The IAAF stands accused by English newspaper, The Sunday Times, German broadcaster, ARD, and their two retained consultants, Dr Michael Ashenden and Mr Robin Parisotto, of cynically tolerating rampant blood doping in athletics from 2001 to 2012. In particular, Dr Ashenden claimed in testimony before the UK Parliament's Culture, Media and Sport Committee in September 2015 that the results of blood tests carried out by the IAAF in that period constitute 'compelling evidence' of blood doping that the IAAF could and should have used to charge and ban the athletes involved, but failed to do so. Mr Parisotto agrees, describing the blood test results as 'damning in that so many athletes appeared to have doped with impunity without repercussions but more damning in that the IAAF appears to have idly sat by and let this happen'. And ARD and The Sunday Times have run a series of sensationalist story-lines on the back of this analysis, under the by-line 'Sport's Dirtiest Secret'.

These allegations are distinct from the allegations made in the report issued by the Independent Commission on 9 November 2015, that high-ranking officials at or associated with the IAAF corruptly delayed the prosecution of up to eight Athlete Biological Passport cases in 2012, thereby allowing certain athletes to compete at the London Olympics who should instead have been provisionally suspended from the sport. The IAAF will respond separately to the Independent Commission's report. In this document, it focuses solely on the allegations made by ARD/The Sunday Times in relation to the blood test results from 2001 to 2012.

These blood test results were recorded in a database that was obtained from the IAAF without consent (not from any 'IAAF whistle-blower', as has been suggested) and provided illicitly to the Sunday Times and ARD. There is a pending police investigation into the circumstances in which it came into the journalists' possession. The IAAF does not raise this point because it is trying to cover up evidence of doping in its sport. To the contrary, the trends shown by the information in the database were reported in a paper published in 2011, with the IAAF's consent, titled '*Prevalence of Blood Doping in Samples Collected from Elite Track and Field Athletes*'.<sup>1</sup> However, that does not change the fact that the database contained confidential personal data relating to many entirely innocent athletes. Dr Ashenden and Mr Parisotto knew from the information in the database the individual names and nationalities of the athletes whose data they were being asked to review; they knew the data to be confidential personal data belonging to those athletes; and they also knew the risks of destroying the reputations of innocent athletes through misinterpretation of that data. They should never have taken that risk.

The IAAF certainly does not deny that there is blood doping in its sport, but it does vehemently deny that it has 'idly sat by and let this happen'. To the contrary, a fair assessment of the <u>facts</u> shows clearly that, rather than sitting idly by while athletes cheat in its sport, the IAAF has in fact consistently been a pioneer at the forefront of the war against blood doping, using every tool available to it to catch the cheats, with considerable success. In summary:

 If the IAAF had wanted to cover up blood doping, it could simply have not collected any blood samples for testing, since there was no mandatory requirement to do so at the time, and most anti-doping organisations did not do so. Instead, however, the IAAF collected thousands of blood samples, and used the results not only to build up a database of intelligence on which to base its test distribution planning, but also to conduct target testing of athletes for rEPO urine testing

when their blood results were abnormal and potentially indicative of blood doping, with a significant degree of success. (See <u>Sections 1-2</u>, below).

- Dr Ashenden and Mr Parisotto cannot deny this, so instead they argue that the blood test results that the IAAF collected were 'compelling evidence' in and of themselves of blood doping, so that there was no need to conduct further testing to see if rEPO could be found in the athletes' urine. Instead, they say, the athletes should have been charged with blood doping based on the blood test results alone. (See Section 3).
- With respect, this is just wrong, and Dr Ashenden and Mr Parisotto know it. The two highest legal authorities on the use of drugs in sport, the World Anti-Doping Agency (WADA) and the Court of Arbitration for Sport (CAS), have confirmed that blood test results can only be used as reliable evidence of doping when (a) the blood samples in an athlete's profile have all been collected in accordance with standardised testing protocols that permit their values to be fairly compared with each other; and (b) procedures have been followed and information has been gathered that enables the experts to assess the possibility that any abnormalities in those values could have an innocent cause. Those protocols and procedures were only finalised and validated by WADA in 2009, which is why no blood doping cases have ever been brought based on pre-2009 samples. (See Sections 4 and 6).
- It is very unfortunate that insinuations of blood doping were made based on incomplete data recorded in a database that was obtained from the IAAF without consent (and not from any 'IAAF whistle-blower', as has been suggested) and provided illicitly to the Sunday Times and ARD. The case of Paula Radcliffe shows how athletes can be wrongly accused based on the misinterpretation of that data. It also demonstrates perfectly why that data could not, of itself, be regarded as reliable evidence of blood doping. And it also shows the lengths that the IAAF went to, including in Ms Radcliffe's case, to ensure that every available test was used to determine whether cheating was going on. (See Section 5).

The IAAF is far from complacent. It understands that there is always more that can and should be done to fight the scourge of doping in sport. It also acknowledges the important role played by journalists not only in unearthing evidence of doping but also in scrutinising the efforts made by antidoping organisations to fight doping in their sports and countries. Such scrutiny, when it is wellinformed, fact-based, and fair, plays an important part in holding the anti-doping movement to account and so maintaining the public's confidence that the IAAF and its fellow stakeholders in that movement are ready, willing and able to do everything necessary to fight doping in sport.

When journalism is not well-informed, fact-based, or fair, however, i.e., when it is simply wrong both as a matter of science and as a matter of law, and therefore gives rise to wholly groundless accusations of inaction/incompetence on the part of the IAAF, as well as damaging false assertions and inferences about individual athletes, then the IAAF has not only the right but also an obligation to set the record straight.

#### 1. What is blood doping?

- 1.1 Blood doping is the abuse of certain substances or methods to increase the number of red blood cells in the body (or, more specifically, the amount of haemoglobin, the oxygen-transporting molecule in those red blood cells, in the blood), so that the blood carries more oxygen to the muscles, enabling those muscles to do more work for longer periods, thereby enhancing sport performance.
- 1.2 The three main methods of blood doping used in sport are believed to be: (1) injecting substances that artificially stimulate the body to produce more new red blood cells than it would naturally produce (erythropoiesis-stimulating agents, or ESAs, such as synthetic erythropoietin, or rEPO, and hypoxia-inducible factor stabilizers such as FG-4592/ASO1517); (2) transfusing one's own previously-extracted blood ('autologous' blood transfusion) or someone else's blood ('homologous' blood transfusion); and (3) infusing synthetic hemoglobin-based oxygen carriers (HBOCs).<sup>2</sup>

#### 2. What tools exist to detect blood doping, and what use has the IAAF made of them?

#### 2.A What tools were available pre-2009, and what use has the IAAF made of them?

- 2.1 It became clear in the 1990s that rEPO abuse and other forms of blood doping were taking place in many sports and many countries. Given the general physical demands on track and field athletes, and the numerous endurance disciplines in the sport, it was clear that athletics would not be immune from blood doping, and so the IAAF turned its attention to identifying ways of detecting and deterring this new form of cheating, starting with the testing of blood samples collected at IAAF meetings in 1993 and 1994 for evidence of blood transfusions.<sup>3</sup>
- 2.2 At this early stage, however, there were limited tools available to the sporting community to test athletes for blood doping. Anti-doping science was still at a developmental stage at the time, and there was no means of detecting rEPO use directly in blood (until 2009-2010) or indirectly, through the Athlete Biological Passport Programme (until 2009). Instead, the sole means of detecting rEPO abuse was through analysis in urine, a test that was first validated in 2000, shortly before the Sydney Olympics.
- 2.3 The IAAF started using the rEPO urine test at the 2001 IAAF World Championships in Edmonton. However, the rEPO urine test was (and still is) very expensive, and can only detect rEPO if the sample is taken within hours, or at most a couple of days, of administration of the rEPO.<sup>4</sup> Therefore, the IAAF followed the approach adopted by the IOC at the 2000 Sydney Olympics,<sup>5</sup> and subsequently approved by both the CAS<sup>6</sup> and WADA<sup>7</sup>: it collected blood samples, tested them for markers of possible rEPO use,<sup>A1</sup> and if such markers were found then a urine sample would be collected from the athlete and analysed using the rEPO urine test. If the test came back positive for rEPO, then the athlete was charged with a doping violation. If

<sup>&</sup>lt;sup>A1</sup> As explained below, the markers ultimately used were the concentration of haemoglobin in the blood and the percentage of young red blood cells (reticulocytes) in the blood, which in combination produce an 'OFFscore'. The idea is that when an athlete comes 'off' a course of rEPO, his haemoglobin concentration will be high (due to the rEPO having stimulated production of extra red blood cells) and his percentage of reticulocytes will be low (because his body will have reacted to the higher red blood cell count by producing fewer new red blood cells), leading in combination to an abnormally high 'OFF-score'. Since one would not expect to see this combination in normal physiological conditions, an abnormally high 'OFF-score' is a potential indicator of blood doping.

on the other hand the urine sample was negative, there was no case for the athlete to answer, although further target testing could be pursued.

- 2.4 In fact, the urine tests for rEPO came back negative in many cases, and with the benefit of hindsight, innocent explanations can often be found for the atypical blood values that triggered those tests. For example, the blood samples in question may have been collected immediately after the athlete had competed or undergone strenuous training. We now know that such exertion causes a reduction of blood plasma volume, which leads to higher reported haemoglobin levels even though there has been <u>no</u> increase in red blood cells. (This was the case, for example, with the abnormal haemoglobin values reported in blood samples collected from Paula Radcliffe at the IAAF World Half-Marathon Championships in Vilamoura in October 2003 and the IAAF World Championships in Helsinki in 2005, as discussed further in <u>Section 5</u>, below).
- 2.5 In many other cases, however, either the first urine sample or a subsequent urine sample obtained by further target testing of the athlete tested positive for rEPO, and the athlete was therefore charged with blood doping and subsequently banned. In fact, 145 athletes have been caught with rEPO in their system from 2001 to date and banned under the IAAF's anti-doping rules.
- 2.6 For example, The Sunday Times highlighted the case of Bahraini athlete Rashid Ramzi, who won gold in the 2005 IAAF World Championships in Helsinki in the 1500 metres (on 10 August 2005) and in the 800 metres (on 14 August 2005):
  - 2.6.1 The Sunday Times noted that blood samples collected from Ramzi on 10 and 14 August 2005 had OFF-scores of 157.8 and 148 respectively. In accordance with the IAAF regulations then in force, in each case those abnormal values triggered the immediate collection by the IAAF of a urine sample from the athlete on the same day, but no rEPO was found in either urine sample. The IAAF also collected two blood samples from Ramzi in Helsinki and had them tested for evidence of blood transfusions, but again with negative results.
  - 2.6.2 The IAAF did not give up, however. Instead, after the 2005 World Championships, it set about target testing the athlete. In fact, in the period up until August 2008 it collected no less than 21 further urine samples from Ramzi, all of which were analysed for rEPO, and all of which returned negative results. Eventually, a targeted urine sample collected from Ramzi at the 2008 Olympic Games in Beijing tested positive for a new form of rEPO called CERA, and he was finally banned from the sport for two years.<sup>8</sup>
  - 2.6.3 The IAAF still wanted to prove that Ramzi had been cheating at the 2005 World Championships. To that end, it had stored Ramzi's samples from Helsinki, for reanalysis once new testing methods were developed. In 2012, it went back and reanalysed the sample from his gold medal race on 10 August 2005 using the most updated rEPO detection techniques. Once again, however, the sample tested negative for rEPO.

- 2.7 The Sunday Times also highlighted the women's 1500 metres final at the 2005 World Championships in Helsinki, on 14 August 2005, which was won by Tatyana Tomashova of Russia, with her compatriots Yuliya Chizhenko-Fomenko, Olga Yegorova and Yelena Soboleva coming 2<sup>nd</sup>, 3<sup>rd</sup> and 5<sup>th</sup> respectively (although Chizhenko-Fomenko was subsequently disqualified for obstructing another runner and so Yegorova and Soboleva were moved up to 2<sup>nd</sup> and 4<sup>th</sup> respectively):
  - 2.7.1 The Sunday Times noted that blood samples taken from those athletes on the day of the final produced OFF-scores of 129 (Tomashova), 140 (Chizhenko-Fomenko), 124 (Yegorova) and 136 (Soboleva), and said: 'The odds against all four teammates in the same race having naturally high off-scores was in the trillions. There could only be one conclusion given the improbable coincidence of such outlandish results. The experts believe they were cheating'.<sup>9</sup> The Sunday Times and its consultants have suggested that the IAAF failed to take any action against the athletes. Mr Parisotto asked: 'Was nobody watching?'<sup>10</sup>
  - In fact, the IAAF was watching carefully, and it acted immediately when it saw the OFF-2.7.2 scores highlighted by The Sunday Times, having urine samples collected from all four athletes on the day of the 1500m final tested for rEPO. And when all of the tests were negative, the IAAF again targeted the athletes in question for follow-up tests. No fewer than 98 urine samples were collected from those four athletes between August 2005 and June 2008, the majority of which were tested for rEPO. When this testing also failed to yield any positive results, the IAAF suspected the testing had been manipulated. It therefore submitted urine samples that it had collected from all four athletes out of competition in April-May 2007 for DNA analysis, alongside samples collected from the same athletes in competition. When the results revealed that the samples collected out of competition did not come from the four Russian athletes but instead came from other (unidentified) persons, the IAAF charged all four athletes (and three others caught in the same way) with fraudulent manipulation of their urine samples. A special commission convened by the Russian federation upheld those charges and banned all four athletes for two years each, but the IAAF appealed to the CAS and got the bans on each athlete increased to two years and nine months, and their results disgualified back to April/May 2007.<sup>11</sup>
  - 2.7.3 The IAAF had had these athletes' Helsinki samples frozen and stored. In 2012, it went back and had those samples re-tested for rEPO using the most up-to-date techniques, but no rEPO was detected. In July 2015, the samples were re-analysed again using new techniques and again no rEPO was detected.
  - 2.7.4 The considerable time and resources committed by the IAAF to catching these cheats cannot be doubted. Indeed, even Dr Ashenden has written: 'For the record, I applaud the innovative use of DNA techniques that eventually led to sanctions for some competitors in the women's 1500 metres in Helsinki 10 years ago. There is no question that it reflects determined and vigorous pursuit of those athletes on the part of your anti-doping department'.<sup>12</sup> The IAAF therefore does not understand why The Sunday Times and Mr Parisotto have pilloried it for failing to take any action in response to these athletes' abnormal blood values in Helsinki.

- 2.8 These cases are just examples highlighted by The Sunday Times, but the IAAF followed up all cases where its blood screening programme identified abnormal values, including by targeted rEPO urine testing of the athletes concerned. WADA has asked its Independent Commission to consider specifically whether what the IAAF did was adequate,<sup>13</sup> and the IAAF has cooperated entirely with the Independent Commission in its investigation, including turning over its copy of the database to the Independent Commission, and giving its experts complete access to the IAAF files showing what follow-up was done in each case. The IAAF now awaits the Independent Commission's conclusions with interest.
- 2.9 In addition, as also acknowledged by Dr Ashenden, the IAAF 'painstakingly' used the data obtained from its blood testing to build a better understanding of an athlete population that is unique in its global reach,<sup>14</sup> thereby enabling a more effective risk assessment to be undertaken. The 2015 World Anti-Doping Code stresses the importance of an intelligence-based approach to testing.<sup>15</sup> This is exactly what the IAAF was already implementing ten years earlier. Nor did it do all of this in secret; to the contrary, its experts published a detailed analysis of the blood test results in 2011, based on which they drew certain conclusions as to the prevalence of doping in the sport.<sup>16</sup>
- 2.10 In addition, after new tests were developed in 2004 to detect HBOCs and homologous blood transfusions through the analysis of blood samples,<sup>17</sup> the IAAF started using them as well (as in the case of the blood samples taken from Rashid Ramzi in Helsinki in 2005), and it continues to do so to this day, even though there is no formal requirement to do so.
- 2.11 In summary, in the period to the end of 2008, the IAAF collected a total of 7794 blood samples from 3711 athletes, and conducted 6621 urine EPO tests in what was one of the world's largest and most comprehensive blood testing programmes in place at the time. The IAAF acted at all times during this period in accordance with its rules and making full use of the anti-doping tools that were available to it, as well as (when those tools proved inadequate) ground-breaking DNA techniques that had never been used before in sport.

## 2B. What further tools became available post-2009, and what use has the IAAF made of them?

- 2.12 There was an important improvement in the regulatory landscape for blood testing from 2009 onwards. The various tools described above were not sufficient on their own to fight blood doping. In particular, apart from the short detection window of the urine test for rEPO, there is still currently no validated test for the direct detection of autologous blood doping. In addition, new types of ESA are developed constantly by the pharmaceutical industry for therapeutic purposes, and it takes significant time and money to validate a new direct detection method for each one. That is why, starting in 2006, the IAAF worked with WADA and other stakeholders and scientists to evaluate the feasibility of developing a new tool, called the Athlete Biological Passport (ABP), that would produce reliable <u>indirect</u> evidence of blood doping that would be 'both scientifically and legally robust'<sup>18</sup>:
  - 2.12.1 The idea behind the ABP, in brief, is to monitor changes over time in parameters in an athlete's blood that would ordinarily be expected to remain relatively stable, but that would deviate from the norm in predictable ways in the event of blood doping. Injecting an ESA or transfusing blood will have a marked and predictable effect on various blood parameters that should otherwise (if everything else is equal) remain relatively stable. Therefore, just as the medical profession tracks certain haematological parameters as biological markers of disease (e.g., haemoglobin

measurements are used in the diagnosis of diabetes), so too changes in haematological parameters can be tracked as biomarkers of blood doping.<sup>19</sup>

- 2.12.2 The WADA working group was asked to determine which blood parameters should be monitored, and to develop standardised technical protocols for the collection, storage, transport and analysis of blood samples, in order to limit variability in the measurement of those parameters in the samples due to pre-analytical and analytical conditions, and to enable valid comparison of the parameters measured in one sample to the parameters measured in other samples in the same profile.<sup>20</sup> The working group was also asked to determine what information would have to be collected to enable the experts to decide whether other potential causes of an abnormal deviation in the values in a profile could safely be excluded. The IAAF was instrumental in the development of those protocols, by sharing its learnings from its substantial blood-testing efforts to that date with WADA and other stakeholders.
- 2.12.3 After much work and several pilot projects, all of the necessary elements of this new 'indirect detection' method had been identified,<sup>21</sup> and they were set out in a document that WADA approved and adopted with effect from 1 December 2009 (the WADA ABP Operating Guidelines & Compilation of Required Elements', or WADA ABP Protocol).<sup>22</sup> The stated aim of the WADA ABP Protocol is 'to evaluate analytical elements and possible confounding factors with a rigorous scientific approach'.<sup>23</sup> In particular, through the protocol, ABP testing 'is strictly regulated by standardised protocols that aim to minimise the impact of such external influences'.<sup>24</sup> A number of blood samples are collected from an athlete over time; they are sent to a laboratory, where various parameters in the samples are measured (including haemoglobin concentration (HGB)<sup>25</sup> and percentage of reticulocytes (RET%),<sup>26</sup> which combined together produce an OFF-score<sup>27</sup>); a longitudinal profile of that data is created; and a standardised Bayesian statistical model (the Adaptive Model) is used to predict the range into which the athlete's future values would normally be expected to fall, assuming the athlete is healthy and not blood-doping.<sup>28</sup> The Adaptive Model calculates the likelihood that future values falling outside that range would be observed in the absence of a medical condition or blood-doping, and if that likelihood is sufficiently small (e.g., no more than 1 in 1,000), then the profile is reviewed first by one and then by three experts, (i) to ensure that the samples have been collected, transported and analysed properly and consistently, so that the values reported are reliable and may be fairly compared from one sample to the next; and (ii) to consider the likelihood of other potential causes of the abnormal deviation from the other values in the profile (such as chance, altitude, recent exercise, a medical condition, etc.). If (but only if) the experts conclude that the values in the profile are reliable and fairly comparable, and that it is highly likely that the abnormal deviation is due to blood doping, and any other explanation is unlikely to be right, then the athlete is contacted and given an opportunity to raise any potentially relevant medical issues. If a medical explanation is offered, then it is sent to the experts to consider whether it is a plausible explanation for the abnormalities in the athlete's ABP profile. If (but only if) the experts consider any medical explanation given to be implausible, the athlete will be charged with blood doping.<sup>29</sup>
- 2.12.4 The IAAF immediately launched its own ABP Programme for athletics in 2009, even though there was then (and still is) no formal requirement on it to do so. And it has since collected over 13,000 blood samples for ABP purposes from more than 5,500 athletes, across all disciplines of the sport. The IAAF has created ABP profiles for each

of those athletes based on those samples, which profiles are visible to WADA and other stakeholders via WADA's database (known as **ADAMS**) and through datasharing agreements that the IAAF has made with more than 20 other anti-doping organisations. The IAAF has engaged the WADA-accredited laboratory in Montreal to act as its Athlete Passport Monitoring Unit, determining which profiles are abnormal and need to be referred to the experts for review. It has also engaged three of the world's leading experts in this field, Professor Giuseppe d'Onofrio, Professor Olaf Schumacher, and Dr Michel Audran, to conduct that expert review in accordance with the detailed results management protocols mandated in the WADA ABP Protocol.<sup>30</sup>

- 2.12.5 If the expert panel decides following review of an abnormal profile that further blood or urine testing is required in order to reach a definitive view, then the IAAF undertakes it. For example, since 2009, the IAAF has conducted more than 7,400 urine rEPO tests, and where samples have tested positive for rEPO the athletes in question have been banned for blood doping, contributing to the total of 145 rEPO positives that the IAAF has recorded since 2001. This includes, for example, the prominent Kenyan marathon runner, Rita Jeptoo, who was targeted for urine testing in October 2014, and was caught with rEPO in her system and banned for two years,<sup>31</sup> which ban the IAAF has appealed to the CAS on the ground that it should have been longer.
- 2.12.6 On the other hand, if the expert panel feels able to conclude (without the need for any further testing) that the abnormal variation in an ABP profile is highly likely to be caused by blood doping, and that any other potential cause of the variation is implausible, the IAAF initiates disciplinary proceedings against the athlete based on the ABP profile alone. So far, the IAAF has charged 69 athletes with blood doping based on their ABP profiles, and has provisionally suspended them from competition pending determination of the charge. To date, 56 of those athletes have had the charges against them upheld and have been banned from the sport. The remaining 13 cases are still pending. Meanwhile, 12 other atypical ABP profiles are undergoing expert review at the time of writing and could lead to further charges.
- 2.12.7 The IAAF currently delegates prosecution of doping cases to its member associations, who bring the cases before their national hearing panels. In certain of those cases, where the national association or its hearing panel either exonerated the athlete or failed to impose what the IAAF considered to be a sufficient sanction for the blood doping established by the athlete's ABP profile, the IAAF appealed those cases to the CAS, seeking to get the athlete sanctioned or an increase in sanctions (as applicable). For example:
  - In <u>IAAF v Çakir-Alptekin</u>, the IAAF appealed against the decision of the Turkish Disciplinary Board to exonerate Turkish middle-distance runner Asli Çakir-Alptekin of the ABP blood doping charge, and ultimately secured an eight-year ban of the athlete (this was her second offence).<sup>32</sup>
  - b. In <u>IAAF v Kokkinariou</u>, the IAAF appealed the two-year ban imposed on Greek steeplechaser Irini Kokkinariou for her ABP offence, and secured an increase in that ban to four years.<sup>33</sup>
  - c. Similarly, in <u>IAAF v Shobukhova</u>, the IAAF appealed the two-year ban imposed on Russian athlete Liliya Shobukhova for her ABP offence, and secured an increase in the ban to three years and two months.<sup>34</sup>

- d. Meanwhile, in <u>IAAF v Yanit</u>, the IAAF appealed to CAS to increase the two-year ban that the Turkish Disciplinary Board had imposed on Turkish hurdler Nevin Yanit after she tested positive for steroid use, on the basis (among others) that her ABP profile showed that she had also been blood-doping during the relevant period. The CAS upheld the IAAF's appeal and increased her ban to three years.<sup>35</sup>
- 2.12.8 The 56 ABP convictions that the IAAF has obtained to date is more than have been obtained by all other sports federations and national anti-doping agencies put together. At the WADA ABP Experts Symposium held in Doha in November 2015, it was reported that there have been 85 ABP cases brought across all sports to date, of which 69 (or 81%) have been from athletics. As noted above, the IAAF has obtained 56 convictions to date, with 13 cases still pending. The UCI (cycling) has secured the next most ABP convictions, with 13. The IAAF is the only anti-doping body to have ever obtained aggravated sanctions for an ABP offence.
- The IAAF agrees that it is not the quantity of drug tests that matters but instead the quality of 2.13 those tests. It believes the results it has achieved demonstrate the effectiveness of its testing. In fact, as noted above, the IAAF was a leader in this field, developing an intelligent, risk-based test distribution plan for athletics including substantial no-notice out-of-competition testing based on collection of daily whereabouts information from thousands of athletes (it currently collects daily whereabouts information from 582 athletes in 78 countries to enable it to implement its out-of-competition test distributions plans<sup>36</sup>), and target testing of athletes for rEPO in their urine based on suspicious blood test results. It was part of the working group that got these principles incorporated into WADA's International Standard for Testing in 2009. It has also created an intelligence unit to gather intelligence to inform its test distribution plans and investigate possible violations;<sup>37</sup> and pursued a successful strategy of storage and retesting of samples once new testing techniques have been developed.<sup>38</sup> Through all these methods, and in particular with the success of its rEPO urine testing and of its ABP Programme instituted in 2009, the IAAF truly believes that it has demonstrated a commitment to fighting doping in its sport that stands comparison with any other.

## 3. On what basis do The Sunday Times' consultants argue that more could and should have been done with the data from the IAAF's 2001-2012 blood-testing?

- 3.1 ARD/The Sunday Times and their retained consultants cannot deny any of the above. So why then did Dr Ashenden suggest in his evidence to the UK Parliament's Culture, Media and Sport Committee in September 2015 that the IAAF 'has been grievously short of energy, at least for long periods over the last 15 years, as regards enforcement and requirements on individual federations to do their job ..., [and] dilatory in not following the lead set by other agencies in other aspects of world sport in combating blood doping ...'?<sup>39</sup> And why did Mr Parisotto tell The Sunday Times that the blood values collected by the IAAF from 2001 to 2012 were 'damning in that so many athletes appeared to have doped with impunity without repercussions but more damning in that the IAAF appears to have idly sat by and let this happen'?<sup>40</sup>
- 3.2 The answer is that the consultants argue that certain of the OFF-score values obtained from the IAAF's blood-testing in 2001-2012 deviated so much from previous values in the profiles of the athletes in question that those OFF-score values <u>in and of themselves</u> constituted 'compelling evidence' of blood doping, and so the IAAF could and should have charged those

athletes with blood doping there and then, i.e., it did not need to bother conducting further testing to try to find rEPO in the athletes' urine samples first:

- 3.2.1 In his oral evidence to the Culture, Media and Sport Committee, Dr Ashenden stated: 'An OFF-score is a signature where you see lots of red blood cells in circulation but you see that the bone marrow is not producing those red cells. It is not a natural scenario to have lots of red cells and no natural source for those cells. <u>When that OFF-score is</u> <u>very high, it provides compelling evidence that the athlete is blood doping</u>. The higher the OFF-score, the more compelling that evidence can be'.<sup>41</sup>
- 3.2.2 Dr Ashenden also told the Culture, Media and Sport Committee: '[T]he anti-doping fraternity has reached a level where they believe that a 1/1,000 likelihood of it coming from a clean athlete is a sufficient balance between being able to effectively detect dopers but also being fair to athletes. <u>That 1/1,000 threshold is where there is generally considered to be sufficient evidence to conclude doping</u>. Anything beyond that increases the confidence that you have, even though it never gets to actual certainty'.<sup>42</sup>
- 3.2.3 Dr Ashenden therefore told the Committee that the OFF-score values in the database that had only a 1/1,000 chance of coming from a clean athlete were 'hard evidence' of doping that constituted a wholly sufficient basis to charge athletes with blood doping: 'There is no question that it was fit for purpose and so, yes, there has been this data that they could have acted on'.<sup>43</sup> This echoed Dr Ashenden's assertion in his written evidence to the Parliamentary Committee that the IAAF 'could and should have pursued disciplinary proceedings against those athletes who recorded highly abnormal blood values before 2009'.<sup>44</sup>
- 3.3 That evidence from Dr Ashenden is the reason why he and Mr Parisotto criticise the IAAF for not taking away the medals won by Bahraini athlete Rashid Ramzi and by Russian athletes Tatyana Tomashova and Olga Yegorova at the 2005 IAAF World Championships in Helsinki. It is also the reason why the Chairman of the Culture, Media and Sport Committee concluded that the database showed a 'very high level of doping ... with some of these athletes, according to the confidence levels you have described',<sup>45</sup> and why another Committee member concluded that the data in the database 'was perfectly respectable, and so it is just a pretence to say that the evidence is a relatively recent thing'.<sup>46</sup>
- 3.4 This brings us to the heart of the issue. If Dr Ashenden is right that the abnormal OFF-score values from blood testing in the period 2001-2012 were reliable evidence of blood doping in and of themselves, and so could support blood doping charges without having to follow up with further tests to try to find rEPO present in the athletes' urine samples, then the IAAF should be criticised, because it is quite true that the IAAF never charged an athlete with blood doping based on his or her pre-2009 blood values, but instead only charged the athlete if follow-up testing triggered by those values led to a urine sample being collected that was found to have rEPO present in it.

3.5 But if Dr Ashenden is <u>not</u> right when he says that those abnormal pre-2009 blood values were sufficient on their own to support blood doping charges against the athletes in question, i.e., if the IAAF is right when it says they could only be used to identify targets for follow-up urine testing, then the entire basis for this particular attack on the IAAF falls away. As noted below, the issue comes down to this: could the values recorded in blood samples collected prior to agreement on and implementation of standardised sample collection, transport and analysis protocols in the WADA ABP Protocol in 2009 be treated as reliable evidence of blood doping or not?

#### 4. Why do the IAAF, and apparently WADA, disagree so strongly with Dr Ashenden?

- 4.1 Dr Ashenden has not always held the view that the values recorded in blood samples taken before the advent of the WADA ABP Protocol in 2009 were sufficient on their own to support charges of blood doping, and nor has Mr Parisotto. To the contrary:
  - 4.1.1 In a 2002 paper, Dr Ashenden noted that because the changes in blood parameters that were being used as a potential indicator of blood doping could also be caused by innocent factors, such as altitude, training, and genes, '[i]t seems that evidence of accelerated erythropoiesis will remain an extremely useful *screening* tool to identify potential drug abusers rather than serve as definitive proof of r-HuEPO abuse'.<sup>47</sup>
  - 4.1.2 Similarly, in a paper that they co-authored with others in 2003, Dr Ashenden and Mr Parisotto noted that 'there would be no consequence for an elevated ON model score<sup>[A2]</sup> (since this evidence must be ratified by the presence of rHuEPO in the urine before a positive doping sanction can be applied)'.<sup>48</sup>
  - 4.1.3 And again, in a 2004 paper, Dr Ashenden noted that the decision of WADA in 2003 that testing for rEPO in urine alone (and not in combination with blood) produced reliable evidence of blood doping 'relegated abnormal hematologic parameters to providing a screening tool to identify suspect athletes for urinalysis'. He expressed the hope that longitudinal analysis of the blood parameters would in the future prove to be a useful detection tool, but noted that 'it is currently unclear what effect the unexpectedly large fluctuations in some key parameters will have on the legal surety of this approach ...'. He concluded that 'a solution to the initial challenge [posed by rEPO abuse in sport] remains frustratingly elusive, and this thoroughfare will demand concerted attention in the future'.<sup>49</sup>
  - 4.1.4 Meanwhile Mr Parisotto, in his 2006 book, 'Blood Sports', accepted that disciplinary action could not be taken against an athlete based on abnormal blood values, because they 'didn't directly "prove" anything at all. The fact our OFF-Model only *implied*, rather than *showed* EPO use made it an easy target' for legal challenge.<sup>50</sup> Instead, he noted (again) that the blood values were useful as a screening tool that identified athletes whose urine should be tested for the presence of rEPO.<sup>51</sup>

<sup>&</sup>lt;sup>A2</sup> While the OFF-model uses blood parameters to try to identify athletes who have recently stopped using rEPO, the ON-model uses the same blood parameters to try to identify those who are still using it.

- 4.2 It is not clear why Dr Ashenden and Mr Parisotto have now changed their view, and decided that the blood values collected in the period before the WADA ABP Protocol was adopted were not just 'a screening tool' but instead were reliable proof of doping and should have prompted disciplinary action by the IAAF. However, it <u>is</u> clear that the IAAF is not alone in rejecting their new stance.
- 4.3 In particular, on 14 August 2015, in response to the stories in The Sunday Times, Dick Pound, the Chair of the WADA Independent Commission, issued the following statement: 'until the Athlete Biological Passport (ABP) was introduced in 2009, none of the test results contained in the database could be used as the basis for a definitive finding that doping had occurred. At best, they could only be used as indicators of the need for targeted future testing of athletes having abnormal or unusual values. The IC considers this to be an essential point of focus, which bears repeating in the circumstances: no test data derived from the IAAF database prior to the adoption of the ABP in 2009 can be considered to be proof of doping. It would be reckless, if not libellous, to make such an allegation. The reported values may be suspicious and lead to targeted testing of the athletes involved, but nothing more could be done with the information'.<sup>52</sup>
- 4.4 Then on 11 September 2015, after giving evidence before the UK Parliament's Culture, Media and Sport Committee, WADA Director-General David Howman said the same thing: 'Let me be clear and reiterate what has already been stated by the Independent Commission as it relates to the *ARD* and *Sunday Times* reports regarding athletes' blood values: no information in the leaked database from before 2009 which was before the Athlete Biological Passport (ABP) was introduced could ever be considered as doping, legally or otherwise. Tarnishing an athlete's name based on values from pre-2009 would be wholly irresponsible. At best, blood values from this time could only be used as indicators of the need for targeted future testing of those athletes that have abnormal or unusual values'.<sup>53</sup>
- 4.5 The IAAF cannot speak for WADA, but it sets out below the reasons why it disagrees so strongly with Dr Ashenden on this key point, and it expects that WADA's reasons will be similar, if not the same.<sup>54</sup>
  - 4A. The values from the blood samples collected prior to 2009 could not be considered scientifically accurate, and could not be fairly compared from one sample to the next, because the necessary standardised conditions for sample collection, transport and collection requirements had not yet been established
- 4.6 Dr Ashenden has acknowledged that 'in order for individual profiling to be an acceptable evidentiary method, it must be implemented in a manner that produces scientifically accurate results'.<sup>55</sup> He has also conceded that looking at the values from one sample alone would be improper; instead, the values only carry weight (they can only be deemed 'abnormal') where they deviate significantly from the athlete's normal values.<sup>56</sup> As a result, as Dr Ashenden has himself noted, 'a quality control system to ensure that results are comparable when analyzed in separate locations is both essential and a convoluted process to instigate'.<sup>57</sup> In other words, all samples in the profile must be collected, transported and analysed in a reliable and consistent way that minimises measurement error and allows the samples to be compared fairly with each other.<sup>58</sup> If they are not, they can be used to identify athletes who might be targeted for rEPO urine testing (because that testing then either leads to standalone evidence of rEPO use or it does not), but they cannot be considered reliable proof of blood doping in and of themselves.

- When the IAAF put this point to him in correspondence,<sup>59</sup> Dr Ashenden responded that he was 4.7 'satisfied that the data [from the IAAF's blood testing] were "scientifically accurate" because the IAAF published their own findings from the database, and in their addendum to that article they stated that "[s]ince 2001, a full blood count has been performed in accordance with the IAAF Blood Testing Protocol." If you re-read your Blood Testing Protocol you will find that all samples were stored and transported in a manner that protected their "integrity, identity and security" and that "without exception" all samples were analysed in a laboratory approved by the IAAF. Consequently, results in the database are scientifically accurate'.<sup>60</sup> In fact, while the IAAF Blood Testing Protocol certainly did include procedures designed to ensure that all samples were stored and transported in a manner that protected their integrity, identity and security, and that they were all tested in a laboratory approved by the IAAF, those requirements are quite distinct and separate from the very detailed standardised sample collection, transport and analysis protocols that are required to ensure that the values recorded in blood samples are reliable and fairly comparable with other values in the athlete's profile. The IAAF Blood Testing Protocol incorporated such protocols bit by bit over time as learning improved, but until 2007 it did not include most of the essential requirements (i.e., the requirements that were eventually identified and agreed upon as part of the WADA ABP Protocol), and it did not include all of them until 2009. And Dr Ashenden knew this, because it was specifically noted in the very same addendum that Dr Ashenden cited in the passage quoted above.<sup>61</sup>
- 4.8 More specifically:
  - 4.8.1 The WADA ABP Protocol requires the athlete to sit down with his or her feet on the floor for at least ten minutes prior to providing a blood sample (because the athlete's posture during sample collection can vary plasma volume, and so haemoglobin concentration, in the order of 10-20%, due to changes in vascular pressure).<sup>62</sup> This was not a requirement of the IAAF Blood Testing Protocols prior to 2007, however, and so some of the samples could have been collected with the athlete lying down, others with the athlete sitting down, etc.
  - 4.8.2 Under the WADA ABP Protocol, the blood sample has to be collected in a 3ml tube containing an anti-coagulant, then stored and transported to the laboratory in refrigerated conditions (maintaining a temperature of between 2° and 12° C), with analysis to take place at the laboratory within 48 hours of collection of the sample.<sup>63</sup> 'These requirements (cool temperature and rapid transport) are important in order to safeguard the stability of the haematological parameters, which is crucial to guarantee accurate and reliable data for implementing and interpreting the ABP'.<sup>64</sup> However, the temperature controls were only introduced step by step over time into the IAAF Blood Testing Protocol, and a deadline for analysis of the samples at the laboratory was not introduced until 2009.
  - 4.8.3 In addition, testing samples using different machines using different technologies may lead to materially different results.<sup>65</sup> This can be true of HGB values (for example, the IAAF observed that for the <u>same</u> sample two different machines reported HGB results that differed by 2g/dl), but is particularly true of RET% values: in a 2006 paper Dr Ashenden and his co-authors noted that 'for the reticulocyte assay it is known that different brands of instrument (eg ADVIA and Sysmex) give substantially different readings'.<sup>66</sup> To avoid this problem (termed 'intermethod bias' by Dr Ashenden and his colleagues<sup>67</sup>), the WADA ABP Protocol mandates that ABP samples may only be tested using 'analyzers with comparable technical characteristics'.<sup>68</sup> The CAS has confirmed

that the same machine must be used throughout and that any values obtained using different machines must be disregarded.<sup>69</sup> Therefore under the WADA ABP Protocol the Sysmex machine is used exclusively by every laboratory. But even then there can be 'intra-method' variability, i.e., variability between different Sysmex machines. To address this, the WADA ABP Protocol specifies that each laboratory must follow the same mandatory procedures in calibrating its machine (with the same internal quality checks, and a common external quality control assessment that is carried out on a monthly basis) and analysing the samples (with each sample analysed twice and with the results required to be within established limits).<sup>70</sup> This was not uniformly required under the IAAF Blood Testing Protocols prior to 2009. Instead the parameters recorded in the database examined by Dr Ashenden and Mr Parisotto were measured using several different machines (Sysmex, Bayer-Siemens, Coulter, Abbott, Advia), with different calibration standards and varying internal and external quality control standards. Dr Ashenden and Mr Parisotto knew this, because the different machines used were recorded in the database. They knew it meant that the values in the profiles could not properly be compared with each other, and so no evidentiary weight could be placed on any apparent deviations in those values. Dr Ashenden did not mention this, however, when he told the Parliamentary Committee that those deviations constituted 'compelling evidence that the athlete is blood doping'.

- 4.9 These are not technical points; they are crucial to the 'scientific accuracy' of the values recorded in respect of each sample, and to the fairness of comparing the values of different samples in the same profile. Therefore, the WADA ABP Protocol is very strict: if there is a profile that contains an abnormal deviation from previous values, the experts reviewing the profile first have to consider whether the abnormality is due to measurement error as a result of failure to comply with the mandatory pre-analytical and analytical requirements.<sup>71</sup> The experts therefore have to review the sample collection forms, the chain of custody forms, and the laboratory documentation packages (including the blood results, the scatter grams, the internal chain of custody, and the internal and external quality controls) in order to ascertain compliance with the mandatory standards. If any departures are found from the mandatory sample collection, transportation and analysis requirements set out in the WADA ABP Protocol, then the values from the sample or samples in question are deemed unreliable and generally have to be disregarded,<sup>72</sup> which may mean the profile is no longer abnormal.
- 4.10 So too, any competent expert would refuse to consider the values from the blood samples collected by the IAAF prior to 2009 as reliable evidence of blood doping, and would certainly have refused to compare the values from one sample in a profile to other samples in the same profile, because those samples were collected before WADA finalised and published the mandatory requirements for collection, transport and analysis of ABP samples that are set out in the WADA ABP Protocol, and so did not all comply with all of those requirements. This did not mean the values were worthless. To the contrary, they could be used to identify athletes who should be targeted for testing, in an effort to collect a urine sample with rEPO present in it, and when (as often happened) rEPO was found in the urine, that adverse finding would then be competent evidence of doping. But it did mean that the pre-2009 blood values could not be said to be reliable evidence of doping in and of themselves, for the reasons just explained.

#### 4B. Avoiding 'the prosecutor's fallacy'

- 4.11 Furthermore, establishing that the blood values are accurate and can fairly be compared with the values from other samples in the same profile is just the first step in the results management process. Successful completion of that step means that it can properly be said that there is an abnormal deviation from the athlete's normal values. But Dr Ashenden was simply wrong when he told the Culture, Media and Sport Committee that a high OFF-score is 'known to occur only when athletes blood dope',<sup>73</sup> and therefore the fact that there is only a one in 10,000 chance (for example) that such a deviation could arise by normal variation is, in and of itself, 'compelling evidence that the athlete is blood doping'.<sup>74</sup> To the contrary, that suggestion is a well-known fallacy, sometimes referred to as 'the prosecutor's fallacy'.<sup>75</sup>
- 4.12 Two of the most senior arbitrators of the Court of Arbitration for Sport (i.e., the very people who would ultimately rule on any case that the IAAF tried to bring) have been clear on this point:
  - 4.12.1 Professor Massimo Coccia, a senior CAS arbitrator from Italy, has explained clearly that an OFF-score that is flagged as abnormal by the Adaptive Model 'does not mean in itself that there is a probability of doping but only that the profile differs from what would be expected in a clean athlete; an atypical profile as such is not evidence of doping. An atypical blood profile may actually have different explanations: pure chance (which is statistically possible if many tests have been performed);<sup>[76]</sup> instrument malfunction or inappropriate storage or transport of some blood samples; pathological or medical condition that has caused an abnormal change in blood variables; and doping in the form of blood manipulation. Therefore, no definite conclusions may be drawn at this stage. The Adaptive Model is only a filter that excludes normal profiles and triggers the expert review of any atypical blood profile'.<sup>77</sup>
  - 4.12.2 Similarly, another senior CAS arbitrator, Professor Richard McLaren, from Canada, who also happens to be a member of the WADA Independent Commission currently considering this matter, has written:
    - a. 'Currently the recommended level of variation required to initiate a review based on the ABP is a blood marker outside the 99.9<sup>th</sup> percentile. This means that the probability that the same value would be observed in a similar healthy, non-doping athlete is approximately one in every thousand times tested. This threshold is referred to as the specificity of the test. This part of review should not be confused with the probability of doping. The profile only establishes the likelihood of observing certain values assuming that the athlete is healthy and not doping. ... The profile cannot establish the probability of doping. An abnormal outcome on the profile does not automatically mean doping occurred, because the abnormality is not based on the true probability of doping. Rather, the decision is based on "how the profile differs from what is expected in clean athletes". The panel of experts therefore plays a crucial role in evaluating the profile to eventually deciding whether or not the athlete has doped'.<sup>78</sup>
    - b. 'A blood marker outside the acceptable levels cannot establish that an athlete has engaged in blood doping. It is only after experts have reviewed the profile and discounted all other possible explanations for the values of the markers that a likelihood of doping can be determined. The three-step process set out

for expert panels to use when reviewing abnormal profiles recognizes this fact. The reasoning in CAS cases also needs to ensure this fact is taken into consideration. Otherwise sanctions will be delivered based on the faulty reasoning earlier referred to as the prosecutor's fallacy'.<sup>79</sup>

- 4.13 Dr Ashenden describes Professor McLaren's paper as 'authoritative ... on the legalities of the ABP approach'.<sup>80</sup> Indeed he cited it no less than six times in his written evidence to the Parliamentary Committee, including (ironically) as authority for his assertion to the Committee that '[t]hat 1/1,000 [OFF-score] threshold is where there is generally considered to be sufficient evidence to conclude doping'.<sup>81</sup> It is difficult to understand how he managed that, given that Professor McLaren specifically stated several times in that paper that '[a] blood marker outside the acceptable levels cannot establish that an athlete has engaged in blood doping'.
- 4.14 The Sunday Times has itself acknowledged that '[t]here are several factors that might elevate blood results, such as genetic disposition, natural biological variation, analyser error, altitude exposure and acute illness'.<sup>82</sup> And Dr Ashenden and Mr Parisotto themselves have previously acknowledged that 'identifying rHuEPO users amongst the elite athlete population will entail differentiating between the fluctuations associated with exposure to such influences, and the atypical variation of hematologic parameters caused by rHuEPO use'.<sup>83</sup> To achieve that differentiation, the WADA ABP Protocol requires that the three experts be given a full documentation pack to review, and they are required to review the detailed information in that pack in order to determine whether there are any other plausible explanations for the deviation observed in the profile.<sup>84</sup> In particular:
  - 4.14.1 Every time a Doping Control Officer collects an ABP sample, he is required to gather and record the following information on the doping control form, and get the athlete to sign the form to confirm that the information collected is accurate: any blood loss or gain by the athlete due to pathology or transfusion (with estimated volume) in the three months preceding the test; any exposure the athlete has had to altitude in the two weeks preceding the test (because exposure to altitude is known to affect blood values<sup>85</sup>); and any recent exposure to extreme heat conditions or participation in any multi-stage intensive endurance event (because dehydration could cause haemoconcentration<sup>86</sup>). Dr Ashenden himself has acknowledged that such factors could cause a temporary increase in blood markers that 'might lead to mistakenly accusing an athlete when no drug was taken'.<sup>87</sup> But most of these factors were only finally settled and agreed upon in 2009, and so most of this information was not collected under the IAAF Blood Testing Protocols prior to 2009.<sup>88</sup> Without this information, it is not possible safely to conclude that these various factors could not have caused or contributed to the deviations seen in the athlete's profile.
  - 4.14.2 Importantly, the WADA ABP Protocol also requires that every time an ABP sample is collected, the Doping Control Officer must first ensure that at least two hours have passed since the athlete last trained or competed.<sup>89</sup> This is crucial, because strenuous exercise leads to a decrease of plasma volume for up to two hours, thereby increasing HGB concentration even though there is <u>no</u> increase in red blood cells, and so causing false positives.<sup>90</sup> Again, however, the IAAF Blood Testing Protocols contained no such requirement prior to 2009. Instead, many of the samples included in the database were taken immediately after the athlete had finished training or competing.
  - 4.14.3 In addition, both Dr Ashenden and Mr Parisotto have acknowledged that there could be a medical explanation for the abnormal variation observed in an athlete's profile,

e.g., a congenital or acquired hematologic disorder (such as a form of anemia, or polycythemia) or a pathological condition (such as blood loss from gastro-intestinal bleeding, or dehydration from gastro-intestinal infection).<sup>91</sup> For this reason, the WADA ABP Protocol requires the experts to consider any medical information in the file, and in addition it requires that the athlete be given a chance to put forward any medical or other explanation for the abnormal values, and the experts have to carefully review whatever he or she puts forward. A charge may only be brought if following that review the experts remain unanimously of the view that the abnormal values are highly likely to have been caused by blood doping and any other explanation is unlikely to be correct.<sup>92</sup> And their view is not binding on the panel hearing the charge. Instead, the party bringing the charge has the burden throughout of proving to the comfortable satisfaction of the hearing panel that the values are highly likely to have been caused by blood doping and any atternative explanation offered by the athlete is not plausible.<sup>93</sup> So it is vital that the experts do a careful and thorough job in the results management process.

- 4.15 Referring to the WADA ABP Protocol, Dr Ashenden and Mr Parisotto claimed that they 'rigorously applied its principles to their analysis of the database'.<sup>94</sup> In particular, they claimed that they 'followed the same procedure as IAAF expert panellists when reviewing ABP profiles, classifying the results as "likely doping" when we were able to confidently exclude all other potential causes ...'.<sup>95</sup>
- However, as Dr Ashenden has subsequently been forced to acknowledge,<sup>96</sup> he and Mr 4.16 Parisotto could not have followed the procedures that the WADA ABP Protocol requires experts to follow in order to exclude other potential causes of abnormal deviations, because they did not have the full documentation package that the WADA ABP Protocol requires be provided to the three experts as part of the mandatory results management process set out in the Protocol, and so they did not have the information required to enable proper interpretation of the data in the ABP profile. In particular, they had no idea whether the abnormal deviations they thought they had identified were due to the fact that the sample was not collected or stored properly, or was not analysed within 48 hours of collection, or was analysed on a different machine to earlier samples in the profile. In addition, they had no idea whether the athlete had suffered blood loss in the three months prior to sample collection, or had been exposed to altitude in the weeks prior to sample collection, or had been subject to extreme heat or had participated in strenuous exercise immediately prior to sample collection. And they had no idea whether the athlete might have a medical condition that could explain his or her abnormal values.
- 4.17 In fact, as Dr Ashenden and Mr Parisotto acknowledged elsewhere, the very most they could do was conduct the 'Initial Review' that is conducted by a single expert as the first stage of the results management process set out in the WADA ABP Protocol, i.e., looking only at the blood values and not looking at any documentation or any other materials that would allow them to assess any of the various potential causes of abnormal deviations in those values other than blood doping.<sup>97</sup> In recent correspondence with the IAAF, Dr Ashenden has been forced to acknowledge that 'reaching an "Initial View" does not entail nor require the same level of evaluation as would "charging" an athlete'.<sup>98</sup> The IAAF agrees. He should have included the same careful caveat in his evidence to the Parliamentary Committee. But of course, if he had included it, then that would have shown that his suggestion that the abnormal values in the database were 'compelling evidence' of blood doping that the IAAF should have used to charge the athletes concerned was legally and scientifically baseless.

#### 5. A case in point: Paula Radcliffe

- 5.1 The dangers of the approach taken by Dr Ashenden and Mr Parisotto become all too apparent when media organisations and others who do not understand the science or the law 'expose' the cases of individual athletes on alleged grounds of 'public interest'. One case in point is that of the British athlete, Paula Radcliffe, who was hounded remorselessly in the media for several weeks until she felt she had no option but to go public in her own defence.
- 5.2 The circumstances in which Ms Radcliffe came to be publicly accused are truly shocking.
  - 5.2.1 In its 2 August 2015 edition, The Sunday Times referred to 'a top British athlete' who 'on three occasions' recorded OFF-scores that 'were so "abnormal" that there was only a one in a thousand chance that they were natural'.<sup>99</sup>
  - 5.2.2 On 7 September 2015, German broadcaster ARD reported that there would be a hearing of the UK's Culture, Media and Sport Committee in London the following day on the subject of blood doping in athletics, and that it was 'imminent that names of suspicious athletes might become public and the IAAF will come further under pressure to act'.<sup>100</sup>
  - 5.2.3 In that open session the next day (a session attended by journalists from both The Sunday Times and ARD), the Chair of the Culture, Media and Sport Committee, Mr Jesse Norman, asserted that 'potentially the winners or medallists at the London Marathon, potentially British athletes, are under suspicion for very high levels of blood doping'.<sup>101</sup>
  - 5.2.4 Given that only two British athletes have made the podium in the London Marathon from 2001 to date, and of those two the only winner was Paula Radcliffe, it is not surprising that in response she felt forced to issue a detailed public statement confirming that The Sunday Times had been referring to her, and explaining why the values from her blood tests did not in fact give grounds to suspect that she had been blood doping.<sup>102</sup>
- 5.3 The IAAF notes the following:
  - 5.3.1 Between July 2001 and May 2015, as one of the world's leading female endurance athletes, Ms Radcliffe was included in the IAAF's Registered Testing Pool, meaning that she had to provide detailed information in advance about her whereabouts each day, so that she could be found at any time for out-of-competition testing.
  - 5.3.2 From July 2001 to August 2008, the IAAF collected fourteen blood samples from Ms Radcliffe for screening purposes, i.e., to check for potential markers of rEPO use that would trigger collection and testing of a urine sample for the presence of rEPO. This was <u>before</u> the standardised procedures for sample collection, transport and analysis were validated and issued by WADA in the form of the WADA ABP Protocol, and so those fourteen samples were not collected under the same uniform standardised conditions. For example, they were not all analysed using the same type of machine, and not all of the necessary quality controls were run on the machines that were used, so that there was no assurance of equal calibration. And as noted above, testing samples with different machines using different technologies can lead to substantially different results. That means that the values recorded for those fourteen samples

cannot properly be compared with each other, and so it is simply not possible to assume that differences reported between a value in one sample and the same values in other samples in the profile are reliable. And therefore no competent scientist would assert (as The Sunday Times did in its 2 August 2015 edition) that 'the athletes' results had varied by as much as 47%'.

- 5.4 No competent expert would proceed beyond this point. However, even assuming for the sake of argument that the values in Ms Radcliffe's profile were reliable and fairly comparable with each other (which is <u>not</u> a fair assumption), there is also <u>another</u> insuperable hurdle to relying on these values as evidence of blood doping: the way in which these samples were collected did not adequately address and enable the assessment of other potential causes of abnormal variations in those values, such as altitude, strenuous exercise, and so on. The impact of this becomes clear when looking at the three samples flagged by The Sunday Times and its consultants as 'abnormal'.
- 5.5 Sample 1 (collected in Vilamoura, Portugal on 4 October 2003):
  - 5.5.1 The blood sample collected from Ms Radcliffe on 4 October 2003 was analysed at a local hospital in Faro using a Coulter machine. The HGB reading was 15.6 g/dl and the RET% was 0.47. (At the time, the OFF-score was not used, but based on these HGB and RET% values, it would have been 114.87). Neither the HGB value nor the RET% value crossed the thresholds used by the IAAF at the time.
  - 5.5.2 In relation to the relatively high HGB value of 15.6 g/dl, this sample was collected incompetition. That fact was plainly recorded in the database accessed by Dr Ashenden and Mr Parisotto, and Ms Radcliffe has confirmed that the sample was collected just after she had just completed the IAAF World Half Marathon Championship in Vilamoura, Portugal in 29° heat. As noted at paragraph 4.14.2 above, it is welldocumented in the scientific literature that strenuous exercise leads to a concentration of plasma volume, thereby increasing HGB concentration even though there is <u>no</u> increase in red blood cells. That is why the WADA ABP Protocol specifies that ABP samples must <u>not</u> be collected within two hours of competition or training. And that is also why the WADA ABP Protocol requires the experts, as part of their standard review in each case, to confirm in respect of each sample in the profile that it was not collected within two hours of competition or training. Any sample that does not meet this requirement must be disregarded.<sup>103</sup>
  - 5.5.3 In relation to the relatively low RET% value of 0.47, two points need to be made. First, research has shown that endurance athletes display significantly lower RET% than normal during the competitive season.<sup>104</sup> Second, Ms Radcliffe came down from a period of high altitude (at Fort Romeu: 1800-2100m) three weeks before the race in Portugal. Research has shown that athletes who train at altitude and then come down to sea-level can experience a drop in RET% for up to 3-4 weeks, so artificially increasing the athlete's OFF-score.

- 5.5.4 In any event, notwithstanding that the HGB and RET% values from the 4 October 2003 sample were below the IAAF's respective thresholds at the time, the IAAF collected a urine sample from Ms Radcliffe on the day of the race in Portugal and had it tested for the presence of rEPO. The results of that test were negative.
- 5.6 Sample 2 (collected in Helsinki, Finland on 6 August 2005):
  - 5.6.1 The blood sample collected from Ms Radcliffe in Helsinki on 6 August 2005 was analysed by a WADA-accredited laboratory, this time using a Sysmex machine. The HGB reading was 15.1 g/dl, and the RET% was again 0.47, giving an OFF-score of 109.87. This was well <u>below</u> the threshold specified for OFF-scores in the IAAF Blood Testing Protocol in use at the time (which was 123 for female athletes).
  - 5.6.2 Furthermore, as again clearly recorded in the database accessed by Dr Ashenden and Mr Parisotto, this sample was also collected in-competition. In fact, Ms Radcliffe was notified of the doping control after finishing the 10,000m final at the 2005 World Championships in Helsinki, and provided her blood sample within two hours. Again, therefore, the high HGB reading could be explained by the reduction in plasma volume and consequent haemoconcentration following extreme exertion, rather than by any increase in red blood cells.
  - 5.6.3 Meanwhile the relatively low RET% value of 0.47 could again be explained by the fact that endurance athletes display significantly lower RET% than normal during the competitive season, and also by altitude exposure: Ms Radcliffe had had a lengthy spell in Fort Romeu (altitude 1800-2100m) until 26 July 2005.
  - 5.6.4 Notwithstanding that the OFF-score from this sample was below the stipulated threshold, the IAAF nevertheless sent a urine sample collected from Ms Radcliffe the same day (6 August 2005) to be tested for the presence of rEPO. The test came back negative. The IAAF also had the blood sample collected from Ms Radcliffe on 6 August 2005 analysed for evidence of blood transfusions. Again, the test came back negative.
  - 5.6.5 Eight days later, on 14 August 2005, Ms Radcliffe won gold in the women's marathon at the same World Championships. After the race, the IAAF collected further urine and blood samples from her. The urine sample was analysed for rEPO and was negative, and the blood sample was analysed for evidence of blood transfusions and was also negative.
  - 5.6.6 Furthermore, the urine sample collected from Ms Radcliffe when she became marathon world champion on 14 August 2005 was re-analysed by the IAAF seven years later, in November 2012, using the then most up-to-date techniques for rEPO detection. Once again, it tested negative for rEPO.
- 5.7 Sample 3 (collected in Monte Carlo on 7 February 2012):
  - 5.7.1 As noted above, the WADA ABP Protocol came into effect in 2009 and was immediately adopted by the IAAF. From then on, the standardised sample collection, transport and analysis procedures set out in the WADA ABP Protocol were followed for all ABP samples.

- 5.7.2 On 7 February 2012, the IAAF collected an ABP blood sample from Ms Radcliffe in Monte Carlo, while she was out of competition. It was analysed at a WADA-approved laboratory using a Sysmex machine. The HGB reading in the sample was 16.2 g/dl and the RET% value was 0.77, giving an OFF-score of 109.35.
- 5.7.3 In accordance with the standard procedures set out in the WADA ABP Protocol, at the time that sample was collected the doping control officer asked Ms Radcliffe to provide details on the doping control form of any exposure to altitude in the previous two weeks. She noted that she had been at an altitude of 2400m in Kenya from 3 January to 29 January 2012, i.e., eight days before sample collection, and had used a hypoxic device following her return. As noted above, it has been established that altitude exposure can affect blood parameters and so artificially raise OFF-score values after the athlete returns to sea level. When Ms Radcliffe's (anonymised) profile was referred for independent expert review, the experts noted that this altitude exposure was a plausible explanation for the values reported for her 7 February 2012 sample, and so concluded that there was no basis to pursue the case as a potential adverse passport finding.
- 5.8 This case is a good example, then, of how dangerous it is to insinuate that an athlete has doped based simply on the raw and incomplete data in the leaked database. Ms Radcliffe should never have been forced to come out and defend herself against such insinuations. Even ignoring the fact that the pre-2009 values could not be fairly compared with each other, what the facts set out above show is that there were plausible alternative explanations for the elevated values in the blood samples collected from Ms Radcliffe. What the facts also show is that Ms Radcliffe was target tested for rEPO on every occasion that the applicable IAAF regulations required (and indeed even when the regulations did not require), and the urine samples she provided always tested negative. Furthermore, her blood was tested for evidence of blood transfusions and again came back negative. The data therefore provide no basis whatsoever for the insinuations made against her.

#### 6. The CAS cases

- 6.1 While The Sunday Times has acknowledged that the data in the database 'does not prove doping',<sup>105</sup> Dr Ashenden has not. In all of his written and oral evidence to the Culture, Media and Sport Committee, Dr Ashenden failed even to acknowledge, let alone to rebut in any way, Dick Pound's clear statement a few weeks earlier that 'no test data derived from the IAAF database prior to the adoption of the ABP in 2009 can be considered to be proof of doping. It would be reckless, if not libellous, to make such an allegation. The reported values may be suspicious and lead to targeted testing of the athletes involved, but nothing more could be done with the information'.<sup>106</sup> Instead Dr Ashenden insisted repeatedly to the Committee that the abnormal OFF-scores identified by the IAAF's pre-2009 blood-doping constituted 'compelling evidence of doping' that could and should have prompted the IAAF to charge the athletes concerned. On what basis did he do so?
- 6.2 In his evidence to the Committee, Dr Ashenden noted correctly that the World Anti-Doping Code permits doping to be proved by 'any reliable means'.<sup>107</sup> However, a detection method will not be considered reliable unless it has been properly validated, and the ABP Programme was not validated by WADA until 2009 (which is why the Code and IAAF Rules did not refer to proving use of a prohibited method by 'conclusions drawn from longitudinal profiling' before 2009).<sup>108</sup> Dr Ashenden argued to the Committee that the values measured in the blood

samples collected by the IAAF prior to 2009 were reliable because they were all collected pursuant to the IAAF Blood Sampling Protocols.<sup>109</sup> He omitted to mention that (as explained above) those protocols were not mandatory in all respects, were changed from year to year, and did not contain all of the detailed requirements for collection, transport and analysis of blood samples that the WADA ABP Protocol identified in 2009 as necessary (1) to ensure that those values were reliable and fairly comparable with one another, and (2) to exclude all other potential explanations for any deviations seen in those values over time.

- 6.3 Dr Ashenden also asserted in his evidence to the Culture, Media and Sport Committee that the IAAF relied on the values measured in pre-2009 blood samples 'to impose anti-doping rule violations' in the appeal that the IAAF brought to the CAS in 2012 against Greek steeplechaser Irini Kokkinariou.<sup>110</sup> That is simply incorrect. The IAAF charged Ms Kokkinariou with blood doping based only on the values measured in blood samples collected from her between 2 July 2009 and 22 August 2011, i.e., once the IAAF ABP Programme was up and running. That charge was upheld by a domestic panel in the first instance proceedings,<sup>111</sup> and was not in issue at all in the CAS appeal, which dealt with sanction only (the IAAF was appealing the two year ban that the domestic panel had imposed for Ms Kokkinariou's offence on the basis that it was too lenient). The IAAF did refer the CAS Panel to data from blood samples collected from Ms Kokkinariou prior to 2009, but not to establish a violation (indeed, consistent with the original charge, its position on appeal was that her violation should be deemed to have started, and so her results should be disqualified from, 2 July 2009, not before<sup>112</sup>). Instead, in its submissions to the CAS, the IAAF carefully distinguished the pre-2009 data from the subsequent data,<sup>113</sup> and cited it only as corroborative evidence going to sanction only. And it was only able to make even that limited use of the pre-2009 data because the pre-2009 data were consistent with the post-2009 (validated) data.<sup>114</sup> In upholding the IAAF's appeal, the CAS Panel sanctioned Ms Kokkinariou for 4 years and disqualified her results from 2 July 2009 onwards.
- 6.4 In The Sunday Times, Dr Ashenden noted that in the 2004 CAS case of <u>USADA v</u> <u>Montgomery</u>,<sup>115</sup> 'USADA submitted alleged abnormal blood test results collected on five occasions between November 2000 and July 2001' as 'reliable evidence' of doping.<sup>116</sup> What he did not mention was that Montgomery challenged the reliability of that evidence, and rather than address the issue, the CAS Panel in that case chose not to rely on that evidence at all, but instead upheld the charge based solely on Montgomery's uncontroverted admissions of doping made to a fellow athlete.<sup>117</sup>
- 6.5 In fact, the IAAF is not aware of <u>any</u> CAS case where a blood doping charge was upheld based on pre-2009 blood values. The IAAF is aware of at least two cases, however, where the CAS <u>rejected</u> the suggestion that pre-2009 blood values constituted reliable evidence of blood doping. Dr Ashenden is certainly aware of those cases, because he was involved in both of them:
  - 6.5.1 In <u>Gusev v. Olympus SARL</u>, Dr Ashenden testified in support of a cycling team's claim that variations over time in the (pre-2009) blood values of one of its cyclists were 'serious indicators' that the cyclist had taken rEPO or CERA, thereby entitling the team to terminate his contract. The cyclist challenged this assertion on various grounds, including that (among other things) (1) there was no information about the measuring instruments used to determine those values, and (2) the one allegedly suspicious variation in his values was due to his having trained at altitude in the week prior to collection of the sample in question. The CAS Panel ruled that the team's evidence amounted only to 'a simple suspicion of doping, which has not in any way been

proved'. It also criticised the team for failing to ensure the rider was given adequate opportunity to present his counter-arguments about the variations in his profile, which it considered to be 'essential' for sake of fairness.<sup>118</sup> The CAS Panel therefore rejected the cycling team's case and the rider, whose contract had been terminated, was reinstated.

- 6.5.2 Similarly, in UCI v Contador, Dr Ashenden testified that the cyclist's ABP data (i.e., the data collected post-2009 in accordance with the mandatory requirements of the WADA ABP Protocol) were normal, but argued that the values from blood samples collected from the cyclist in the 2007 and 2008 seasons were also reliable, and suggested that the difference between the 2007-2008 values and the post-2009 values was evidence that the cyclist had blood-doped in 2010. The CAS Panel resoundingly rejected this argument, on the following basis: 'The Panel is not convinced that the comparison conducted by Dr Ashenden is a sufficiently secure method of establishing inconsistencies in Mr Contador's ABP. More specifically, after considering the positions of all the parties and the expert reports of Dr Ashenden and Mr Scott, the Panel finds that the inconsistencies that Dr Ashenden sees in Mr Contador's ABP are not conclusive and are deducted from too many uncertain blood parameters and comparisons, making them too speculative and insufficiently secure to rely on as convincing supporting evidence that an athlete underwent a blood transfusion'.<sup>119</sup>
- Dr Ashenden did not mention either of those cases in his evidence to the UK Parliament's 6.6 Culture, Media and Sport Committee. Instead, he cited only Pechstein v ISU,<sup>120</sup> which he described to the Committee as 'a legal precedent for establishing an anti-doping rule violation using blood results collected outside of WADA guidelines'.<sup>121</sup> In fact, the ISU was careful to charge Ms Pechstein with an anti-doping rule violation based only on values obtained from samples collected after 1 January 2009 (i.e., after the World Anti-Doping Code had been amended to expressly permit the use of longitudinal profiling to establish a 'Use' violation), and the CAS Panel hearing the case made clear that it upheld the charge on the basis of the 2009 values alone, with previous values being used only to assist in the understanding and interpretation of the 2009 values (which explains why the CAS did not disqualify any of the athlete's results prior to February 2009).<sup>122</sup> And even if those February 2009 samples were collected shortly before the WADA ABP Protocol was formally approved, the CAS was clear that values taken from those samples could only be considered reliable where the ISU could show that (1) the samples were transported under adequate cooling conditions; (2) they were all measured using the same type of machine at the laboratory (with results obtained using different machines being disregarded, to avoid inter-method error); and (3) even where the same instrument was used, in the case of each use detailed calibration protocols had been followed to address the risk of intra-method error<sup>123</sup> (which was not the case with all of the samples collected by the IAAF prior to 2009). Furthermore, even limited in this way, the CAS award in Pechstein has since been challenged twice by the athlete in the Swiss federal courts on the basis that she had a medical condition that provided an innocent explanation for the values said to reflect blood doping. Even now, six years after the award was issued, she is still challenging the award on this basis (and asserting a damages claim of several million euros against the ISU for her allegedly unlawful doping ban) in the German courts.<sup>124</sup> For all of these reasons, the IAAF does not agree that the Pechstein case constitutes a strong precedent that would justify ignoring the analysis and authorities set out above showing why charges could not have been brought for blood-doping based on the IAAF's pre-2009 blood-testing data, without any need for further testing.

# 7. Why hasn't the IAAF adopted a 'no start' rule, to prevent athletes with 'abnormal' blood values competing in events like the London Marathon?

- 7.1 Dr Ashenden has suggested that the IAAF should adopt a 'no start' rule, i.e., a rule that anyone with blood parameters (e.g., HGB) over a certain limit immediately before competition is not allowed to compete. He argues this would enable the IAAF to exclude from competition 'athletes whose values were suspicious but not sufficiently drastic outliers to support a sanction being imposed'.<sup>125</sup>
- 7.2 As far as the IAAF is aware, four international federations (the UCI, IBU, ISU and FIS) have had such rules, which were anti-doping rules disguised as rules safeguarding an athlete's health.<sup>126</sup> However, such a 'no start' rule was not included in the World Anti-Doping Code when it was introduced in 2004, because of (among other things) serious concerns that it would produce a material number of false negatives, i.e., an athlete might exceed such an arbitrary blood value limit for entirely innocent reasons, such as genetics, altitude training, dehydration, etc. Indeed, Dr Ashenden himself has previously noted that if a 'no start' rule is adopted based on a maximum HGB level calculated using general population data, 'a significant proportion of athletes (up to 5%) may exceed the threshold because of genetic factors and be unfairly banned from competition'.<sup>127</sup> And Dr Ashenden and Mr Parisotto co-authored a 2002 paper that estimated that 10% of male athletes living at altitude would fail a 'no start' rule without blood-doping at all.<sup>128</sup>
- 7.3 Instead, the World Anti-Doping Code is clear: an athlete may only be suspended from competition without a hearing if the Anti-Doping Organisation has strong *prima facie* evidence that is sufficient to charge an athlete with an anti-doping rule violation. Such evidence would have to be considered sufficient to establish that violation to the comfortable satisfaction of the hearing panel when the case comes to trial.<sup>129</sup> In the absence of such evidence, no charge and therefore no provisional suspension is permitted. In short, suspicions are not enough to exclude an athlete from competition; proof is required, at least on a *prima facie* basis, before that step can or should be taken. This is considered the only appropriate way to balance the public interest in protecting clean competition with the athlete's private interest in not having his reputation tainted and being excluded from competition absent a determination that he has committed an anti-doping rule violation.
- 7.4 Exactly the same principle applies in cases based on the ABP programme, which is a far more sensitive method of detecting blood doping than an arbitrary 'no start' HGB limit.<sup>130</sup> If the experts are comfortably satisfied that the abnormal values are highly likely to be due to blood doping and that any alternative explanation is implausible, then the athlete will be charged and provisionally suspended with immediate effect. If the experts are not comfortably satisfied of this, i.e., if other explanations are plausible, then there is simply no proper basis to keep an athlete out of competition.

#### Conclusion

To reiterate, the IAAF is far from complacent about the problem of blood doping in its sport. It will continue to use every tool available to it to fight that scourge, and hopes that investigative journalists will continue to assist it by unearthing evidence of cheating for it to follow up. The IAAF also acknowledges the important role of the media in holding it and other anti-doping organisations to account in their efforts to fight the scourge of doping. But the IAAF cannot sit idly by while public confidence in its willingness to protect the integrity of its sport is undermined by allegations of inaction that (as demonstrated above) are based on inaccurate and unfounded scientific and legal argument.

International Association of Athletics Federations Monaco, November 2015

#### END NOTES

<sup>1</sup> Sottas et al, *Prevalence of Blood Doping in Samples Collected from Elite Track and Field Athletes*, Clinical Chemistry 57:5; 762-769 (2011).

<sup>2</sup> See <u>https://www.wada-ama.org/en/questions-answers/blood-doping</u> (accessed 12 September 2015); Zorzoli M., *Biological passport parameters*, J. Hum. Sport Exerc. Vol. 6, No. 2, pp.205-217 (2011); WADA Independent Commission Report No.1, dated 9 November 2015 (<u>https://www.wada-ama.org/en/resources/world-anti-doping-program/independent-commission-report-1</u>) (**IC Report**), at p.88.

<sup>3</sup> See Birkeland, Donike, Llungqvist et al, *Blood sampling in doping control. First experiences from regular testing in athletics,* Int. J. Sports Med. (1997) 18(1):8-12 (noting the importance of taking into account the special circumstances during sampling when interpreting results from blood testing in athletes, and suggesting that future research should focus on developing more sensitive and specific tests to detect doping with endogenous substances such as EPO).

<sup>4</sup> C. Gore, R. Parisotto, MJ Ashenden et al, *Second-generation blood tests to detect erythropoietin abuse by athletes*, Journal of Hematology, vol. 88(03), March 2003, p.333.

<sup>5</sup> WADA Q&A, *EPO Detection* (<u>https://www.wada-ama.org/en/questions-answers/epo-detection</u>), accessed 18 October 2015

<sup>6</sup> See e.g. <u>UCI v Hamberger</u>, CAS 2001/A/343, award dated 28 January 2002, *Digest of CAS Awards Vol 3* 2001-2003 (Kluwer, 2004) (<u>http://dopingjournal.org/lib/20020128-arbitral-award-court-of-arbitration-for-sport-case-2001-a-343-union-cycliste-internationale-vs-hamburger.pdf</u>), para 26 ('the expert witnesses heard in the instant case all confirmed that the levels found quickly and cost-effectively in a blood test (the test is made on the spot with mobile equipment and there is no "B sample"), especially a higher level of haematocrit or a significant increase in the number of reticulocytes, are reliable indications of abnormal EPO levels. The blood test thus serves, on the one hand as a way of screening the person being tested, i.e. it determines whether certain blood parameters justify a suspicion of rEPO having been administered exogenously and therefore justify an additional urine test, which is time consuming and costly, being carried out').

<sup>7</sup> See WADA Q&A, *EPO Detection* (<u>https://www.wada-ama.org/en/questions-answers/epo-detection</u>), accessed 18 October 2015 ('In June 2003, WADA's Executive Committee accepted the results of an independent report stating that urine tests alone can be used to detect the presence of recombinant EPO. This report, requested by WADA's stakeholders and commissioned by the Agency to evaluate the validity of urinary and blood tests for detecting the presence of recombinant EPO, concluded that urinary testing is the only scientifically validated method for direct detection of recombinant EPO. This report also recommended that urine testing be used in conjunction with blood screening for a variety of reasons, including the cost savings of performing blood screening prior to testing urine').

<sup>8</sup> Bahrain ban disgraced Ramzi for two years, 9 January 2010 (<u>http://archives.gdnonline.com/NewsDetails.aspx?date=04/07/2015&storyid=268166</u>).

<sup>9</sup> *A clean sweep in the dirtiest race,* The Sunday Times, 2 August 2015, p.11.

<sup>10</sup> *A clean sweep in the dirtiest race*, The Sunday Times, 2 August 2015, p.12.

<sup>11</sup> <u>IAAF v Yegerova et al</u>, CAS 2008/A/1718-1724, award dated 18 November 2009 (<u>http://www.doping.nl/media/kb/680/CAS%202008 A 1718%20IAAF%20vs%20All%20Russia%20Athletic%20F</u> ederation%20%26%20Olga%20Yegorova%20(S).pdf).

<sup>12</sup> Ashenden, *Chase dopers, Seb, like you chased gold*, The Sunday Times, 9 August 2015.

<sup>13</sup> WADA, 'Statement regarding Extended Mandate of Independent Commission', 14 August 2015, <u>https://www.wada-ama.org/en/media/news/2015-08/statement-regarding-extended-mandate-of-independent-commission</u>.

<sup>14</sup> Ashenden, *Chase dopers, Seb, like you chased gold*, The Sunday Times, 9 August 2015 (acknowledging that the IAAF has 'painstakingly collected blood samples since 2001 to refine its risk profile of suspect athletes').

<sup>15</sup> See 2015 World Anti-Doping Code, Article 5.4.2: 'each Anti-Doping Organization with Testing authority shall develop and implement an effective, intelligent and proportionate test distribution plan that prioritizes appropriately between disciplines, categories of Athletes, types of Testing, types of Samples collected, and types of Sample analysis, all in compliance with the requirements of the International Standard for Testing and Investigations'.

<sup>16</sup> Sottas et al, *Prevalence of Blood Doping in Samples Collected from Elite Track and Field Athletes*, Clinical Chemistry 57:5; 762-769 (2011).

<sup>17</sup> Cycling Independent Reform Commission Report to the President of the UCI, 2 March 2015 (<u>http://www.uci.ch/mm/Document/News/CleanSport/16/87/99/CIRCReport2015\_Neutral.pdf</u>), p.43.

<sup>18</sup> Vernec, *The Athlete Biological Passport: an integral element of innovative strategies in antidoping*, Br J Sports Med, published online first on 21 March 2014 as 10.1136/bjsports-2014-093560.

19 See. UCI v Valjavec, CAS 2010/A/2235, award dated 21 April 2011 e.g., (http://www.newcyclingpathway.com/wp-content/uploads/2011/04/valjavec-CAS-award-21-4-11.pdf), para 7 ('While direct detection methods aim to detect the doping agent itself, the focus of the ABP is not on the detection of prohibited substances but rather on the effect of these substances on the body. Designed, as they are, to create physiological enhancements, biological markers of disease are used in medicine to detect pathological conditions. Biomarkers of doping are used to detect doping').

<sup>20</sup> Vernec, *The Athlete Biological Passport: an integral element of innovative strategies in antidoping*, Br J Sports Med, published online first on 21 March 2014 as 10.1136/bjsports-2014-093560; Zorzoli, *Biological passport parameters*, J. Hum. Sport Exerc. Vol. 6, No. 2, pp.205-217 (2011).

<sup>21</sup> See, e.g., Sottas et al, *The Athlete's Biological Passport and Indirect Markers of Blood Doping*, in Doping in Sports (Springer 2010, Thieme and Hemmersbach eds), pp. 307, 310 (describing the scientific research and findings from 2001 to 2008 that would henceforth permit reliance on indirect blood marker measurements as evidence in and of themselves of blood doping).

<sup>22</sup> The current version (5.0), issued in October 2014, can be found at <u>https://wada-main-prod.s3.amazonaws.com/resources/files/wada abp operating guidelines 2014 v5.0 en.pdf</u>.

<sup>23</sup> Vernec, *The Athlete Biological Passport: an integral element of innovative strategies in antidoping*, Br J Sports Med, published online first on 21 March 2014 as 10.1136/bjsports-2014-093560.

<sup>24</sup> Schumacher et al, *Diurnal and exercise-related variability of haemoglobin and reticulocytes in athletes*, In J Sports Med 2010;31;225-30.

<sup>25</sup> Haemoglobin is the protein inside the red blood cell that carries the oxygen molecules. Haemoglobin concentration (or **HGB**) is the mass of the haemoglobin in the blood divided by the volume of the blood. It is commonly expressed in grams per deciliter (g/dL).

<sup>26</sup> The usual life cycle of a red blood cell is about 120 days. Therefore, each day 1/120 of the red blood cells in circulation in the body need to be replaced by new blood cells (called 'reticulocytes'). As a result, assuming a normal level of red cell production, in normal physiological circumstances (i.e., absent pathology or blood doping) each day approximately 0.8% of the total red blood cells in the body will be reticulocytes.

<sup>27</sup> See, e.g., <u>IAAF v SEGAS & Kokkinariou</u>, CAS 2012/A/2773, award dated 30 November 2012 (<u>http://jurisprudence.tas-cas.org/sites/CaseLaw/Shared%20Documents/2773.pdf</u>), para 114 ('association of high haemoglobin with low reticulocytes is a strong evidence of artificial inhibition of reticulocyte formation caused by the suspension of an ESA (or, less likely, by reinfusion of multiple blood bags). It is an indicator of the so-called OFF phase, which is seen when an ESA has been suspended one to three weeks before, such as is observed in doped athletes before important competitions. When the ESA is stopped, hemoglobin remains high for at least two to three weeks, depending on the dosage, while reticulocytes are reduced because the high hemoglobin inhibits endogenous EPO production').

<sup>28</sup> See Pottgiesser and Schumacher, *Biomarker monitoring in sports doping control*, Bioanalysis, 2012;4(10): 1245-1253, at 1247 ('The model ... is based on a global Bayesian inference approach for the detection of abnormal values over time. In such a Bayesian network, the causal relationship between a doping activity and the induced modification in the blood markers is represented as probabilities where every causal relationship is itself a model represented by a conditional probability density function'). See generally Sottas et al, *The Athlete's Biological Passport and Indirect Markers of Blood Doping*, in Doping in Sports (Springer 2010, Thieme and Hemmersbach eds), pp.317-324; Sottas et al, *A forensic approach to the interpretation of blood doping markers*, (2008) 7 Law, Probability and Risk, 191-201.

<sup>29</sup> See generally <u>https://www.wada-ama.org/en/questions-answers/athlete-biological-passport</u> (accessed 12 September 2015); IAAF Athlete Advisory Notes, *The Athlete Biological Passport*, <u>http://www.iaaf.org/about-iaaf/documents/anti-doping</u> (accessed 12 September 2015).

<sup>30</sup> See e.g. <u>UK Anti-Doping v Tiernan-Lock</u>e, National Anti-Doping Panel decision dated 15 July 2014 (<u>http://www.ukad.org.uk/anti-doping-rule-violations/download-decision/a/6605</u>), para 36 ('Professor Schumacher and Professor d'Onorio [*sic*] are clearly experts of considerable distinction and unparalleled knowledge in the field of anti-doping, in particular relating to the ABP programme').

<sup>31</sup> *Rita Jeptoo: Kenyan marathon runner banned for doping,* <u>http://www.bbc.co.uk/sport/0/athletics/31062211</u>, accessed 22 October 2015.

<sup>32</sup> <u>IAAF v TAF and Cakir-Alptekin</u>, CAS/2014/A/3498, award dated 17 August 2015 (<u>http://www.tas-cas.org/fileadmin/user\_upload/consent\_award\_3498\_final\_.pdf</u>).

<sup>33</sup> <u>IAAF v SEGAS and Kokkinariou</u>, CAS 2012/A/2773, award dated 30 November 2012 (<u>http://jurisprudence.tas-cas.org/sites/CaseLaw/Shared%20Documents/2773.pdf</u>).

<sup>34</sup> WADA statement regarding Liliya Shobukhova's sanction, 24 August 2015 (<u>https://www.wada-ama.org/en/media/news/2015-08/wada-statement-regarding-liliya-shobukhovas-sanction</u>).

<sup>35</sup> Nevin Yanit's suspension increased from 2 years to 3 years, CAS statement dated 6 March 2015 (<u>http://www.tas-cas.org/fileadmin/user\_upload/Media\_Release\_3373.pdf</u>).

<sup>36</sup> See IAAF Medical & Anti-Doping Department,, The IAAF Registered Testing Pool, <u>http://www.iaaf.org/download/download?filename=32d9e98f-b3ca-49f5-820b-</u> <u>b161e95f3ee3.pdf&urlslug=The%20IAAF%20Registered%20Testing%20Pool</u>.

<sup>37</sup> IAAF Medical & Anti-Doping Department, *Advisory Note – The Intelligence Function*, International Association of Athletics Federations, June 2013 (<u>http://www.iaaf.org/download/download?filename=ba05df77-2267-4a3f-8e36-</u>

 $\underline{af826d7f613e.pdf\&urlslug=Athlete\%20Advisory\%20Notes\%3A\%20The\%20Intelligence\%20Function).}$ 

<sup>38</sup> See, e.g., IAAF, *Latest Success of IAAF Re-Testing Strategy Reveals 32 More Adverse Findings From Helsinki 2005 and Osaka 2007*, IAAF press release dated 11 August 2015 (<u>http://www.iaaf.org/news/press-release/positive-retests-helsinki-2005-osaka-2007</u>).

<sup>39</sup> Ashenden, transcript of oral evidence to Culture, Media and Sport Committee (<u>http://data.parliament.uk/writtenevidence/committeeevidence.svc/evidencedocument/culture-media-and-sport-committee/blood-doping-in-athletics/oral/21309.pdf</u>) (**CMSC Tr**.) at p.20, answer to Q62.

<sup>40</sup> *A clean sweep in the dirtiest race,* The Sunday Times, 2 August 2015, p.12.

<sup>41</sup> Ashenden oral evidence to Culture, Media and Sport Committee, CMSC Tr. p.3, answer to Q6 (emphasis added).

<sup>42</sup> Ashenden oral evidence to Culture, Media and Sport Committee, CMSC Tr. p.2, answer to Q4 (emphasis added).

<sup>43</sup> Ashenden oral evidence to Culture, Media and Sport Committee, CMSC Tr. p.7, answer to Q20.

<sup>44</sup> Ashenden written evidence to Culture, Media and Sport Committee, September 2015 (<u>http://data.parliament.uk/writtenevidence/committeeevidence.svc/evidencedocument/culture-media-and-</u> <u>sport-committee/blood-doping-in-athletics/written/21284.pdf</u>), para 51.

<sup>45</sup> CMSC Tr. p.3, Q8.

<sup>46</sup> CMSC Tr. pp.34-35, Q54.

<sup>47</sup> Ashenden, A strategy to deter blood doping in sport, Haematologica March 2002 87(3): 225-232, at 228 (emphasis in original).

<sup>48</sup> MJ Ashenden, CJ Gore, R Parisotto, et al, *Effect of altitude on second-generation blood tests to detect erythropoietin abuse by athletes*, Haematologica January 2003 88: 1053-1062.

<sup>49</sup> Ashenden, *Contemporary issues in the fight against blood doping in sport*, Hamatologica, 2004; 89(8): August 2004.

<sup>50</sup> Parisotto, 'Blood Sports: The inside dope on drugs in sport' (Hardie Grant Books, 2006), Chapter 9, 'The trap is set'.

<sup>51</sup> Parisotto, 'Blood Sports: The inside dope on drugs in sport' (Hardie Grant Books, 2006), Chapter 6, 'Blood in outer space' ('Although some argued that a direct urine test [for rEPO] would render any indirect blood test redundant, this criticism failed to take the practical realities into account. For one thing, EPO leaves the urine quickly. A urine test is only good for three to five days after EPO use. For another thing, the proposed urine test was still time-consuming, taking days to get a result. If hundreds or even thousands of tests were to be done during an Olympic Games, it would be years before they could all be analysed. A complementary blood tested ... could be used to narrow the field to the suspicious samples only, saving time, money and needless investigations. The potential for a two-pronged test was genuine and together, we might be able to give the anti-doping authorities an almost foolproof test').

<sup>52</sup> <u>https://www.wada-ama.org/en/media/news/2015-08/statement-regarding-extended-mandate-of-independent-commission</u>, 14 August 2015.

<sup>53</sup> <u>https://www.wada-ama.org/en/media/news/2015-09/statement-from-wada-director-general,</u> statement dated 11 September 2015.

54 At pages 231-232 of its report dated 9 November 2015 (https://www.wadaama.org/en/resources/world-anti-doping-program/independent-commission-report-1), the WADA Independent Commission explained that before the introduction of the WADA ABP Protocol in 2009, blood profiling was not considered reliable evidence of doping because 'there were no standard protocols regarding how blood was collected; what constituted proper handling in the circumstances; what equipment should be used for measurements; the appropriate variables and how they should be defined; or, what were the applicable

pre-testing conditions and how relevant comparisons should be made'. And UK Anti-Doping CEO Nicole Sapstead set out the other half of the equation in her letter to the Culture, Media and Sport Committee dated 5 October 2015

(http://data.parliament.uk/writtenevidence/committeeevidence.svc/evidencedocument/culture-media-andsport-committee/blood-doping-in-athletics/written/23236.pdf), when she said (at p.2): 'It is important to note that any data pre 2009 had no WADA regulations or protocols underpinning it. You have to look at any data in the context of the individual who provided it and the circumstances in which it was provided. For example, was it provided at altitude, after an intensive training session, are there any medical conditions that existed at the time and so on. So there may be data that to a layperson may look odd, but means nothing to an anti-doping authority'.

<sup>55</sup> Ashenden written evidence to Culture, Media and Sport Committee, September 2015, para 7.

<sup>56</sup> The Sunday Times conceded this point in its edition published on 13 September 2015. In response to Paula Radcliffe's explanation that the abnormal OFF-score values in her profile were due to altitude training and (in one case) the collection of the sample immediately after a half-marathon run in baking heat, The Sunday Times wrote: 'It was immediately clear that the figures carried little weight without comparison with other tests. A key element that experts would usually examine to determine doping is any big fluctuation that deviates from an athlete's normal blood value levels': *Testing Times*, Sunday Times, 13 September 2015, main section, p.30.

Dr Ashenden himself made his reliance on deviations from the norm clear in subsequent correspondence with the IAAF, arguing that 'the magnitude of the deviations caused by EPO administration enable it to be distinguished from simulated altitude exposure. Similarly, when deviations are sufficiently large, directional, and/or characteristic of doping, it is possible to confidently exclude the other factors you mention'. See letter from Dr Ashenden to Thomas Capdevielle of the IAAF dated 11 October 2015.

See also the comment of Robin Parisotto in an interview with Cycling Tips published in 2014 (<u>http://cyclingtips.com.au/2014/08/anti-doping-expert-parisotto-explains-inherent-delays-in-biological-passport-system/</u>): 'with the biological passport. It is not a one-off test, where you may simply test positive and then the case goes ahead. In this case you have to accumulate a great amount of detail. You have to cast your eye over perhaps years of data to see if there is some sort of pattern that is suspicious'.

<sup>57</sup> Ashenden, A strategy to deter blood doping in sport, Haematologica March 2002 87(3): 225-232. See also, e.g., McLaren, Athlete Biological Passport: The Juridical Viewpoint, [2012] ISLR Issue 4, p.8 ('Only after longitudinal profiling is standardized across organizations can there be legal certainty') and p.10 ('The result of this construction is that individual profiling is an acceptable evidentiary method if implemented in a manner that produces scientifically accurate results ...'); Sottas et al, *The Athlete's Biological Passport and Indirect Markers of Blood Doping*, in Doping in Sports (Springer 2010, Thieme and Hemmersbach eds), p.311 ('A biological passport is valid only if the conditions under which samples are collected, transported and analysed obey strict rules. Such compliance is necessary to reduce pre-analytical and analytical uncertainties').

The WADA ABP Protocol could not be clearer on this point, stating (at page 5): 'These mandatory protocols have been established to harmonize the results of monitored variables within the Athlete Biological Passport to ensure both legal fortitude and scientific certainty. Each ADO remains free to adapt the recommended process suggested herein to reflect its own resources and context, but to operate an ABP program as defined in this document, the attached protocols provided herein as Appendices must be rigorously observed'. The 2012 version of the WADA ABP Protocol also noted that '[t]he Athlete Biological Passport, when implemented in accordance with the Technical Documents, is a reliable method for indirectly detecting doping that can withstand legal and scientific challenges at the highest level' (at p.8, emphasis added). See also <u>UKAD</u> <u>v Tiernan-Lock</u>e, National Anti-Doping Panel decision dated 15 July 2014 (<u>http://www.ukad.org.uk/anti-dopingrule-violations/download-decision/a/6605</u>), para 45 ('the experts are only permitted under the WADA operating guidelines to take into account results obtained from analyses conducted under the ABP programme, which comply with strict criteria').

In contrast, the WADA Guidelines for Blood Sample Collection (June 2008) noted their limitations in this regard upfront (at p.3): 'Longitudinal hematological profiling ("the passport") may be used for anti-doping

purposes in accordance with Article 2.2 of the Code (*Use*). Mandatory technical documents to supplement both the IST and the ISL will soon be made available to Anti-Doping Organizations who wish to employ the indirect detection (passport) methodology'.

<sup>59</sup> Letter from Thomas Capdevielle of the IAAF to Dr Ashenden dated 9 October 2015.

<sup>60</sup> Letter from Dr Ashenden to Thomas Capdevielle of the IAAF dated 11 October 2015, p.2. In the letter to which he was responding, Dr Ashenden was specifically asked how he had come to conclude that the samples had been collected, transported and analysed under standardised conditions (so that it was appropriate to compare the values from one sample with values from other samples in the profile). He failed to answer that question.

<sup>61</sup> Sottas et al, *Prevalence of Blood Doping in Samples Collected from Elite Track and Field Athletes*, Clinical Chemistry 57:5; 762-769 (2011), Addendum: Method used to provide prevalence estimates ('Since 2007, respectively 2009, blood samples were mainly, respectively exclusively, sent to the network of WADA accredited laboratories and protocols for the collection, transport and analysis of blood samples were followed as recommended by WADA for the ABP ...').

<sup>62</sup> WADA ABP Protocol, p.26. See Parisotto, Gore, Emslie, Ashenden et al, A novel method utilizing markers of altered erythropoiesis for the detection of recombinant human erythropoietin abuse in athletes, Haematologica, 2000; 85:564-572 ('hemoconcentration could cause false positives by artificially elevating blood markers such as sTfr and Hct. Hemoconcentration can be caused by dehydration associated with prolonged exercise or by posturally-induced shifts in plasma volume, and may be in the order of 10-20%').

<sup>63</sup> WADA ABP Protocol, p.31.

<sup>64</sup> Coccia, *The Athlete Biological Passport: Legal And Scientific Aspects* [2013] I.S.L.R., Issue 1, p.9, p.15. See also Robinson et al, *Time and Temperature Dependant Changes in Red Blood Cell Analytes Used for Testing Recombinant Erythropoietin Abuse in Sports*, Clin. Lab. 2004: 50:317-323 ('this experiment demonstrates the importance of temperature on the conservation of blood samples specially for the determination of the haematocrit percentage, the haemoglobin concentration and the reticulocyte count').

<sup>65</sup> See, e.g., Robinson et al, *Time and Temperature Dependant Changes in Red Blood Cell Analytes Used for Testing Recombinant Erythropoietin Abuse in Sports*, Clin. Lab. 2004: 50:317-323 ('Blood analyses are very complex, and determination of the red blood cell profile can be dependent on the technology used. Each machine has its own way of establishing the red blood indices and for some of the parameters, significant differences can appear').

<sup>66</sup> K Sharpe, MJ Ashenden, YO Schumacher, *A third generation approach to detect erythropoietin abuse in athletes*, Haematologica January 2006 91: 356-363.

<sup>67</sup> MJ Ashenden et al, *Standardisation of reticulocyte values in an antidoping context*, Am J Clin Pathol, 2004 June; 121(6):816-25 ('Thresholds for OFF-hr model scores have been published that enable practitioners to recognize the probability associated with unusual deviations from expected scores. However, these thresholds were derived using data collected only on the ADVIA 120 platform (Bayer, Tarrytown, NY), so that if reticulocyte values derived from other platforms are substituted into the equation, intermethod bias might compromise the integrity of this approach. The absence of a reticulocyte calibration material that can be used by all methods prevents technicians from quantifying intermethod bias').

<sup>68</sup> WADA ABP Protocol at p.32.

<sup>69</sup> <u>Pechstein, DESG v ISU</u>, CAS 2009/A/1912-1913, award dated 25 November 2009 (<u>http://sottas.info/Index/FINAL%20AWARD%20PECHSTEIN.pdf</u>), para 152 ('in general, the Advia Machine tends to yield higher reticulocyte values than the Sysmex Machine. Given this difference between the two machines and the importance for blood profiling that the same technology is always used, the panel will disregard any Athlete's hematological values deriving from a Sysmex machine and will only take into account values deriving

from analyses performed by the Advia Machine. In this way, the Panel is comfortably satisfied that the values are all comparable between themselves ...').

<sup>70</sup> WADA ABP Protocol, p.32. See, e.g., Robinson et al, *Stability and robustness of blood variables in an antidoping setting*, Int. Jnl. Lab. Hem. 2010:1-7, at 7 ('Strict quality control conditions, with the possibility of a real-time interinstrument comparison ... should be required as a prerequisite for laboratories performing analysis for the ABP'); Parisotto, Gore, Emslie, Ashenden et al, *A novel method utilizing markers of altered erythropoiesis for the detection of recombinant human erythropoietin abuse in athletes*, Haematologica, 2000; 85:564-572 (carefully noting that in their study '[a]ll analyzers were calibrated against appropriate reference materials and checked daily against internal and external quality controls').

<sup>71</sup> WADA ABP Protocol, pp.47-48. See K Sharpe, MJ Ashenden, YO Schumacher, *A third generation approach to detect erythropoietin abuse in athletes*, Haematologica January 2006 91: 356-363 ('the most obvious potential sources' of 'unusually large passport variations' were 'a particular group of athletes, measurement error or data input errors').

<sup>72</sup> WADA ABP Protocol, p.44. See also <u>UKAD v Tiernan-Lock</u>e, National Anti-Doping Panel decision dated 15 July 2014 (<u>http://www.ukad.org.uk/anti-doping-rule-violations/download-decision/a/6605</u>), para 45 ('the experts are only permitted under the WADA operating guidelines to take into account results obtained from analyses conducted under the ABP programme, which comply with strict criteria').

<sup>73</sup> Ashenden written evidence to Culture, Media and Sport Committee, September 2015, para 20.

Ashenden oral evidence to Culture, Media and Sport Committee, CMSC Tr.p.3, answer to Q6.

<sup>75</sup> See e.g. Mlodinow, *The Drunkard's Walk* (Penguin 2008), pp.117-121; Sottas et al, *The Athlete's Biological Passport and Indirect Markers of Blood Doping*, in Doping in Sports (Springer 2010, Thieme and Hemmersbach eds), pp.319-320.

<sup>76</sup> There will be athletes who will have values above the OFF-score thresholds simply as a matter of natural biological variability. C. Gore, R. Parisotto, MJ Ashenden et al, *Second-generation blood tests to detect erythropoietin abuse by athletes*, Journal of Hematology, vol. 88(03), March 2003, p.343. And even if this is only 1 in 1,000 athletes (for example), that does not mean it can be ruled out as a possible cause of the 'abnormal' variation observed. For example, Dr Ashenden once tested ten subjects as part of an experiment and one of them happened to have an abnormal OFF-score even before being given rEPO (initially 138, but even when adjusted for instrument bias it was 132), i.e., he was the one athlete in 1,000 who has such OFF-scores simply as a matter of normal variation. Ashenden M, Gough C, Garnham A, Gore C, Sharpe K, *Current markers of the Athlete Blood Passport do not flag microdose EPO doping*, Eur J Appl Physiol. 2011;111:2307–2314. Therefore, as Professor McLaren has also noted: 'With the large number of tests being performed as result of the ABP there will certainly be some profiles flagged incorrectly due to chance'. McLaren, *Athlete Biological Passport: The Juridical Viewpoint* [2012] I.S.L.R., Issue 4, p.88.

77 Coccia, The Athlete Biological Passport: Legal and Scientific Aspects [2013] I.S.L.R., Issue 1, p.9, pp.15-16. CAS 2010/A/2235, award See also UCI v Valjavec, dated 21 April 2011 (http://www.newcyclingpathway.com/wp-content/uploads/2011/04/valjavec-CAS-award-21-4-11.pdf), para 88 ('In principle, such explanation could fall into one or more of five categories: (i) pure chance; (ii) incorrect analysis; (iii) breaches in the chain of custody both to and in the laboratory which tested the samples; (iv) medical condition, physiological or psychological; (v) manipulation of blood').

<sup>78</sup> McLaren, *Athlete Biological Passport: The Juridical Viewpoint* [2012] I.S.L.R., Issue 4, pp.83-84.

<sup>79</sup> McLaren, *Athlete Biological Passport: The Juridical Viewpoint* [2012] I.S.L.R., Issue 4, p.93.

<sup>80</sup> Letter from Dr Ashenden to Thomas Capdevielle of the IAAF dated 11 October 2015.

<sup>81</sup> Ashenden oral evidence to Culture, Media and Sport Committee, CMSC Tr., p.2, answer to Q4.

<sup>82</sup> How the data was checked, The Sunday Times, 2 August 2015.

<sup>83</sup> Sharpe, Hopikins, Emslie, Howe, Trout, Kazlauskas, Ashenden, Gore, Parisotto, Hahn, *Development of reference ranges for markers of altered erythropoiesis*, Haematologica, 2002; 87:1248-1257 ('the erythropoietic-dependent parameters included in our models could potentially be confounded by a number of factors. These include biological factors such as disease, physiological factors such as exercise, environmental factors such as altitude exposure and also the biological variation of blood parameters over time. Consequently identifying rHuEPO users amongst the elite athlete population will entail differentiating between the fluctuations associated with exposure to such influences, and the atypical variation of hematologic parameters caused by rHuEPO use').

<sup>84</sup> WADA ABP Protocol at pp.47-48. Nicole Sapstead (UK Anti-Doping CEO) referred to this in her evidence to the Parliamentary Committee: 'When we provide our experts with information about an atypical result we also tell them the conditions under which that sample was collected. So we will tell them whether it was just prior or post competition, if the athlete was tested at altitude, if the athlete had just completed a rigorous training programme, and those are relevant to their determination of whether that blip is anything beyond just how their body is behaving under those extreme circumstances or whether it is suspicious'. [CMSC Tr. p.24, answer to Q12].

<sup>85</sup> WADA ABP Protocol, p.7. See e.g. C. Gore, R. Parisotto, MJ Ashenden et al, *Second-generation blood tests to detect erythropoietin abuse by athletes*, Journal of Hematology, vol. 88(03), March 2003, p.342 ('the effect of altitude is unambiguous – if the blood sample was collected from the athlete while at altitude, a compensation should be made for this. Further research is required to establish the persistence of this hemoconcentration when the athlete is tested at sea level, and whether any allowance should be made for athletes who have recently been to altitude'); MJ Ashenden, CJ Gore, R Parisotto, et al, *Effect of altitude on second-generation blood tests to detect erythropoietin abuse by athletes*, Haematologica January 2003 88: 1053-1062 ('In addition to inter-individual variability, factors such as ethnicity, type of sport and residence at altitude also influence blood model scores. ... it would seem judicious for antidoping agencies to seek information concerning recent altitude exposure before instigating any consequences for an athlete with elevated OFF model scores').

<sup>86</sup> Parisotto, Gore, Emslie, Ashenden et al, *A novel method utilizing markers of altered erythropoiesis for the detection of recombinant human erythropoietin abuse in athletes*, Haematologica, 2000; 85:564-572 ('hemoconcentration could cause false positives by artificially elevating blood markers such as sTfr and Hct. Hemoconcentration can be caused by dehydration associated with prolonged exercise or by posturally-induced shifts in plasma volume, and may be in the order of 10-20%').

Ashenden, *A strategy to deter blood doping in sport*, Haematologica March 2002 87(3): 225-232, at 227-28 ('Altitude/training/genetic factors may also be associated with a transient increase in erythropoiesis (albeit of a much smaller magnitude) which might lead to mistakenly accusing an athlete when no drug was taken').

<sup>88</sup> The exception is that, from 2007 on, the IAAF Blood Testing Protocol required the testers to get from the athlete the 'time and description of last exercise' before sample collection.

<sup>89</sup> WADA ABP Protocol, pp.25-26.

<sup>90</sup> See e.g. Sawka et al, *Blood volume: importance and adaptations to exercise training, environmental stresses, and trauma/sickness*, Med Sci Sports Exerc 2000:32;332-48; Parisotto, Gore, Emslie, Ashenden et al, *A novel method utilizing markers of altered erythropoiesis for the detection of recombinant human erythropoietin abuse in athletes*, Haematologica, 2000; 85:564-572 ('hemoconcentration could cause false positives by artificially elevating blood markers such as sTfr and Hct. Hemoconcentration can be caused by dehydration associated with prolonged exercise or by posturally-induced shifts in plasma volume, and may be in the order of 10-20%'); Schumacher et al, *Diurnal and exercise-related variability of haemoglobin and reticulocytes in athletes*, In J Sports Med 2010;31;225-30 ('The most relevant confounder is physical exercise, which significantly increased Hb. This increase can be explained by exercise induced plasma volume concentration. Many previous

investigations have highlighted this issue. The data of our investigation demonstrates that Hb returns to values around pre-exercise baseline within approximately 2h after the cessation of physical activity'). In short, red cells (which are 95% haemoglobin) normally make up 45% of the total blood volume. Plasma (a water, sugar, fat, protein and salt solution) makes up about 55% of the total blood volume. During prolonged exercise, plasma volume can decrease by 10-20%, for several reasons. In particular, contraction of muscles as well as higher blood pressure in the arteries forces plasma out of the capillary vessels and into the tissues. In addition, much of the water and electrolytes within the plasma is lost through the pores as sweat. That reduction in plasma automatically increases the concentration of haemoglobin in the blood, even though no extra red blood cells have been produced.

91 Parisotto R, Ashenden MJ, et al, The effect of common hematologic abnormalities on the ability of blood models to detect erythropoietin abuse by athletes, Haematologica. 2003 Aug;88(8):931-40 ('it is conceivable that the hematologic disturbances associated with blood disorders may give rise to elevated model scores, which could be mistakenly interpreted as evidence that an individual had used rHuEPO') and ('because the parameters included in our models are not a sufficient foundation for establishing the presence of a hematologic abnormality, in the event of a blood profile exceeding a cut-off score, medical evaluation and subsequent classification of a hematologic disorder by a hematologist should constitute persuasive evidence that the unusual blood profile was not caused by rHuEPO use'); C. Gore, R. Parisotto, MJ Ashenden, et al, Secondgeneration blood tests to detect erythropoietin abuse by athletes, Journal of Hematology, vol. 88(03), March 2003, p.343 ('In response to the unusual score, the federation might seek a genetic/environmental explanation. In the absence of mitigating circumstances explaining why the athlete possessed a blood profile typical of recent/discontinued blood doping, the athlete should at least be requested to participate in a medical evaluation to ascertain the basis of their abnormal score. This follow up may detect an undiagnosed medical condition (although it should be noted that the hematologic milieu of increased Hb together with abnormally low reticulocyte and EPO levels has not been ascribed to any known pathological abnormality in the literature), or provide the federation with additional data to help recognize the probable reason for the elevated OFF model score'); K Sharpe, MJ Ashenden, YO Schumacher, A third generation approach to detect erythropoietin abuse in athletes, Haematologica January 2006 91: 356-363 ('For an athlete who provides a blood sample showing suspicious changes from historical values, a subsequent step may be to conduct an in-depth hematologic evaluation to identify any congenital or acquired hematologic disorders. We support the notion presented by Malcovati et al whereby a careful hematologic evaluation is undertaken, consisting of at least a blood cell count and iron status evaluation. The addition of more extensive testing proposed by Malcovati, including bilirubin, lactate dehydrogenase, serum iron, total iron binding capacity, serum ferritin, soluble transferrin receptor and serum erythropoietin levels, is in our opinion a logical and well-founded extension of this evaluation'). See also McLaren, Athlete Biological Passport: The Juridical Viewpoint [2012] I.S.L.R., Issue 4, p.21 (noting that in ABP cases it is 'crucial to understand how medical conditions can affect blood markers') and p.89 ('Fluid loss from extensive bleeding or digestive conditions has been suggested to cause abnormal blood values. [...] A loss of fluid results in dehydration, a decrease in plasma volume and consequently an increase in the level of all concentration-based markers in blood markers, including haemoglobin').

<sup>92</sup> WADA ABP Protocol, Version 5.0, September 2014, Appendix E, sections 6 and 7. See McLaren, *Athlete Biological Passport: The Juridical Viewpoint*, [2012] ISLR Issue 4, p.77 at section VI(v) ('the initial analysis performed when the profile is anonymous differs from the analysis conducted after the athlete is given the opportunity to explain the abnormalities. The initial analysis is focused on quantitative and statistical analysis of the results and the probability of the abnormality. After the athlete presents additional information, including potential medical explanations, the analysis is qualitative and focuses on the evaluation of realistic causes of the abnormality'). See also ibid, p.77 at section (vi) ('The panel of experts therefore plays a crucial role in evaluating the profile to eventually deciding whether or not the athlete has doped. ... Their task is to consider whether there is an explanation other than blood doping for the values recorded in the athlete's profile. The experts will also try to determine which doping scenario the athlete engaged in').

<sup>93</sup> Coccia, *The Athlete Biological Passport: Legal And Scientific Aspects* [2013] I.S.L.R., Issue 1, p.17; <u>UK Anti-Doping v Tiernan-Lock</u>e, National Anti-Doping Panel decision dated 15 July 2014 (<u>http://www.ukad.org.uk/anti-doping-rule-violations/download-decision/a/6605</u>), para 34 and para 49.

In June 2009, Mr Parisotto noted: 'Because this [the ABP] is such a shift, the UCI has to cross every t and dot every i. Even with direct drug testing, there are all sorts of legal loopholes that the athlete will try to take advantage of. So with this test you have got to be even more circumspect and be absolutely water-tight with your evidence' (<u>http://www.cyclingnews.com/features/anti-doping-expert-parisotto-speaks-on-blood-passport/</u>).

<sup>94</sup> Seb Coe faces grilling by MPs over dopers, The Sunday Times, 9 August 2015.

<sup>95</sup> Ashenden/Parisotto joint statement, 5 August 2015. This echoed The Sunday Times' claim on 2 August 2015 that Dr Ashenden and Mr Parisotto 'flagged up many athletes who were "likely" to have doped and should have faced a potential ban as they were able to rule out all other factors. Others were classified as "suspicious" requiring further investigation. They found that doping had become so widespread that 146 medals fell into these two categories, including 55 golds': *Revealed: sport's dirtiest secret*, The Sunday Times, 2 August 2015, p.1. 'When the experts were able to exclude other possible causes, they could confidently say that blood-doping was more likely than any other factor. They marked these athletes' scores as red on the database. However, if the score was suspicious but there was a possibility that the doping [*sic*] could be caused by another factor and further investigation was required, the experts marked that in yellow. The judgments ... followed the model of the athletes' "biological passport": *How the data was checked*, The Sunday Times, 2 August 2015, p.13.

<sup>96</sup> Letter from Dr Ashenden to Thomas Capdevielle of the IAAF dated 11 October 2015 (saying that a question asking how he and Mr Parisotto could have followed the procedures mandated in the WADA ABP Protocol for exclusion of potential confounding facts was moot because they only 'came to an "Initial View" as to whether the profile was likely due to blood doping'). In that letter, Dr Ashenden says he did not have to follow the necessary procedures for excluding other potential explanations for the abnormal deviations he saw in some athletes' profiles, because he was not charging athletes with blood doping, but was merely replicating the <u>initial</u> expert analysis of those profiles that would be conducted under the WADA ABP Protocol, which 'does not entail nor require the same level of evaluation as would "charging" an athlete'.

<sup>97</sup> In fact, they also knew the names of the athletes whose data they were reviewing. That information would <u>not</u> be made available to the experts reviewing an ABP profile under the WADA ABP Protocol, in order to avoid undermining the objectivity of their analysis of the data. Because they had the names of the athletes, the analysis conducted by Dr Ashenden and Mr Parisotto was not objective.

<sup>98</sup> Letter from Dr Ashenden to Thomas Capdevielle of the IAAF dated 11 October 2015.

<sup>99</sup> *A dozen top British athletes have recorded abnormal blood scores,* The Sunday Times, 2 August 2015, p.12.

<sup>100</sup> ARD, WDR Sport Inside, broadcast 7 September 2015 (<u>youtube.com/watch?v=sNQSxBoYCM0</u>).

<sup>101</sup> Mr Jesse Norman, Chair, Culture, Media and Sport Committee, SC Tr. p.38, Q131.

<sup>102</sup> Statement of Paula Radcliffe following the Culture Media and Sport Committee Hearing of 8 September 2015 regarding the Sunday Times' allegations concerning blood data. 8 September 2015 (<u>http://www.paularadcliffe.com/statement-september-2015/</u>). In her statement, Ms Radcliffe said: 'Their experts [i.e., Dr Ashenden and Mr Parisotto] gave their assessment of what they say "may" have led to abnormalities in my data. However, they did so without any knowledge of context, of personal circumstances, and of any other facts; all of which would be, and in fact were, available to the multiple experts who examined my data at the time and more recently. The consideration and indeed necessity of that type of extrinsic information is paramount for all proper evaluation and interpretation of test data. Sadly, in my case the Sunday Times' experts failed appallingly'. The IAAF agrees.

<sup>103</sup> WADA ABP Protocol, Appendix E, p.44. See also <u>UKAD v Tiernan-Lock</u>e, National Anti-Doping Panel decision dated 15 July 2014 (<u>http://www.ukad.org.uk/anti-doping-rule-violations/current-violations/search/P20</u>), para 45 ('the experts are only permitted under the WADA operating guidelines to take

into account results obtained from analyses conducted under the ABP programme, which comply with strict criteria').

<sup>104</sup> Schumacher et al, *Reticulocytes in athletes: Longitudinal aspects and the influence of long-and shortterm exercise*, Drug Testing and Analysis, 2010 Oct;2(10):469-74, doi: 10.1002/dta.180; Lombardi et al, *Reticulocytes in Sports Medicine: An Update*, Advances in Clinical Chemistry, Volume 59, dx.doi.org/10.1016/B978-0-12-405211-6.00005-X, p.139

<sup>105</sup> Shadow over the London Marathon, The Sunday Times, 9 August 2015.

<sup>106</sup> See also <u>https://www.wada-ama.org/en/media/news/2015-08/statement-regarding-extended-mandate-of-independent-commission</u>, 14 August 2015.

<sup>107</sup> 2015 World Anti-Doping Code, Article 3.2.

<sup>108</sup> See 2009 World Anti-Doping Code, comment to Article 3.2 ('an Anti-Doping Organization may establish an anti-doping rule violation under Article 2.2 ... based on ... conclusions drawn from the profile of a series of the Athlete's blood or urine Samples'). Similarly, Article 6.2 of the 2009 Code stated that samples 'shall be analyzed to detect Prohibited Substances and Prohibited Methods ... or to assist an Anti-Doping Organization in profiling relevant parameters in an Athlete's urine, blood or other matrix ... for anti-doping purposes'. In contrast, the 2003 World Anti-Doping Code made no mention whatsoever of longitudinal profiling. The IAAF's anti-doping rules and regulations followed the Code in these respects, and therefore it was not until 2009 that they said that blood samples could be collected 'for the measurement of individual Athlete blood parameters within the framework of the Athlete Biological Passport' and that 'Athlete blood profile information may further or alternatively be used as evidence in support of an anti-doping rule violation under Rule 32.2'.

<sup>109</sup> Ashenden written evidence to Culture, Media and Sport Committee, September 2015, para 53. See also para 4.7, above.

<sup>110</sup> Ashenden written evidence to Culture, Media and Sport Committee, September 2015, para 58.

<sup>111</sup> Decision by hearing panel convened by the Hellenic Amateur Athletics Federation (SEGAS) dated 24 January 2012 in the matter of Irini Kokkinariou.

<sup>112</sup> <u>IAAF v SEGAS and Kokkinariou</u>, CAS 2012/A/2773, award dated 30 November 2012 (<u>http://jurisprudence.tas-cas.org/sites/CaseLaw/Shared%20Documents/2773.pdf</u>), para 132.

<sup>113</sup> <u>IAAF v SEGAS and Kokkinariou</u>, CAS 2012/A/2773, award dated 30 November 2012 (<u>http://jurisprudence.tas-cas.org/sites/CaseLaw/Shared%20Documents/2773.pdf</u>), para 23.

<sup>114</sup> <u>IAAF v SEGAS and Kokkinariou</u>, CAS 2012/A/2773, award dated 30 November 2012 (<u>http://jurisprudence.tas-cas.org/sites/CaseLaw/Shared%20Documents/2773.pdf</u>), paras 71-72, 125.

Similarly, in <u>IAAF v Yegerova et al</u>, 2008/A/1718-1724, award dated 18 November 2009 (<u>http://www.doping.nl/media/kb/680/CAS%202008 A 1718%20IAAF%20vs%20All%20Russia%20Athletic%20F</u> ederation%20%26%20Olga%20Yegorova%20(S).pdf), the IAAF argued that the Russian athletes' pre-2009 blood tests had produced 'suspicious results which were consistent with the use of rh-EPO or other forms of blood doping', which 'circumstantial evidence' provided a motive for the athletes to provide someone else's urine samples to the drug testers. Ibid paras 152, 184.

<sup>115</sup> USADA v Montgomery, CAS 2004/O/645, award dated 13 December 2005, para 43(4).

<sup>116</sup> *Chase dopers, Seb, like you chased gold*, The Sunday Times, 9 August 2015.

<sup>117</sup> USADA v Montgomery, CAS 2004/O/645, award dated 13 December 2005, paras 7, 45.

<sup>118</sup> <u>Gusev v Olympus SARL</u>, CAS 2008/O/1643, award dated 15 June 2009 (<u>http://www.centrostudisport.it/PDF/TAS CAS ULTIMO/68.pdf</u>), paras 43-44, 84, 92-93, 122.

<sup>119</sup> <u>UCI v Contador & RFEC</u>, CAS 2011/A/2384, award dated 6 February 2012 (<u>http://jurisprudence.tas-cas.org/sites/CaseLaw/Shared%20Documents/2384,%202386.pdf</u>), paras 367-69.

<sup>120</sup> <u>Pechstein, DESG v ISU</u>, CAS 2009/A/1912-1913, award dated 25 November 2009 (<u>http://sottas.info/Index/FINAL%20AWARD%20PECHSTEIN.pdf</u>), paras 152-158, 164.

<sup>121</sup> Ashenden written evidence to Culture, Media and Sport Committee, September 2015, para 59. It was also presumably the case brought by the ISU in <u>Pechstein</u> that Dr Ashenden was referring to in his oral evidence when he told the Parliamentary Culture, Media and Sport Committee that 'other federations have used blood data [collected] before 2009 to impose a sanction' (Ashenden oral evidence to Culture, Media and Sport Committee, CMSC Tr.p.7, answer to Q20).

<sup>122</sup> <u>Pechstein, DESG v ISU</u>, CAS 2009/A/1912-1913, award dated 25 November 2009 (<u>http://sottas.info/Index/FINAL%20AWARD%20PECHSTEIN.pdf</u>), paras 108-109, p.63.

<sup>123</sup> <u>Pechstein, DESG v ISU</u>, CAS 2009/A/1912-1913, award dated 25 November 2009 (<u>http://sottas.info/Index/FINAL%20AWARD%20PECHSTEIN.pdf</u>), paras 152-158, 164.

<sup>124</sup> The most recent decision in this long-running legal saga was issued by the Higher Regional Court of Munich (OLG Munchen-U1110/14 Kart) on 15 January 2015, which decision (reported in Schieds VZ 2015, 40 et seq, in German) is currently under appeal by the ISU to the German Supreme Court. Dr Ashenden's assertion that 'as recently as March 2015 the CAS robustly defended the merit of its decision and argued against the case being reheard by the Appeals Court of Munich/Germany' (Ashenden written evidence to Culture, Media and Sport Committee, para 63) is wholly disingenuous. The CAS statement he refers to (dated 27 March 2015, http://www.tas-cas.org/fileadmin/user upload/CAS statement ENGLISH.pdf) addresses only the argument that it was a breach of competition law for a sports body to require its athletes to submit to arbitration before CAS because the CAS rules did not sufficiently guarantee the independence of the CAS panels appointed to hear and determine cases brought before it. If that argument is wrong (as the CAS insists), then the merits of the particular dispute resolved by the CAS award at hand are irrelevant. Presumably for that reason, the CAS statement did not address the merits of the decision in <u>Pechstein</u> in any way.

<sup>125</sup> Ashenden written evidence to Culture, Media and Sport Committee, September 2015, para 68.

<sup>126</sup> See Zorzoli M., *Biological passport parameters*, J. Hum. Sport Exerc. Vol. 6, No. 2, pp.205-217 (2011) at p.206 ('Because rhEPO could not be yet detected, in order to dissuade athletes from using rhEPO, some International Federations ... introduced the so called "no start rule"); Sottas et al, *The Athlete's Biological Passport and Indirect Markers of Blood Doping*, in Doping in Sports (Springer 2010, Thieme and Hemmersbach eds), p. 307 ('the official objective of the introduction of the haematocrit rule in 1997 was to protect the health of athletes. In practice, however, it is evident that this rule was a deterrent to the abuse of rHuEPO which was undetectable by direct means at the time').

<sup>127</sup> Ashenden, A strategy to deter blood doping in sport, Haematologica, March 2002 87(3): 225-232, at p.227 ('The concept of an arbitrary limit as incorporated by the Hematocrit rule has since attracted criticism because a significant proportion of athletes (up to 5%) may exceed the threshold because of genetic factors and be unfairly banned from competition. It may also permit athletes to titrate their Hb/Hct to approach but not exceed the limits adopted by their sport, or to expand plasma volume and thus remain below allowable limits'). See also Jelkmann W and Lundby C, *Blood doping and its detection*, Blood, 1 September 2011, Vol 118(9), 2395-2404 ('However, Hb and Hct are influenced by external factors, such as body posture, exercise or residence at altitude. In addition, "clean" athletes can have naturally high Hb and Hct values. ... In addition, ... the adoption of upper Hb and Hct limits may paradoxically generate more blood doping because, by ESA misuse, Hb and Hct can be manipulated with the aim of approaching the target value without exceeding it'); McLaren, *Athlete Biological Passport: The Juridical Viewpoint*, [2012] ISLR Issue 4, p.5, and ibid. at footnote 20 ('The CAS

jurisprudence demonstrates the test can have an unfair effect on competitors. If the excluded athlete's qualifier or competition arises within two days of the test they will be unable to compete whereas others who compete on a later day will retain their competition rights').

In his open letter to Lord Coe (Ashenden, *Chase dopers, Seb, like you chased gold*, The Sunday Times, 9 August 2015), Dr Ashenden could not deny that a 'no start' rule risked excluding innocent athletes from competition. Bizarrely, his answer was to argue that if the IAAF suspended the Russian federation for doping failures (as he has advocated), that would exclude even more innocent athletes from competition.

<sup>128</sup> Sharpe, Hopkins, Emslie, Howe, Trout, Kazlauskas, Ashenden, Gore, Parisotto, Hahn, *Development of reference ranges for markers of altered erythropoiesis*, Haematologica, 2002; 87:1248-1257, at 1255.

<sup>129</sup> 2015 World Anti-Doping Code, Articles 7.9 and 3.1.

<sup>130</sup> Sottas et al, *The Athlete's Biological Passport and Indirect Markers of Blood Doping*, in Doping in Sports (Springer 2010, Thieme and Hemmersbach eds), p.323.