Treating or Cheating? The TUE Question

Recent fallout over the hacking of the World Anti-Doping Agency's athlete medical data files has been far-reaching. Most of the world now knows which champion athletes have competed using a therapeutic use exemption, or TUE; the use of doctor-prescribed medication in and/or out of competition. Despite this unfair invasion of the athletes' privacy by a hacking group called Fancy Bears, the old ethical question has again been raised – as to whether the TUE is a progressive development to preserve health and equitable career opportunities, or whether it is simply another loop-hole which can be exploited by certain athletes to win at any cost. And a new question is coming to light: if the TUE database can be hacked, can the process of obtaining a TUE be hacked as well?

Cycling, like many other sports overseen by the WADA codes, allows athletes to receive TUEs from their respective national anti-doping organizations, but only after rigorous medical testing and diagnosis confirmation. The most recognizable examples of TUEs in elite cycling involve athletes with asthma being allowed to use an inhaler or similar medication, insulin for diabetes, (or as WADA's data breach confirmed) exemptions for corticosteroids to treat bronchitis or allergies.

Even without the recent revelations surrounding the Sky pro team and various individual star athletes, the TUE has been one of the most polarizing topics in competitive cycling. International federations like the UCI have the discretion to impose even tougher TUE approval standards for their respective sports. As a result of this, and the removal of some over-the-counter medications and more benign substances from the WADA banned list, the number of TUEs issued at the top-level of pro cycling has actually declined in recent years, despite the recent news and high-profile athletes named.

But TUEs not only affect the elite strata of the sport; closer to home, it is particularly troubling in U.S. amateur Masters racing. There are other potent medications which can be used as performance enhancing drugs such as those prescribed for thyroid conditions, or synthetic testosterone replacement therapy (TRT) for hypogonadism (low testosterone, or "Low T") in men. Testosterone is one of the most potent and widely abused doping substances and is at the center of U.S. cycling's TUE debate. Several Masters racers have been issued a special type of certificate called a Recreational Competitor TUE for TRT since June 2015, and now many Masters racers are asking if competition in those categories will really be fair in the future.

The U.S. Anti-Doping Agency (USADA) and other national anti-doping bodies oversee more than just pro athletes – comprising age ranges all the way from Juniors to the Masters level competitors. The age range of most Masters-level competitors sits right in the primary population for hypogonadism. In fact, this demographic segment of USA Cycling's licensed racers has grown significantly as the U.S. population has aged. Almost predictably, there have been increasing number of "hits," where older, non-elite cyclists on physician-prescribed TRT test positive for their medication in the past few years.

USADA has been criticized over its handling of some of these cases. Hence, in what may have been a response to this situation, it launched the Recreational Competitor TUE (or RCTUE) on April 10, 2015 to differentiate elite, professional athletes from casual racers. However, USADA continued to place so much focus on the medical testing, the physician/patient relationship, the legal definition and criteria for diagnosis, that the procedural challenge of obtaining a RCTUE might *itself* be perceived as a deterrent to requesting one. The athlete must submit an exacting and comprehensive medical history, which is then reviewed by an independent USADA TUE committee comprised of experts in that specific condition or disease. (USADA has a network of more than twenty highly-qualified medical experts from around the country, in different disciplines, from which individual TUE review committees are convened.)

This review committee *can* approve a TUE if it meets the four key criteria in the international WADA-established TUE requirements, and comes to the same conclusion as the athlete's physician – in terms of

the medication need, dosage and duration. The process is expensive, time-consuming, not covered by medical insurance as an elective action, and potentially exposes private medical information to many parties. Even though the introduction of the RCTUE has been perceived as potentially lowering the bar, USADA in fact rejects the vast majority of all TUE applications. Hence, the apparent perception – based on early media reports – that RCTUEs are "rubber stamps" or easy to obtain, is simply not true.

However, on the other hand, USAC's Master's men's category contains some of the most affluent and litigious demographics in all of U.S. sports. Many of these aging weekend warriors have demonstrated their willingness to take on USADA in the courts. And complicating the issue from a social perspective, the pharmaceutical industry has popularized testosterone replacement programs with a long-term advertising campaign and the catchy hook, "Low T." While this has undoubtedly helped improve the lives of many men who otherwise might never have sought diagnosis and treatment for hypogonadism, it has also desensitized the public and created the popular belief that testosterone is a readily-available magic elixir – as ubiquitous as caffeine, Ibuprofen, or Viagra.

Overall, the explosion of testosterone prescriptions in the last ten years has, not surprisingly, built a profitable $2 billion market, not including the influx of dubious over-the-counter testosterone "boosting" supplements. TRT is unfortunately no longer perceived as a complex medical treatment, but has been recast as something more like cosmetic surgery. However, instead of fixing a scar or a crooked nose, Low T redefines feeling weak or fatigued as an "ailment" – a medical condition rather than a natural progression of the human condition.

The Outer Line reached out to medical experts in endocrinology, cardiology, family practice, laboratory testing and oncology to discuss how the Recreational Competitor TUE for testosterone could be diverted from legitimate patient treatment into the realm of cheating. Several key factors were pointed out as potentially increasing the risk of abuse in sports.

The goal of TRT is to return a patient to a normal level of testosterone and restore their baseline level of health – not to extend an athlete's performance beyond what it would otherwise be in the absence of the disease. However, that "normal level" could be manipulated to improve the effects. A healthy 35-55 year-old's testosterone level sits in a specific range, and TRT could potentially increase it right up to the limit for a specific age without fear of a positive test – analogous to the UCI's "speed limit" of a 50% hematocrit during the EPO era. Synthetic testosterone is proven to decrease recovery time and increase lean muscle mass, but it can also raise the hematocrit in some patients by up to 10% – similar to the supercharging effects of blood doping.

Physicians also have more leeway to prescribe synthetic testosterone for a condition it is not explicitly approved to treat – an "off-label" prescription – than ever before. This shift in physician discretion means that more prescriptions for testosterone are being dispensed, and not always for patients diagnosed with diseases for which the FDA has approved testosterone as a treatment. This indirectly affects RCTUE policies by directly increasing the accessibility of testosterone to athletes, and the amount of testosterone which can be diverted for cheating.

Several of the physicians we spoke to believe that a RCTUE for TRT could be abused through a strategy of "gaming" the system. For example, suppose that a Masters athlete dopes himself with synthetic testosterone a week or so before going in for a physician's lab test. It is scientifically proven that the presence of excess testosterone creates a negative feedback effect on the pituitary gland, causing a rapid *decrease* in the production of natural testosterone – and this phenomenon would occur during the timeframe prior to the lab work. The synthetic testosterone would not be detectable by a standard hospital laboratory, while the test results for overall testosterone levels would be deceptively low. Hence, the analytical results would tilt the RCTUE request in the athlete's favor.

This potential TRT abuse example highlights a key policy alternative for USADA to consider: perhaps its own accredited labs should do at least some of the physician diagnostic tests, or that tests must be performed by higher-sensitivity “reference” labs with more sophisticated equipment which have the capability to tell the difference between synthetic and natural testosterone. USADA could perform a targeted test on that applicant at any time, but of course this begs the vexing question of who would pay for any additional and more detailed tests. This method of gaming the system has allegedly already been used by some in the U.S. to obtain TRT and to fool insurance companies into reimbursing the considerable long-term medication, physician and lab testing costs.

The general concept behind the TUE is a vital component of a strong and healthy anti-doping strategy, even at the highest levels of pro cycling. It is a kind of containment policy which permits the medical community to actively treat patients for real issues while allowing them to pursue professional competitive careers, have normal lives, or just enjoy the camaraderie that comes with sports participation. However, it also just so happens that some of these athletes may be your local Masters weekend racing arch-enemies.

Those Master’s categories are among U.S. competitive cycling’s most important demographics, providing the National federation with much of its financial stability in recent years. USAC must continue to meet the needs of these constituents, even as it moves to increase membership in the Women's and Juniors ranks. But when some weekend warrior with a Recreational Competitor TUE suddenly transforms from “criterium pack-filler” into a big-time event winner, how will the USAC, USADA or other Masters athletes react?

USADA recognizes that it must balance the oversight and policing of this issue, with its more significant mission of monitoring elite athletes. But USADA is also an organization with limited resources trying to oversee a huge population of amateur athletes, and it is almost certainly feeling the strain as it stretches to cover more and more non-elite competitors. USADA admits that it can’t possibly test or track all amateur events. “We’re trying to utilize the resources we have as efficiently as possible,” says Ryan Madden, USADA’s Communications Manager. “We’ve heard the voice of the athletes, and we’re working with local cycling associations to try to create and preserve a level playing field, the best we can.”

USA Cycling could work with USADA to impose a more balanced, or perhaps more restrictive, overall TUE policy. But in the bigger picture, physician governance bodies – not just the ad-hoc and established physician TUE review committees – need to devise a consensus for how to protect the health of patients who are competitive athletes, and make this a standard against which future sporting policy can be weighed.

The question, “How sick is *too* sick to compete?” now begs for a definitive answer at all levels of sanctioned competition, not just the elite level of the Tour de France. Hypogonadism, for example, is a serious medical condition; and like many diseases, it should not be viewed as a simple athletic handicap to be quickly corrected, especially as increases in testosterone can worsen pre-existing medical conditions, and in some cases, trigger new and serious illnesses. Other conditions eligible for a TUE or RCTUE should be viewed in the same light.

Pro cycling has tended to focus on what is best for its economics rather than what is best for the affected or ill individual, and this in turn tends to push TUEs in the direction of sanctioned doping. Global TUE reforms must focus on athlete health to reinforce sporting integrity and uphold competitors’ rights; not just the rights of athletes with legitimate medical conditions, but also those of healthy athletes around them. As long as there is a gray area between a doctor’s dedicated care and a consensus legal opinion, TUEs will represent a thin line between “treating the athlete” and “a cheating athlete.” It may be time for cycling to start prescribing enforced rest as freely as some professional teams apparently prescribe potent corticosteroids.

Joe Harris and Steve Maxwell, October 3, 2016