

BEFORE A FOOTBALL ASSOCIATION REGULATORY COMMISSION

B E T W E E N:

THE FOOTBALL ASSOCIATION

-and-

MR ALAN JUDGE

Written Reasons of the Regulatory Commission

David Casement QC (Chairman)

Keith Allen

Gareth Farrelly

Charge

1. By charge letter dated 23 December 2015 The Football Association (“The FA”) charged Alan Judge (“the Player”) with a breach of Rule E1(b) of the The FA Rules. The Player provided a urine sample on 15 August 2015 following the Bristol City FC v Brentford FC match. It is alleged in the charge letter that the Player’s sample tested positive for salbutamol, at a concentration measured to be 1,600 ng/ml. Salbutamol, when found at a concentration in excess of 1,000 ng/ml, is a Prohibited Substance listed in S3 (Beta 2 – agonists) of Schedule 3 of the FA Anti-Doping Regulations unless the Player can prove, on the balance of probabilities, that it was the result of having inhaled no more than 1600 µg for therapeutic purposes in the 24 hour period prior to the Sample being provided.. At the level alleged to have been detected it was contended in the charge letter that the presumption under the Regulations is that the substance was not

intended for therapeutic use. The FA Anti-Doping Regulations are in accordance with the 2015 Prohibited List under the World Anti-Doping Code.

2. The charge letter amongst other things included the test report and accompanying documentation, correspondence with the Player, a report of the Controlled Pharmacokinetic Study (“the Study”) dated 9 November 2015, a research article by Haase and others (“the Research Paper”) which was produced in 2015 and also a witness statement from Professor David Cowan dated 22 December 2015.
3. The Player plays for Brentford FC and is now 27 years of age. It was common ground throughout these proceedings that the Player has suffered from Asthma since he was a child and has been using an inhaler throughout that period.
4. The main point in issue in these proceedings was whether the Player could prove on the balance of probabilities, pursuant to Rule 27 of The FA Rules (page 233), by way of a pharmacokinetic study, that the presence of salbutamol in his urine at a concentration of over 1,000 ng/ml was the consequence of a therapeutic inhaled dose of no more than 1,600µg taken over the 24 hour period prior to the sample being provided.
5. The Player’s B sample was tested pursuant to his request and by letter dated 29 September 2015 The FA notified the Player that the B sample also disclosed the presence of salbutamol at a concentration above the allowed threshold. The Study took place on 4 November 2015. The Player provided responses to The FA on 10 September 2015, 9 October 2015 and 21 October 2015 the contents of which were the subject of examination at the final hearing together with the evidence of both experts.

6. The conclusion reached by the Commission was that the Player had failed to discharge his burden of proof on the balance of probabilities, pursuant to Rule 27 of The FA Rules (page 233) . In short he was not able to prove on the balance of probabilities that the concentration of salbutamol in his sample was a result of his taking a therapeutic dose of no more than 1,600µg in the 24 hour period prior to the sample being provided as outlined in The FA Rules in accordance with the 2015 Prohibited List World Anti-Doping Code. The circumstances were such that the Commission found there to be No Significant Fault or Negligence and as a result of that no period of ineligibility was imposed. The Player was given a warning and a reprimand and was also ordered to pay the costs of the proceedings. In addition the Player will be the subject of target testing for two years. The decision was notified to the Player on the day. This document constitutes the written reasons of the Commission for that decision.

Procedure

7. This matter came on for final hearing at Wembley on 25 May 2016. Apart from the Commission those attending the hearing were as follows:

Alan Judge

Nick de Marco – barrister (Blackstone Chambers)

Isabel Buchanan –pupil barrister (Blackstone Chambers)

Edward Canty – solicitor (Centrefield LLP)

Deirdre McCarthy – solicitor (Centrefield LLP)

Professor Hochhaus – Expert Witness (by videolink)

Nick Cussack – PFA Representative

Lisa Hall – Brentford FC Club Secretary

Phil Giles – Brentford Co-Director of Football

Dr Matt Stride – Brentford Club Doctor

Tom Flavin – Advocate for The FA

Rob Henderson – The FA Anti-Doping Manager

Joel Wallace – FA Legal Administrator

Professor David Cowan – Expert Witness

Paul Ousely – UKAD Results Manager

Paddy McCormack - Judicial Services Manager

8. This matter has taken longer to be listed for final hearing than would normally be the case as a result of the need to allow for further time for the experts in the case to provide reports. In the event, the matter was fully fought out in respect of the expert evidence as well as the evidence of fact.
9. The Study was carried out by Professor Cowan of Kings College, London on 4 November 2015. When the report in respect of the Study was provided to the Player Professor Cowan also provided a copy of the Research Paper. The Research Paper provided evidence in respect of recent analysis and presentation of results from pharmacokinetic studies and the potential impact of dehydration, exercise and rest on the results. The conclusion of the research paper was that it was possible that concentrations of salbutamol may be found in a sample substantially above the limit of 1000 ng/ml even when the athlete took no more than the maximum permissible amount of 1,600µg over the 24 hour period prior to the sample being provided.
10. It was entirely proper for Professor Cowan to provide the Research Paper to the Player as it was potentially of use to the Player and his representatives as they addressed the charges brought by The FA. As a result of the Research Paper there appears to have been further consideration of the matter between The FA and Professor Cowan. Professor Cowan produced a witness statement on 11 December 2015 addressing the Research Paper and concluding that, on balance, the data provided in the Study was “more consistent with the Player having

administered a dose of salbutamol greater than the WADA permitted maximum of 1600 micrograms per day.” This was further supported by an email from Professor Cowan dated 16 December 2015 in which he addressed questions put by The FA. The Player lodged detailed submissions on 9 February 2016 drafted by Mr De Marco along with an expert report from Professor Hochhaus dated 2 February 2016 concluding that “the Pharmacokinetic Study Results, when properly adjusted for, indicated that the salbutamol concentrations in the Player’s 15th of August urine samples can be explained by high (1,600µg), but therapeutic doses of salbutamol.”

11. The Player also lodged two witness statements of his own, one witness statement from his mother Ann Judge and also a letter from Dr Stride who is the Club doctor. The Player took the opportunity to place his medical records before the Commission and these were also considered in examination during the hearing.
12. The FA served a witness statement from Professor Cowan dated 10 March 2016 and the Player responded with the second of his witness statements, a further letter from Dr Stride, a copy of his prescription and a second report from Professor Hochhaus.
13. Further to the directions of the Chairman, David Casement QC, the parties served further skeleton arguments so as address the most recent evidence: the Player’s further skeleton argument (13 May 2016), The FA skeleton argument in response (19 May 2016) and the Player’s skeleton argument in reply (23 May 2016).

Relevant Regulations

14. The relevant regulations are as follows:

Regulation 3, which concerns *“Presence of a Prohibited Substance or its Metabolites or Markers in a Player’s Sample”*:

“(a) The presence of a Prohibited Substance ... in a Sample provided by a Player is prohibited unless the Player establishes that the presence is consistent with a Therapeutic Use Exemption that has been granted to the Player.

(b) Sufficient proof that an Anti-Doping Rule Violation has been committed pursuant to Regulation 3 is established ... where the Player’s “B” Sample is analysed and the analysis confirms the presence of the Prohibited Substance or its Metabolites or Markers found in the Player’s “A” Sample...

(c) It is a Player’s duty to ensure that no Prohibited Substance enters his body, and a Player is therefore strictly responsible for any Prohibited Substance or its Metabolites or Markers found to be present there. It is not necessary that intent, fault, negligence or knowing Use on the Player’s part be demonstrated in order to establish an Anti-Doping Rule Violation pursuant to Regulation 3. A Player’s lack of intent, Fault, negligence or knowledge is not a valid defence to a charge that an Anti-Doping Rule Violation has been committed pursuant to Regulation 3.

(d) Subject to Regulation 3(e), the presence of any quantity of a Prohibited Substances or its Metabolites or Markers in a Player’s Sample will constitute an Anti-Doping Rule Violation.

(e) The Prohibited List may make special provision for substances which have a quantitative reporting threshold and/or which can be produced endogenously.”

Schedule 3 of the Regulations incorporates the WADA 2015 Prohibited List. Section S3 (*“Beta-2 Agonists”*) states:

“All beta-2 agonists...are prohibited.

Except:

- *Inhaled salbutamol (maximum 1600 micrograms over 24 hours);*

...

The presence in urine of salbutamol in excess of 1000 ng/mL...is presumed not to be an intended therapeutic use of the substance and will be considered as an Adverse Analytic Finding (AAF) unless the Athlete proves, through a controlled pharmacokinetic study, that the abnormal result was the consequence of the use of the therapeutic inhaled dose up to the maximum indicated above."

15. Inhaled salbutamol is therefore not always a Prohibited Substance, and it is not necessary for athletes to have a Therapeutic Use Exemption to use it. Presence of salbutamol in concentrations below 1,000ng/ml is presumed to reflect permitted therapeutic use, and it is open to an athlete to show that a higher concentration likewise resulted from therapeutic inhalation of no more than 1,600µg in the 24 hour period prior to the sample being given.

16. It is common ground that the onus is on the Player to show that the concentration in the Sample was a consequence of permitted therapeutic use. As to the standard of proof, Regulation 27 provides:

"27. Where these Anti-Doping Regulations place the burden of proof on a Participant to rebut a presumption or establish specific facts or circumstances the standard of proof shall be on the balance of probabilities."

17. Regulation 66 provides that if a person establishes that he bears "No Fault or Negligence" for an ADRV, "any otherwise applicable period of suspension shall be eliminated".

18. Regulation 67 provides for a reduction in sanction based on “No Significant Fault or Negligence” in cases involving a “Specified Substance”, such as salbutamol:

“67. Where the Anti-Doping Rule Violation involves a Specified Substance, and the Participant can establish that he bears No Significant Fault or Negligence for that violation, then the penalty shall be (at a minimum) a reprimand and no period of suspension, and (at a maximum) two years’ suspension, depending on the Participant’s degree of Fault.”

19. The current Regulations reflect a refashioning of the Rules:
- a. Previously, cases involving “Specified Substances” were generally dealt with via separate provisions. These provisions enabled Commissions to reduce or eliminate any period of ineligibility, based on a player’s degree of fault, if the player established (i) that the ADRV involved a “Specified Substance”; (ii) how the “Specified Substance” entered his body; and (iii) that there was no intention to enhance performance or mask a performance-enhancing substance.
 - b. These previous provisions are now subsumed into No Fault or Negligence/No Significant Fault or Negligence.
 - c. Regulation 67 (No Significant Fault or Negligence) provides the Commission with a wider measure of discretion than it previously had for such cases. It allows for the elimination of any period of ineligibility for an ADRV involving a “Specified Substance”, providing a player establishes NSFN, and NSFN is no longer confined to “exceptional circumstances”.
20. The changes reflect the amendments which WADA made to the World Anti-Doping Code with effect from 1 January 2015. WADA has stated that the aim of the changes is to “provide for longer periods of

Ineligibility for real cheats, and more flexibility in sanctioning in other specific circumstances”

Evidence

21. The starting point in respect of the evidence is that of the Player himself. He gave two accounts in the correspondence that he provided to The FA after receipt of the charge letter dated 9 September. In his letter dated 10 September he contended as follows:
- “I was diagnosed with Asthma as a child and have had previous hospital admissions for Asthma attacks. In light of this I have been further tested for exercise-induced Asthma both at Blackburn Rovers and Notts County. This has also resulted, when it was relevant, in the application and use of a TUE. I have been medically advised to take two puffs of the Ventolin inhaler before training and matches to reduce the effects of this condition. This has been regular usage since I have been a professional. In the circumstances of this test I wish to clarify my use of Ventolin inhaler. As I recall the preceding week, which was particularly warm and humid, I noticed more chest tightness than usual when training. This was exacerbated by high pollen count and I recall having to take antihistamines. The following was my usage of my Ventolin inhaler; Friday, 14th two puffs of (100 mcg) Ventolin before training around 10am. Saturday 15th I had two puffs before warm up around 2pm, I felt quite tight chested and took another two puffs at 2.55pm and a further two puffs at half time...”
22. Therefore the account on 10 September 2015 was that the Player took 4 puffs of 100 mcg each within the 24 hours prior to the Sample being provided. The Sample was provided after 5.05pm on 15 August. If that were accurate the question for the final hearing would have been whether the 400 µg produced the level of concentration found in the Sample namely 1600 ng/ml.

23. However the position changed in the Player's letter of 9 October 2015. The Player stated "... I think I would have used my inhaler more frequently than usual during the week in the run up to the match. When I use my inhaler I normally take two puffs at a time as I recall from when I was a child that is what my doctor said to take around four times a day if needed. However I do not always count how many puffs I take at any one time, especially if I am using my inhaler when I am in a rush on match day, whether before kick off or in the dressing room at half-time. I just use my inhaler as needed in order to get by breathing level back to normal as I was told by my doctor to do whenever I experience shortness of breath."
24. After being pressed further by The FA as to how much salbutamol he had taken prior to the Sample, the Player stated in his letter of 21 October 2015 that he could not be certain how many puffs he had taken but "What I can say, as you have asked for a maximum, is that I do not think I would have taken more than 20-25 puffs of my inhaler in the 24 hours prior to the test, and I expect I would have taken less than this, but more than 2-3 puffs. I am afraid I cannot be more certain than this."
25. The obvious point about this evidence is that 20-25 puffs of the inhaler with each puff representing 100µg of salbutamol would create an upper limit on the Player's own case of 2000 to 2500µg. That is well above the limit of 1600 µg in the 24 hour period. That is highly significant because it is the Player that carries the burden of proof, on the balance of probabilities, to prove that he took no more than 1600 µg in that period. In the Player's witness evidence and oral testimony he did not provide any better account and certainly did not say that the upper limit of what he might have taken was any lower than the limits he set out in his letter of 21 October.
26. The evidence of the Player and also that of Dr Stride gave an account of the Player and also the Club's approach to salbutamol when taken to treat Asthma. There appeared to be a serious lack of understanding, prior to

the date of the notification of the Adverse Analytical Finding, that the amount of salbutamol that could be taken even for therapeutic purposes was limited under the Regulations to an amount not exceeding 1600µg in the previous 24 hour period. Dr Stride gave evidence that he prescribed and dispensed inhalers to the players who suffered from Asthma but did not explain the restrictions on its use as far as the Regulations were concerned. In his evidence Dr Stride told the Commission "At no point did I tell the player if you take more than 16 puffs you will be in excess of the WADA limit. Even though that may mean they are committing an ADRV if they do." Dr Stride gave evidence that the system at the Club had now changed and now players are warned both in writing and verbally as to the limits for salbutamol under the Regulations.

27. The expert evidence adduced by the parties took up most of the time available for the final hearing. These written reasons reflect the expert evidence only to the extent necessary. The Commission considered all of the evidence provided both in terms of the written reports and also the oral evidence during the hearing. Professor Cowan is a most experienced expert who has conducted many pharmacokinetic studies and presented their findings in reports. He was challenged in cross-examination by Mr De Marco in respect of the Study as well as his subsequent reports and witness statement. It was put to him that he had presupposed an inappropriately low level of Salbutamol for the purposes of the Study, namely 400µg when in fact the maximum permissible was 1600µg. His account of why he used a lower figure was that he considered that there was no proper basis for assuming 1600µg when 1200µg was the normal intake. With a calculation of 1200µg the Study provided for a level of salbutamol in a sample of 920 ng/ml. This was well below that found in the Sample in question which was 1600 ng/ml. In fairness, Professor Cowan had not been provided with the information given by the Player in his letter of 21 October and it was unclear why that had not been provided. Further, Professor Cowan was challenged as to why he had not, at the outset engaged with the finding of the Research Paper which

showed that those who undertook strenuous exercise prior to providing the Sample (whether dehydrated or not) showed substantially higher readings for salbutamol. It was contended by Mr De Marco that the report of Professor Hochhaus, on which he relied, showed that if the full limit is assumed (1600µg in the prior 24 hour period) and one looks at the potential effects of strenuous exercise it was possible to exceed the 1000 ng/ml limit and also to reach or exceed the levels recorded for the Player namely 1600 ng/ml.

28. Professor Cowan contended that he did engage with the findings of the Research Paper and also with the assumption of the maximum amount of 1600µg in the prior 24 hour period in his witness statement. He correctly noted that it was in fact he who drew everyone's attention to the Research Paper. He nonetheless maintained that on a proper interpretation of the Research Paper whilst it was possible to reach a level of 1600 ng/ml or more in a sample having taken 1600µg in the previous 24 hour period, it was unlikely.
29. Professor Hochhaus is Professor of Pharmaceutics at the University of Florida. His research focuses on the clinical pharmacology of anti-asthmatics including Beta - 2 adrenergics such as salbutamol. In his analysis of the Study taken alongside the findings in the Research Paper he found that if one assumed 1600µg had been taken in the prior hour period, and adjusted for the effects of exercise then after four hours the adjusted figures for the Study would have been either 2394 ng/ml or 1573 ng ml (Hochhaus Report 2 February 2016 para 33). The difference between the two figures provided by Professor Hochhaus was a result of whether one adjusted for urine specific gravity (USG). Professor Cowan and Professor Hochhaus disagreed as to whether an adjustment for USG was required at all and if so at what stage of the equation.
30. In the skeleton argument Mr De Marco set out notes to which Professor Hochhaus would speak in identifying three methods of considering the

data (a) one with no adjustment for USG (b) Method A which adjusted for USG but allowed an increase of 129% for the effect of exercise and (c) Method B allowed an adjustment for USG and for an increase of 240%. The percentages were drawn from different interpretations of the Research Paper findings. Even allowing for an averaging of Method A and Method B one ended up with an adjusted concentration of 1890 ng/ml, and therefore in excess of the Player's own Sample results but on the basis of a permissible 1600 µg of salbutamol being inhaled in the prior 24 hours.

31. The major point in dispute between the two experts came down to whether to allow for USG and also the extent of potential increase as a result of strenuous exercise.
32. Mr De Marco and Professor Hochhaus identified some very compelling points. It is clear that more research is required in this area as Professor Cowan was prepared to concede. The Research Paper appears to be the only significant analysis of the effects of exercise on the findings for salbutamol. The assertion that, for the purposes of analysis the full 1600 µg should have been assumed in the present case is a forceful one particularly bearing in mind the information provided by the Player prior to the Study. The effects of strenuous exercise appear to be borne out by the Research Paper. That there is an increased showing of concentration for salbutamol following strenuous exercise appears clear although it is much less clear what methodology should be adopted to determine the extent of that increase.
33. However in the end and after full debate between two experts who were both impressive and seeking to assist the Commission we do not find that the experts' views even taken at their highest assist the Player in discharging the burden of proof which rests upon him. Professor Hochhaus' evidence at its height is summed up in paragraph 14 of his second report: " Therefore my initial opinion remains that the highest

allowable dose of 1600µg should have been used in the Pharmacokinetic Study or at least should have been considered during the interpretation of the results when deciding whether the Player's urine concentration on the day of the test was due to therapeutic or non-therapeutic doses of salbutamol and that the Pharmacokinetic Study results, when properly adjusted, indicate that the salbutamol concentrations in the Player's urine sample of 15th August 2015 can be explained by high, but therapeutic doses of salbutamol."

34. Both experts therefore were in agreement that 1600µg of salbutamol consumed in the 24 hour period prior to the Sample being taken could have produced the concentration of 1600 ng/ml. When the debate between the experts had finished it was clear that their analysis did not show whether it was more likely than not that the Player had taken more than 1600µg in the prior 24 hour period.
35. In those circumstances the evidence of the Player is of crucial importance. The evidence of the Player as set out in his correspondence had been very damaging to his case. He admitted of a potential upper limit which could have been as high as 2500 µg, well above the permissible limit of 1600 µg. In the absence of any better evidence from the Player he failed to discharge his burden of proof. The fact that the Player gave evidence that at the time he was ignorant of what the limits were in respect of the use of salbutamol did not help his case because without such knowledge he was more likely to exceed the permissible amount. On that basis the Commission is clear and unanimous that the Player has committed an Anti-Doping Rule Violation.

Sanction

36. The FA have accepted throughout that the Player did not intend to enhance his performance. He did not seek to cheat by using salbutamol which he requires for his Asthma condition. Mr Flavin for The FA also

submitted that he was not suggesting that anything more than a warning and reprimand were appropriate in this case.

37. The Commission considers that this case has been brought about as a result of a lack of understanding on the part of the Player and the Club that there are strict limits on the extent to which salbutamol can be taken. This case should serve as a warning to all Clubs to address this issue and ensure that proper information and education is provided to Players. The Commission considers that the Player did not intend to enhance his performance through his use of salbutamol which he clearly highlighted at the time of the Sample and which is recorded on the relevant form.
38. This is not a case of No Fault or Negligence because the Player clearly could and should have done more to prevent the offence from occurring. However it is a case of No Significant Fault or Negligence and The FA agrees with that categorisation. Mr De Marco referred the Commission to a number of cases in which warnings and reprimands were given, including some where the excess amount of salbutamol taken was significantly more than in this case. These have included the case of The FA v Chey Dunkley (17 June 2015), UK Anti-Doping v Y (10 August 2011), UK Anti-Doping v X (6 August 2013) and WADA v Sibbit (RFL Anti-Doping Tribunal 9 February 2009). Again, The FA submitted that the sanction in this case should be in keeping with the sanction in those other cases. In the circumstances the Commission finds that a warning and reprimand are appropriate sanctions to reflect the degree of fault. The Player will also be the subject of target testing for a period of 2 years.

Conclusion

39. The Player has failed to discharge his burden of proof, namely to prove that the amount of Salbutamol taken in the 24 hour period prior to the Sample being given did not exceed 1600 µg. The Player has therefore

committed an Anti-Doping Rule Violation by reason of the presence of Salbutamol in his Sample above a concentration of 1000 ng/ml.

40. The Player is hereby given a warning and reprimand and will be the subject of target testing for a period of 2 years. The Player will pay £2000 as a contribution towards the costs of the Commission.
41. This decision may be appealed in accordance with the relevant regulations within The FA Rules.

David Casement QC (Chairman)

Keith Allen

Gareth Farrelly

8 June 2016