 18-hour period before his sample was collected.⁹⁵ On appeal to CAS, the Panel found Volandri had failed to establish on the balance of probabilities that the AAF was as a result of his compliance with the TUE. While the Panel interpreted 'two puffs if necessary' to equate to 32 puffs of Ventolin (per the Global Initiative for Asthma guidelines), Volandri 'did not offer any scientific evidence whatsoever' to support his position that the use of salbutamol was consistent with its therapeutic use.⁹⁶ In finding Volandri had committed an ADRV, the Panel issued him with a reprimand and disqualified his competitive results accumulated at the time of the ADRV.

Similarly, in *Comitato Olimpico Nazionale Italiano v Alessandro Petacchi & Federazione Ciclistica Italiana* and *World Anti-Doping Agency v Alessandro Petacchi & FCI*,⁹⁷ Alessandro Petacchi received a one-year sanction preventing him from competing in competitive cycling after his A Sample returned positive for salbutamol in levels exceeding those permitted by his TUE. While Petacchi was granted a TUE for three doses of 200mcg of salbutamol by inhalation per day (600 mcg maximum per day), his A Sample collected shortly after his win of the 11th stage of the Giro d'Italia recorded the concentration of salbutamol as being 1353 ng/ml.⁹⁸ In exercising its appellate jurisdiction, the Panel held Petacchi had failed to establish on the balance of probabilities that his AAF was the consequence of correct use of his TUE. Nevertheless, the Panel found that there had been 'no significant fault or negligence' as Petacchi had 'simply and, possibly, accidentally, taking too much salbutamol on the day of the test, but that the overdose was not taken with the intention of enhancing his performance.'⁹⁹ As a result, the Panel reduced the period of ineligibility he would have suffered,

⁹² Ibid art 6.10 15.

⁹³ CAS 2009/A/1782 ('*Volandri v ITF*').

⁹⁴ Ibid 4.

⁹⁵ Ibid 21[51].

⁹⁶ Ibid 17[39].

⁹⁷ CAS 2007/A/1362 and CAS 2007/A/1393 ('*CONI v Petacchi & FCI & WADA v Petacchi & FCI*').

⁹⁸ Ibid [52]- [54]; Petacchi won the 11th stage of the Giro d'Italia on 23 May 2007; *Prohibited List 4*.

⁹⁹ Ibid [54].

imposed a 12-month sanction and disqualified all of his results from the 2007 Giro d'Italia.

The Panel's reasoning and decisions in both cases is sound, and demonstrate the need to educate athletes with TUEs, clarify ambiguous wording of TUEs, and ensure athletes strictly comply with the TUE.

F *Therapeutic Use Exemption Statistics Management*

WADA asserts that athletes' personal information must be protected to 'ensure the continued confidence and trust of those involved in organized sport.'¹⁰⁰ Under art 14.4 of the WADA Code, WADA and ADOs are required to annually publish a 'general statistics report' of their doping control activities.¹⁰¹ Despite having power to publish reports disclosing the names and dates of each athlete tested, this practice is seldom used by ADOs.¹⁰²

In *Olympic Doping, Transparency, and the Therapeutic Exemption Process*, Luke Cox, Andrew Bloodworth and Mike McNamee argue that increased disclosure of TUE data would place greater pressure on physicians to prescribe medication legitimately. If the TUE process is perceived to be under greater public scrutiny, the TUE regime is less likely to be exploited.¹⁰³

Greater transparency would further enable TUE trends to be monitored. Where concerning trends surface (such as increases in TUE grants for substances with significant performance enhancing abilities, or spikes in TUE grants prior to competition) stakeholders may encourage WADA to investigate.¹⁰⁴

Sports lawyer, Luke Sayer, suggests the current TUE regime could be improved by requiring WADA to publish annual statistics in relation to TUEs prescribed per capita, across countries, and their prevalence within certain sports. This would provide adequate transparency throughout the TUE regime while still upholding the anonymity of athletes and the protection of their medical information.¹⁰⁵

In the 2021 WADA Code Review, United Kingdom Anti-Doping ('UKAD') suggested confidence in the TUE regime could be strengthened by not only requiring all ADOs to register TUE decisions in ADAMS in order to give WADA's Medical Department 'greater oversight of the system' but also requiring:

¹⁰⁰ World Anti-Doping Agency, *International Standard for the Protection of Privacy and Personal Information* (1 June 2018) <https://www.wada-ama.org/sites/default/files/resources/files/ispppi-final_-_en.pdf> 31.

¹⁰¹ A copy of which must also be provided to WADA.

¹⁰² WADA Code (n 1) art 14.4 92.

¹⁰³ Luke Cox School, Andrew Bloodworth and Mike McNamee, 'Olympic Doping, Transparency, and the Therapeutic Exemption Process' (2017) 1 *Diagoras: International Academic Journal on Olympic Studies* 55-74.

¹⁰⁴ As certain sports attract certain medical conditions, TUE grants that indicate athletes are receiving uncharacteristic treatments may also be monitored and reviewed.

¹⁰⁵ FEO P-S, 'Possible ways the Therapeutic Use Exemptions system can be improved to prevent abuse', *The Gateway* (online) 27 September 2016 <<https://www.thegatewayonline.ca/2016/09/medical-records-doping-reform/>>.

The Therapeutic Use Exemption under the WADA Code

ADOs to publicise anonymised annual statistics of their TUE programme to increase public transparency and to identify policy areas within national and international TUE systems that may need further review or scrutiny.¹⁰⁶

Though the exploitation of any process or system on a global scale is foreseeable, better statistics management may provide the current TUE regime with greater transparency and accountability in upholding the integrity of elite sport.¹⁰⁷

IV CONCLUSION

The current TUE regime has received criticism in recent times for the perceived high number of TUEs granted per annum. While the number of TUEs recorded in ADAMS has increased, this was attributed to greater compliance by ADOs in registering TUEs in ADAMS, and *not* directly due to an increase of TUEs actually granted. In the Australian sporting context, statistics indicate a decline in the number of TUEs granted, proportionate to the number of TUE applications submitted. ASADA attributed these trends to the readily accessible educational resources available to athletes enquiring about the TUE application process.

In examining the current TUE application process, the decision reached by the Panel in *ISSF v WADA* has strong implications. Namely, the difficulty faced by an athlete in discharging the burden under art 4.1 of the ISTUE. This is especially so where the athlete is seeking a TUE for a Prohibited Substance or Method which has the potential to enhance performance. The result of such a burdensome requirement can be unjust outcomes. The Panel's ruling in *ISSF v WADA* essentially meant the 'talented'¹⁰⁸ 17-year old athlete was required to choose between participating in her chosen sport at the expense of her health, or retiring from the sport to receive the recommended medical treatment.

To ensure all applicants have the opportunity to argue their case without setting themselves up for failure, the *Beweisnotstand doctrine* may assist in eliminating any injustice if applied to art 4.1 of the ISTUE or art 4.2 of the 2021 ISTUE. Additionally, a TUE Committee Peer Review and Audit Process ought to be implemented to promote objectiveness, transparency, and balance in the TUE application, recognition, review, and appeals processes. With the introduction of the 2021 ISTUE nearing, close attention should be paid to the effect of the reviewed criteria which removes the need for the athlete to establish they suffer from an *acute* or *chronic* medical condition.

Under the current regime, there are primary concerns surrounding the role of physicians acting as Athlete Support Personnel. Under the current TUE regime, the rights of clean athletes are not adequately protected as there is room for intentional and inadvertent

¹⁰⁶ World Anti-Doping Agency, *2021 Code Review – First Consultation: Questions to Discuss and Consider* (6 January 2018) <https://www.wada-ama.org/sites/default/files/2018_06_04_stakeholdercomments.pdf> 237.

¹⁰⁷ World Anti-Doping Organisation, *Who We Are*, World Anti-Doping Organisation <<https://www.wada-ama.org/en/who-we-are>>.

¹⁰⁸ *ISSF v WADA* (n 29) [50] 21.

abuse of the regime by physicians.¹⁰⁹ In devising innovative and practical solutions to assist with WADA Code compliance, it is reasonable to suggest that all athlete physicians obtain WADA accreditation and training as suggested by Paul Dimeo and Verner Møller in, *The Anti-Doping Crisis in Sport: Causes, Consequences, Solutions*. In doing so, physicians would be seen as impartial and would possess much-needed knowledge to treat athletes within the confines of the WADP.

Under the WADA Code, retroactive TUEs effectively protect the rights of athletes to receive medical treatment where obtaining an in-advance TUE is not possible. Though it may difficult to obtain a retroactive TUE (as the case of *Nasri v UEFA* demonstrates), there is hope that the 2021 ISTUE provides greater fairness to athletes who require urgent medical treatment in their unique circumstances while still upholding values of clean sport.

Athlete supervision also remains a pressing issue under the TUE regime. CAS jurisprudence, such as *Volandri v ITF*, and *CONI v Petacchi* and *WADA v Petacchi* indicates that athletes require greater education about the TUE regime in order to fully understand the conditions and implications of their TUE.

A final recommendation relates to statistics management of TUEs. Though the conduct of Fancy Bear is to be condemned, the data leaks led to productive and insightful debate about the TUE regime within the global sporting community. WADA and all ADOs could publish annual statistics in relation to TUEs prescribed per capita, across countries, and the prevalence within certain sports while still protecting the privacy of athletes.¹¹⁰ Such transparency would further demand compliance by physicians and ensure concerning trends in TUE data do not go unnoticed.

While it is within WADA's aims to advance the fight against doping through the banning of Prohibited Substances and Prohibited Methods, the abolition of the TUE regime would see many talented athletes deprived of their ability to participate in their chosen sports. Removal of the TUE regime would also facilitate a culture of unlawful and unsafe doping practices. WADA's TUE regime can certainly be admired for its ability to protect the rights of athletes who require legitimate medical treatment while still advancing the fight against doping.

However, ongoing changes must be made by WADA to ensure the TUE regime reflects the shared values of the international sporting community. With the 2021 WADA Code Review now complete, it is important that ongoing change to the TUE regime is not overlooked. By recognising the need for improvement to the current regime and

¹⁰⁹ Australian Crime Commission, *Organised Crime in and Drugs in Sport* (February 2013) <<http://www.medsafe.govt.nz/consultations/acc-pieds.pdf>>; Marie Overbye and Ulrik Wagner, 'Between medical treatment and performance enhancement: An investigation of how elite athletes experience Therapeutic Use Exemptions' (2013) 24 *International Journal of Drug Policy*; Dusan Antic, 'Evaluation of knowledge on doping in sports among Serbian general practitioners' (2017) LXX *Medicinski pregljed* 25-31.

¹¹⁰ Luke Sayer, 'Possible ways the Therapeutic Use Exemptions system can be improved to prevent abuse', *Law in Sport* (online), 18 October 2016 <<https://www.lawinsport.com/topics/articles/item/are-therapeutic-use-exemptions-open-to-abuse-and-how-can-they-be-improved?>>.

The Therapeutic Use Exemption under the WADA Code

implementing such changes, WADA can continue to remain a guiding light for sporting stakeholders worldwide in coordinating the fight against doping.

