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### IN THE COURT OF ARBITRATION FOR SPORT

IN THE MATTER OF FLOYD LANDIS,

CAS 2007/A/1394

FLOYD LANDIS V. UNITED STATES ANTI-DOPING AGENCY

### **APPELLANT'S CLOSING BRIEF**

I.

### INTRODUCTION

This case should be about a search for the truth. Mr. Landis's defense has consistently attacked the many fundamental flaws in the methods and procedures of the Laboratorie National de Depistage et Dopage ("LNDD"), including its failure to use properly validated methodology, and the many deviations from the applicable International Standard for Laboratories and sound laboratory practice. As a scientific case, Mr. Landis' issues have remained the same as when they were presented in the AAA proceedings and its CAS briefs and declarations. This closing brief will not repeat these arguments, but focuses on the evidence introduced at the CAS hearing as it relates to those issues, which are:

- 1. LNDD failed to use an accredited or validated method to identify testosterone compounds when it conducted the Carbon Isotope Ratio test ("CIR") of Mr. Landis' Stage 17 samples. USADA did not prove that the method was reliable and cannot do so, given that USADA failed to even establish what method the LNDD staff used. Because USADA cannot establish what method of CIR analysis LNDD used and that it was reliable, this case must end. Even if this Panel concludes that USADA somehow established what method LNDD used to analyze Mr. Landis' sample, and has further established that this method was either accredited or otherwise reliable, Mr. Landis should prevail because he has proved that LNDD repeatedly failed to comply with the ISL when performing that analysis;
- 2. LNDD failed to validate its positivity criteria in violation of the ISL;
- 3. LNDD had no effective or appropriate quality controls in violation of the ISL;
- 4. The Isoprime1 was not linear;
- 5. LNDD's chromatography was poor in violation of the ISL and LNDD improperly manually processed IRMS test results;
- 6. LNDD failed to use the same column in the CIR test as required by its SOP;
- 7. LNDD failed to properly train and supervise its laboratory technicians;
- 8. LNDD failed to comply with the ISL when it deleted data;

- 9. LNDD failed to maintain chain of custody pursuant to the ISL and the WADA technical documents;
- 10. LNDD failed to comply with the ISL regarding laboratory documentation;
- 11. The reprocessing and retesting process does not constitute a waiver of Mr. Landis' claims on appeal;
- 12. Dr. DeBoer's attendance at the Sample B testing does not constitute a waiver of Mr. Landis' claims on appeal;
- 13. The total picture of LNDD's laboratory test results in this case are inconsistent with the known science on testosterone metabolism;
- 14. The presence and importance of fraudulent documents, bias, false statements, cover-up and witness credibility and,

#### 15. Sanctions

Altogether, these issues paint a cohesive picture that shows that for the testing of Sample 995474 and the other tests from the other stages of the 2006 Tour de France ("Tour"), numerous errors were committed that render the test results unreliable and of no evidentiary value. In order to focus on citation references, the format of this brief will be an expanded outline with citations to the critical points.<sup>1</sup>

This brief will primarily focus on the discussion of the critical issues and responding to USADA's evidence, and not repeating the testimony of Mr. Landis' experts or the arguments already contain his Opening Brief, all of which are incorporated here by reference.<sup>2</sup> In order to

The AAA hearing transcript is cited as "AAA Tr. Page:Line." The CAS hearing transcript is cited as "CAS Tr. Page: Line." The exhibits are cited by exhibit number. The pleadings and correspondence are cited by descriptive name (if they have no assigned exhibit number).

The scientific conclusions of Mr. Landis' IRMS experts were largely unchallenged on cross-examination, and Dr. Amory's conclusions were adequately addressed in his redirect testimony and cross-examination, and little time will be devoted here to repeating those conclusions.

understand the absurdity of USADA's current arguments in this appeal, it is critical to understand the context of the history of the arguments USADA has made in connection with this case. Many of the arguments USADA tried to defeat during this appeal were actually arguments that they presented in earlier discovery responses, briefs and testimony at the AAA proceeding. Three glaring examples, among others, include: (1) USADA and LNDD first contended that the internal standard was added to each sample as a quality control, and an assurance of excellent laboratory procedure; (2) USADA and LNDD contended that they identified peaks in the IRMS chromatograms by matching the retention times of the peaks with the retention times of the peaks in the GC/MS chromatograms; and (3) USADA and LNDD contended that chain of custody was complete and easy to determine from the documents. It was only after Mr. Landis established that these assertions were incorrect that USADA changed their story. During the CAS hearing, USADA spent considerable time trying to establish that these previous points are wrong or scientifically insignificant, while ascribing their genesis to Mr. Landis. In order to shift their stories in order to win at any cost, USADA and LNDD have argued against the plain meaning of the documents, apparently abandoned the assertion that all of the alleged positives are scientifically supported and have seen their witnesses contradict each other.

Most troublingly, Mr. Landis' search for the truth in this case has been obstructed – often with devastating results – by the presence of bias, inconsistent and false statements and fraudulent documents. When he identifies an error with the column, a witness magically appears to clear up the error, but the documents are fraudulent. When the AAA Panel notes that LNDD failed to monitor linearity in compliance with its SOP, a new linearity testing document magically appears to help repair the damage. These incidents are not the hallmarks of a search for the truth, but of a desire to win at all costs. The decision to include these arguments was not

made lightly and only after deliberation and careful analysis of the record. Much of this evidence went completely unanswered at the CAS hearing. The search for truth should end with the vindication of Mr. Landis, not the affirmation of a litany of bad lab practices and poor oversight.

II.

### BURDEN AND STANDARD OF PROOF

### A. The Burden of Proof

- 1. USADA bears the significant burden of "establishing that an anti-doping violation has occurred." WADA Code, Art. 3.1; UCI Anti-Doping Rules, Art. 16. There are three elements to USADA's case: method reliability, compliance with mandatory laboratory standards, and absence of causation.
- 2. USADA benefits from certain presumptions as to the first two of these elements if the method used by the LNDD was accredited by the national accreditation entity; in this case, COFRAC. WADA Code, Art. 3.2.1, 3.2.2; UCI Anti-Doping Rules, Art. 18; *Hamilton v. USADA*, CAS 2005/A/884, Paragraphs 50 and 52.
- 3. Method reliability. If USADA has established that the method actually used by the LNDD to analyze Mr. Landis's Stage 17 sample was, in fact, accredited by COFRAC, that method used will be presumed to have been a reliable one, and it will be presumed that the lab performed the method in compliance with the ISL (the "compliance" element). WADA Code, Art. 3.2.1; UCI Anti-Doping Rules, Art. 18; *Hamilton* at Paragraph 50. However, in order to be entitled to the Code's presumptions, USADA must establish to the comfortable satisfaction of the Panel that the Carbon Isotope Ratio test actually used by LNDD was an accredited method.
- 4. If USADA fails to establish that the CIR method actually used by LNDD was accredited by COFRAC, it loses the benefit of the presumption in Section 3.2.1, and must prove that the method was reliable. This is mandated by Article 3.2 of the WADA Code, which dictates that the anti-doping agency must establish the facts related to the anti-doping violation—in this case, the Adverse Analytical Finding (AAF)-- "through any reliable means." WADA Code, Art. 3.2; Hamilton at Paragraph 48; UCI Anti-Doping Rules, Art. 17; USADA's Response Brief at 18, quoting WADA Prohibited List, S1.1b, at 3 (proof that a Prohibited Substance is of exogenous nature may be established by using a "reliable analytical method").
- 5. Where the AAF relies upon an unaccredited analytical test as the "means" of proof, Art. 3.2 of the Code and Hamilton mandate that the anti-doping agency first establish what the lab's method was, and then prove that the lab's method was a "reliable" means. The agency does so by proving to the comfortable satisfaction of the Panel that a) the method conformed to the "scientific community's practices and procedures," and b) the lab "satisfied

itself as to the validity of the method before using it." *IAAF v. Boulami*, CAS/2003/A/452, Section 5.49, quoting *Muehlegg v. IOC*, CAS 2004/A/374 at Section 7.1.8; *Hamilton*, CAS 2005/A/884, Paragraphs 48, 52-53. In the absence of accreditation, then, USADA bears the burden of establishing to the comfortable satisfaction of the Panel what method LNDD used to perform the CIR analysis of Mr. Landis's Stage 17 sample, that the method used by LNDD "conformed to the "scientific community's practices and procedures" and that LNDD validated the method before using it. Failing that, USADA cannot prevail, and the Panel need not reach the other elements of the case.

- Nevertheless, the Tyler Hamilton case provides useful guidance about the types of proof that should be proffered if USADA is to prevail. In that case, USADA used an unaccredited HBT method, but carried its burden of establishing that the method was reliable by producing substantial persuasive evidence including proof that: (1) the positivity criteria it used were more conservative than would usually be required (Para. 61); (2) practitioners and researchers had concluded that the method used was valid (Para. 62); (3) a lab-specific validation study had been performed (Para. 62); (4) the scientific rigor of the test had been confirmed by outside experts (Para. 62); (5) the methodology used had been published in the peer-reviewed literature (Para. 64); (6) experts for both sides agreed that those peer-reviewed articles provided "proof of principle" (Para. 64); and (7) the actual method used had been previously validated in at least three WADA labs (Para. 64).
- 7. Compliance. If USADA establishes that the laboratory used a validated and reliable method--either through proof of accreditation or proof of reliability—USADA will benefit from Article 3.2.1's presumption that the method used by LNDD was indeed performed in conformance with the International Standard for Laboratories (ISL), ISO 17025 (ISO), and the relevant WADA Technical Documents at the time it was used to analyze Mr. Landis's sample, #995474. *Hamilton*, Para. 54; UCI Anti-Doping Rules, Art. 18; WADA Code, Art. 3.2.1, 3.2.2.
- 8. Mr. Landis may rebut the presumption of compliance with proof (that he establishes by a balance of the probabilities), that the laboratory did not in fact comply with the ISL or other relevant standards when it analyzed his sample. WADA Code, Art. 3.2.1, 3.2.2. If he does so, the burden shifts back to USADA to establish to the comfortable satisfaction of the Panel that the deviation from the standards did not cause the alleged AAF.
- 9. Absence of Causation: If the athlete rebuts the presumption of compliance, the burden shifts back to USADA to establish to the comfortable satisfaction of the Panel that the alleged AAF was not caused by the deviation from the ISL and other relevant standards. WADA Code, Art. 3.2.2; UCI Anti-Doping Rules, Art 18. Simply put, USADA must present sufficient evidence that had the deviation not occurred, the analytical testing method still would have resulted in the alleged AAF. As was noted in Landaluce case, this burden is significant because proving the negative is difficult.

### B. Standard of Proof

1. USADA must carry the burdens described above to the comfortable satisfaction of the Panel. The amount of comfort required by the Panel is different in every case because the

standard is dependent on the "seriousness of the allegation which is made." WADA Code, Art. 3.1, 3.2.1, comment. The WADA Code states that the standard of comfortable satisfaction is more than a balance of the probabilities, but less than beyond a reasonable doubt. Therefore, the "more serious the allegation the higher the degree of probability, or 'comfort,' required." *USADA v. Montgomery*, Paragraph 36, GDC 00134-00160 at 00148-50. Or, put differently, the more serious the allegation, the closer the standard shifts to the "beyond a reasonable doubt" standard. *Montgomery*, Paragraph 36, GDC 00134-00160 at 00148-50.

- 2. The seriousness of the allegations in this case cannot be understated. For the first time in the history of the race, the winner of the Tour de France has been charged with a doping violation. USADA's burden should therefore be close to the "beyond a reasonable doubt" standard.
- 3. Mr. Landis's burden is lighter. If necessary, he satisfies his burden by producing evidence tipping the "mere balance of probabilities" in his favor. WADA Code, Art. 3.1, emphasis added; *Montgomery*, GDC 00149, Para. 36. To satisfy his burden, Mr. Landis must present evidence that establishes that it is "more likely than not" that the burden is satisfied. WADA Code, Comment, Art. 3.2.1 (using the term "preponderance of the evidence" in place of "balance of probabilities"); *Montgomery*, GDC 00149, Para. 36.

#### III.

# LNDD DID NOT PERFORM THE CARBON ISOTOPE RATIO TEST IN ACCORDANCE WITH THE ISL, ISO, ITS OWN SOPS AND SCIENTIFIC PRINCIPLES AND METHODS

### A. LNDD's Carbon Isotope Ratio Test Was Not Accredited

1. The accreditation must be of the same CIR test method that was in fact used to test the samples at issue. In other words, neither accreditation of the laboratory as whole, nor accreditation of a different CIR test method is sufficient. This is clearly conceded by USADA's counsel to the AAA Panel below:

"I'm a laboratory and I want to use the IRMS method to detect testosterone...And so I have to — we know that the IRMS method works generally. But I have to demonstrate that I can make it work on my machine in my lab. And so I do validation studies on samples...The next thing that happens in this process is that the international standard says that for me to be using this method, I need to get it ISO certified. And they don't just ISO certify the lab—I mean, they do ISO certify the lab—but they also ISO certify particular methods that are employed by the lab."

*USADA v. Floyd Landis*, AAA No. 30 190 00847 06, Tr. of Proceedings, February 23, 2007, Vol. II at 100:6-7, 14-18; 101:4-9, emphasis added.

2. USADA has consistently and incorrectly maintained throughout this case that LNDD used an accredited method when it conducted the GC/C/IRMS testing of Mr. Landis's

sample. This is false. According to the accreditation documents themselves, Exhibit 26, at LNDD 0086, the method used by LNDD was not an accredited method in July 2006:

- a. The COFRAC accreditation document lists the CIR test assay as EC31 and notes that the components of the assay are EC31-VA1, I-CONF-31, M-Ex-24 and M-An-41. See Exhibit 26, LNDD 0086. However, M-An-52, which is the method LNDD used to perform the GC/MS portion of the CIR test, is not listed on the accreditation documents. See Exhibit 24, USADA 0124-26, Exhibit 25, USADA 0303-05; Goldberger Decl. at ¶ 81.
- b. The COFRAC accreditation document lists the measurement of uncertainty for the EC31 method as 20%. Indeed, this 20% measurement of uncertainty is listed in no fewer than three documents by COFRAC. *See* Exhibit 26, LNDD 0086, LNDD 0414, LNDD 0429. This is contrary to LNDD's purported measurement of uncertainty for the CIR test used by LNDD in testing Appellant's sample, which was 0.8%.<sup>3</sup>
- c. In an attempt to overcome these direct contradictions, USADA has argued that the failure of the GC/MS portion of the CIR test to be listed in the component section of the May 2006 accreditation document is meaningless. The evidence presented to support this argument is not sufficient to give this Panel a comfortable satisfaction that the CIR test used to analyze Appellant's sample was accredited:
- i. Dr. Ayotte asserts that the inclusion of a statement referring to the GC/MS portion of the CIR test method in quality document M-EX 24 on January 1, 2006, somehow establishes that COFRAC evaluated the SOP M-An-52 but failed to include it in the accreditation document. Ayotte Rebuttal Decl. at ¶ 45. This is simply nonsensical. Dr. Ayotte wants this Panel to assume that because the COFRAC auditor may have seen a document referring to GC/MS in relation to the CIR test, the auditor must have given careful consideration to the GC/MS portion of the test and simply failed to include M-An-52 in the component section of the May 2006 accreditation. Not a shred of evidence supports this assumption. Furthermore, Dr. Ayotte is not competent to tesify on this topic. She does not work for COFRAC, has never been regulated by COFRAC, and did not in any way participate in the particular COFRAC review of the LNDD's IRMS method. Her testimony is completely speculative.
- ii. Mr. LeGuy testifies that the COFRAC auditor had all of the relevant SOPs and documents and would not have accredited the method without approving the M-An-52 SOP. This testimony presumes that the auditor in fact had and knew that the CIR test

<sup>3</sup> LNDD also failed to use an accredited method for the T/E ratio test performed on Appellant's sample. The assay method EC24D was the T/E test method used by LNDD to test Appellant's sample, but the only accredited method was EC24C. Additionally, despite LNDD in fact using an unaccredited testing method, USADA, and in particular Dr. Ayotte, as led in questioning by USADA's counsel, was willing to testify at the AAA hearing that LNDD used the accredited method, EC24C. See AAA Tr. at 831:12-23. Such statements are simply incorrect and were false statements made to the Panel.

method used by LNDD should include a GC/MS portion and also presumes that, if the auditor was aware of M-An-52, he would not have accredited it unless he approved of the SOP. *See* LeGuy Letter. However, Mr. LeGuy was not the COFRAC auditor and has provided no foundation for his statements. *See* Exhibit 26, LNDD0393 (listing Bruno le Bizec as the auditor present on February 10, 2006). It is telling that USADA made no attempt to provide the testimony of the actual auditor and subject that auditor to cross-examination.

- d. USADA next argues that the December 2006 accreditation document was actually an erratum, which corrected an error in the May 2006 document. But the evidence proffered in support of this assertion is equally unpersuasive and does not satisfy its burden:
- i. While it is undisputed that the December 2006 accreditation document lists for the first time a measurement of uncertainty level of 0.8% for LNDD's CIR method, the cover letter of this new accreditation document drafted by Mr. Robin LeGuy of COFRAC does not state that the accreditation document should be back-dated to the May 2006 accreditation document. Exhibit 26, LNDD0447.
- ii. Dr. Ayotte also purports to testify that the 20% uncertainty figure was a "mistake." But this testimony should not cause this Panel any concern and must be disregarded because taken at face value, the testimony does not establish that the December 2006 document should be back-dated to the May 2006 accreditation document. Rebuttal Declaration of Dr. Ayotte at ¶ 44. Further, there is no support for the proposition that the laboratory has always had a measurement of uncertainty of 0.8‰ or that the purported undated validation study provided during discovery was in fact completed or submitted to COFRAC before the May 2006 accreditation was issued at any time prior to December 14, 2006. Rebuttal Declaration of Dr. Ayotte at ¶ 44, Exhibit 26, LNDD0477. Finally, as stated above, Dr. Ayotte does not work for COFRAC and is in no position to interpret its documents. In sum, Dr. Ayotte's testimony on this issue is mere speculation.
- iii. This purported correction of COFRAC's mistake came only after Mr. Landis pointed out this deficiency in an early pleading. The alleged correction came at the request of an LNDD staff member who sent an email to COFRAC asking it to correct this "mistake." *See* Exhibit 26, LNDD0477. Neither the actual email was produced to Appellant, nor was any supporting documentation that may have been sent to COFRAC, was provided in this litigation. All that has been provided by LNDD is an unsigned and undated study asserted to establish that LNDD's CIR test measurement of uncertainty was 0.8%. Exhibit 26, LNDD 0451-0457. This should be contrasted with the documentation provided to support the T/E measurement of uncertainty for method EC24C (Exhibit 26, LNDD 0461-0471). Note that LNDD 0462 provides dates for each step of the validation of the measurement of uncertainty for T/E, signed and dated contemporaneously with the completion of each such step. No such similar form exists for the purported validation of the measure of uncertainty for EC31 (the CIR test). Exhibit 26, LNDD0451-0457.
- e. The March 2008 letter provided by Mr. LeGuy should be given no evidentiary weight as it was written almost one and one-half years after the December 2006 accreditation document and provides no details for why the December 2006 accreditation document was in fact an erratum. *See* LeGuy Letter.

- f. A further deficiency in USADA's accreditation argument is that USADA did not and can not even identify the method used by LNDD to identify testosterone metabolites as part of the CIR test. *See* III.B., infra. USADA cannot prevail on the argument that its CIR test method was accredited because it cannot establish *what* method was used to analyze sample 995474.
- g. In addition to the above arguments, USADA made a wholesale argument that the CIR testing method used by LNDD must have been the CIR test method accredited because the COFRAC auditor observed the LNDD technicians performing the same CIR test method used on Appellant's sample during the COFRAC audit. This argument has no evidentiary support:
- i. USADA presented no evidence from the COFRAC auditor, Bruno LeBizec, who observed the CIR test method during the audit. *See, e.g.*, Exhibit 26, LNDD0400.
- ii. Mongongu indicated that Mr. Le Bizec was not informed that LNDD manually processed quality control samples and does not recall whether Mr. Le Bizec observed the manual processing of quality controls. CAS Tr 693:11-24.
- iii. No information or documentation (if any such documentation exists) about the identification of peaks in the blank urine pool 4 was provided to the COFRAC auditor. CAS Tr. 699:16-19.
  - h. Lastly, USADA's accreditation argument should be rejected because:
- i. At the time Ms. Frelat supposedly performed the CIR test method during the COFRAC audit, she was not validated by LNDD and was not permitted to work on actual samples. CAS Tr. at 870:14-19.
- ii. Ms. Frelat admitted that she was not fully trained on the CIR test method at the time she performed the CIR for purposes of the COFRAC accreditation. *See* CAS Tr. at 870:14-19. Frelat Decl. at pp. 1, 2.
- and there is no credible evidence that the auditor actually observed manual processing being performed during the audit. Ms. Mongongu suggests that the auditor "did indeed" witness manual processing, but when asked, she "[does not] know" details. CAS. Tr. at 693:11-24. Also, while Ms. Mongongu was present at the accreditation, she was not the operator witnessed by the auditor. CAS Tr. 679:13-20. Frelat, whom the auditor did witness, speculated that the auditor would have seen her manually integrate "when necessary," but gave no testimony about what the auditor did or did not actually witness. Frelat Decl. at pp. 2, 3.
- 3. While LNDD was accredited to conduct *some CIR test method* in July 2006, USADA should not be given the benefit of the Code's presumptions because it cannot establish *that the method LNDD actually used* was the method allegedly accredited by COFRAC. Accordingly, LNDD was not properly accredited to conduct CIR test method and is not entitled to a presumption.

# B. USADA Did Not, and Cannot, Prove That LNDD Had a Documented and Validated Method for Identification of Testosterone's Target Compounds, All in Violation of the ISL and TD2003IDCR

- 1. A critical component of the CIR test in testing for testosterone is the proper identification of the testosterone metabolites.<sup>4</sup> This requirement is embodied in the ISL 5.4.4.3.1, which requires that LNDD "establish criteria for identification of a compound at least as strict as those stated in any relevant Technical Document." WADA TD2003IDCR requires that "the appropriate analytical characteristics must be documented for a particular assay. The Laboratory must establish criteria for identification of a compound." WADA TD2003IDCR continues that an example of a proper identification criteria is for the retention time of an analyte to match by (1) percent or ± 0.2 minutes (whichever is smaller) from that of the same substance in a spiked urine sample, reference collection, or reference material. LNDD is in violation of both the ISL and TD2003IDCR because USADA has failed to set forth any documented method for identification of target analytes, and, even worse, did not and cannot identify what method LNDD actually used to identify the target analytes in Sample 995474.
- 2. LNDD's technicians admitted that there is no SOP or documented validation study that describes LNDD's method for identifying compounds in the CIR test. CAS Tr. at 660:5-661:20, 838:15-22. This demonstrates the falsity of USADA's repeated statement that the COFRAC auditor examined all relevant documents for compliance with the ISL and related technical documents, and if those documents were missing, would have created a "deficiency report." See e.g. Tr. 193:3–194:15. COFRAC did not create any deficiency report, and no COFRAC documents exist for the absence of any documentation for the critical and required (by the ISL 5.4.4.3.1 and TD2003IDCR) step of compound identification.
- 3. USADA and LNDD have presented multiple and different stories describing the method used to identify the testosterone metabolites in this case. The sheer number of stories, the "development" of these stories over time, the lack of documentation of any of these stories and the after the fact nature of these stories all strongly demonstrate that LNDD cannot prove what method was used on the day that Sample A and Sample B of Sample 99547 were analyzed.

### a. <u>The Discovery Response</u>

i. On January 22, 2007, Mr. Landis served his request for production of documents on USADA requesting: "All DOCUMENTS that relate to the identification of each of the peaks in the IRMS analysis for any sample tested by LNDD from Floyd Landis during the 2006 Tour de France." See Jan. 22, 2007 Discovery Served on USADA, at 7. On February 7, USADA and LNDD replied with the following response: "LNDD is providing full GC-MS scans for each of the six peaks used in the IRMS analysis of the A and B sample, as well as for the standards." See Feb. 7, 2007, USADA Discovery Response, at Exhibit B (LNDD

<sup>&</sup>lt;sup>4</sup> The absence of any documented or validated method stands in stark contrast to the fact that documentation exists for such things as the IRMS parameters and an extraction method.

Response to Second Request for Documents) at 10. Nowhere in this discovery response did USADA and LNDD state that LNDD identified testosterone metabolites using (1) peak matching or peak pattern matching, (2) Mix Cal Acetate or (3) Blank Urine, as later testified to by USADA's experts at the CAS hearing. In the discovery responses, USADA and LNDD solely referenced Mix Cal Acetate and Blank Urine as quality control measures. See id. at 7-9.

ii. The discovery responses were consistent with statements by Mr. Young to the AAA panel, when he explained how testosterone metabolites are identified in the CIR test. See Transcript of Proceedings, February 2007, 101:21-22 ("The way you identify the substance is using GC/MS link to the IRMA (sic)."

### b. USADA's AAA Briefs

USADA's Pre-Hearing Brief states that compound identification is "achieved by matching GC retention times and MS ion patterns (ion ratios) between the compound in the sample and a reference standard." *See* USADA Pre-Hearing Brief, at 41. Nowhere does USADA's Pretrial Hearing Brief refer to Mix Cal Acetate or Blank Urine as part of the identification method. Nowhere does USADA refer to any peak matching or peak pattern matching of any kind.

### c. AAA Hearing: Testimony of Dr. Brenna

At the AAA Hearing, Dr. Brenna was the second witness to testify, and in response to the question of how peak identification was conducted, he stated: "Well, they have retention times that match on the previous, with the previous GC/MS, and the GC/MS delivers structural information, like aliquots and so forth, that tell us which is which. *See* AAA Tr. 255:16-22. When Dr. Brenna was cross-examined and learned that GC/MS retention times do <u>not</u> match, the story changed.

### d. USADA's CAS Brief

- i. In its CAS Brief, USADA asserts that the AAA Panel correctly identified LNDD's method for identifying the testosterone metabolites: "Specifically to identify the substances in question, one would compare the pattern of peak heights and retention times in the GC/C/IRMS chromatograms, anchored by the internal standard with a known RT, with the pattern of peak heights and RTs in the GC/MS chromatograms . . . ." USADA CAS Brief, at 50. USADA goes on to say that the 5 beta from the Mix Cal Acetate also acts as a retention time marker. *Id*.
- ii. Again, this description is contained nowhere in USADA's discovery responses and the testimony of Dr. Brenna before cross-examination. Moreover, this description of method is different than the method described by the LNDD technicians at the CAS hearing.

## e. <u>USADA's Expert Testimony at CAS</u>

i. First and foremost, the testimony of USADA's expert witnesses should be given no weight when it comes to establishing *what* LNDD actually did. While

experts may be competent to testify about the scientific reliability of LNDD's method, they are *not* competent to testify about what LNDD *actually used for a method*, because they were not present. What happened is a matter for fact witnesses, not expert witnesses, so the testimony of experts purporting to testify about facts should be disregarded. Moreover, in at least one instance, USADA simply told one of its experts, Dr. Matthews, what LNDD's laboratory practices were – in contradiction to USADA's own discovery response. *See* CAS Tr. 1102:11-24. Lastly, and most importantly, even these experts cannot agree upon LNDD's precise method.

- ii. Dr. Brenna testified (in his current version of testimony on this subject) that "[LNDD] acquires GC/MS data for their test steroids in the samples and in their urine pools that are comparable to standard GC/MS data, thereby establishing the major peaks and their order of elution . . . [i]njection of a steroid mixture on the GC-C-IRMS therefore produces a pattern that reveals the identity of the peaks. *See* Decl of Dr. Brenna, at 13.
- iii. Dr. Matthews testified that LNDD used retention time of the 5 Beta P-Diol to "find the 5a-Adiol, and Pdiol from the peak elution patterns." *See* Decl. of Dr. Matthews, at 8.
- iv. Dr. Jumeau testified that LNDD used a two step method. First, LNDD used a peak pattern matching analysis, followed by the use of Mix Cal Acetate to apply a retention time analysis between the internal standard and the etio, 5 beta diol and 11-keto-etio. *See* Decl. of Dr. Jumeau, at 8-11.
- f. When the LNDD technicians testified at the CAS Hearing on cross-examination, they described different methods for identifying the testosterone metabolites:
- i. Ms. Frelat testified on cross-examination that the method for identification of testosterone metabolites was as follows. The first step was peak matching between the GC/MS chromatogram and the GC/C/IRMS chromatogram for the sample. CAS Tr. 832:5-838:3. Step two involved matching relative retention times between blank urine in the GC/C/IRMS with studied blank urine values. CAS Tr. 838:15-842:17. Nowhere in the discovery responses or USADA's AAA brief or USADA's CAS brief is Blank Urine or peak pattern matching described as a method of identification.
- ii. Cynthia Mongongu testified on cross-examination that the method for identification of testosterone metabolites was as follows. The first step was a pattern matching step between the GC/MS Blank Urine and the GC/C/IRMS. The second step was a retention time/relative retention time analysis between the GC/C/IRMS Blank Urine and the GC/C/IRMS sample fraction. *See* CAS Tr. 669:20-683:11; 734:21-748:19. Nowhere in the discovery responses or USADA's AAA brief or USADA's CAS brief is Blank Urine or peak pattern matching described as a method of identification.
- iii. Dr. Buisson did not testify on cross-examination, but in her declaration, she states that the method involves a two step method of pattern peak matching and comparison of relative retention times to the blank urine. See Decl. of Buisson, at 8-9. Nowhere

in the discovery responses or USADA's AAA brief or USADA's CAS brief is Blank Urine or peak pattern matching described as a method of identification.

- g. Additionally, in neither their declarations nor on cross-examination do the LNDD technicians suggest that they use retention times or relative retention times in GC/C/IRMS of substances in the Mix Cal Acetate to assist them to identify peaks in the sample. Only after being prompted by leading questions from Mr. Young on re-examination do the technicians discuss it and even then they do not say that they in fact do use Mix Cal Acetate for their identification method, but instead only indicated that the peaks in the Mix Cal Acetate also match. See CAS Tr. 770: 7-17. Finally, there is no document that compares retention time or relative retention times of the GC/C/IRMS peaks in the Cal Mix Acetate to retention time or relative retention times of GC/C/IRMS peaks in the samples. In short, contrary to the suggestion of some of USADA's IRMS experts, this is simply not a procedure used at LNDD.
- h. Moreover, the use of the Blank Urine values at LNDD 309 and LNDD 310 is irrelevant in the relative retention analysis because those documents contain no information related to how those peaks were initially identified; these documents simply provide the isotopic value of the peaks in the blank urine. See Exhibit 26, LNDD 309, 310; CAS Tr. 698:6-699:24, 1083:6-1084:8.
- i. To the extent that USADA now hopes to comply with the requirements of TD2003IDCR by contending that LNDD 309 and 310 constitutes a reference collection pursuant to ISL 5.4.6.2, USADA is in error.
- i. ISL 5.4.4.2.1 states that "Reference standards should be used for identification, if available." In the discovery, it is clear that LNDD possessed reference standards for the metabolites 5 alpha androstandiol (Exhibit 26, LNDD 287), 5 beta pregnandiol (Exhibit 26, LNDD 278) and Androsterone (Exhibit 26, LNDD 284). First of all, because a reference standard is available, LNDD should have used reference standards for identification pursuant to the ISL.
- ii. Second, WADA TD2003IDCR requires that "the Laboratory must establish criteria for identification of a compound," an example of proper criteria for capillary gas chromatography is that "the retention time (RT) of the analyte shall not differ by more than one (1) percent or ±0.2 minutes (whichever is smaller) from that of the same substance in a **spiked urine sample, Reference Collection sample, or Reference Material analyzed contemporaneously.**" (emphasis added). The Blank Urine Pool 4 does not qualify as any one of these.
  - iii. Blank urine is obviously not a "spiked sample."
  - iv. Blank urine is not a Reference Collection under the ISL:

### 5.4.6.2 Reference Collections

A collection of samples or isolates may be obtained from a biological matrix following an authentic and verifiable administration of a Prohibited Substance or Method, providing that the analytical data are sufficient to justify the identity of the relevant chromatographic peak or

isolate as a Prohibited Substance or Metabolite of a Prohibited Substance or Marker of a Prohibited Substance or Method.

- v. These criteria are not met. Firstly, the sample must come from an "authentic and verifiable administration." That has not been established here: (1) no evidence was provided as to the origin of the sample Blank Urine 4, (2) no administration of the substances of interest was conducted, and (3) no evidence exists that the sample is from a pooled urine of several LNDD technicians and specifically not that of a single individual made the subject of an administration study.
- Secondly, the "analytical data [must be] sufficient to justify the vi. identity of the relevant chromatographic peak." In this case, no evidence has been provided that the metabolites/substances in Blanc Urine pool 4 are the substances LNDD claim them to be. We have only LNDD's unsupported assertion that 5 Alph-Diol IRMS peak in the Blanc Urine is in fact 5 Alpha-Diol. The studies Ms. Mongongu claims to have performed on the Blu Pool 4 were not provided. Ms. Mongongu asserted, when asked if peak patterning matching absent a comparison to blank urine is sufficient to identify IRMS peaks, she replied "No. Not peak matching alone." See CAS Tr. 669:23-670:2. She also unequivocally states that it is impossible to use retention time and relative retention time comparison between GC/MS and GC/C/IRMS to identify peaks in GC/C/IRMS. CAS Tr. 680:17-20. Thus, there is no method identified by the LNDD technicians – including Ms. Mongongu (the technician who claimed to have done the validation on Blu Pool 4) to identify the peaks in the initial GC/C/IRMS run of Blu Pool 4. Finally, the only documents provided regarding Blu Pool 4 are LNDD0309 and LNDD0310 (SOP E-P-32) and there is no information on these pages that could provide identification of the peaks in Blu Pool 4. See CAS Tr. 698:6-699:24, 1083:6-1084:8.
- vii. Lastly, Blank Urine is not a Reference Material, pursuant to the ISL 3.2, which defines it as a "material or substance one or more of whose properties are sufficiently homogeneous and well established to be used for the calibration of an apparatus, the assessment of a measurement method or for assigning values to materials."
- j. Also, peak pattern matching is not a consistent scientific method. Dr. Goodman and Dr. Simon Davis testified that peak pattern matching is not appropriate and USADA never challenged them on this topic in cross-examination. See Declaration of Dr. Goodman ¶¶ 84-87, Declaration of Dr. Davis at ¶ 48. Ms. Mongongu testified that it would be "difficult" for her to identify the peaks in GC/C/IRMS chromatogram at Exhibit 91, LNDD 1362, with the GC/MS chromatogram at Exhibit 91, LNDD 1339. See CAS Tr. 752:18–753:3. Ms. Frelat had difficulty in matching the peaks during her cross-examination. See CAS Tr. at 831:4-834:12.
- k. This history, which describes USADA's and LNDD's attempts to explain and prove just what method the LNDD staff used for testosterone identification, illustrates that the effort should not have been what it clearly was: a shifting, *post hoc* attempt to justify a result. A scientific method should not require repeated and conflicting attempts at explanation. The lack of clarity alone, and the struggle that USADA has undergone to prove the method that LNDD used to perform the CIR analysis on Mr. Landis' sample, is evidence itself that no documented, accredited and validated method existed.

### C. LNDD Failed to Validate Its Positivity Criteria

- 1. LNDD's stated positivity criteria allows LNDD to declare an AAF based upon one out of four testosterone metabolites measuring in excess of 3.0 per mil, plus .8 measurement of uncertainty. Exhibit 25, USADA0352.
- 2. In this case, Sample 995474 only has only one such metabolite. Exhibit 25, USADA0352.
- 3. It is clear that a laboratory must still validate its positivity criteria, whichever testosterone metabolites it tests, and however many it chooses to use to declare an AAF. ISL 5.4.4.2.1 states that: "confirmation methods for non-threshold substances must be validated." (ISL 5.4.4.2.2 carries the same requirements for threshold substances). Even Dr. Ayotte stated that a laboratory should validate the positivity criteria in her testimony. AAA Tr. at 856:13-857:9.
- 4. LNDD did not validate its positivity criteria of 1 out of 4 metabolites. See CAS TR. 755:12-24. The problem with using this unvalidated positivity criteria is highlighted by the 2001 Aguilera Study. In that study, had Aguilera applied LNDD's positivity criteria of 1 out of 4 metabolites to the samples measured in his study, at least one of his known negatives would have resulted in an AAF. Exhibit 43, USADA0815, Table 3. In other words, the Aguilera study demonstrates that use of only 1 out of 4 metabolites can render the IRMS method incapable of discriminating between positive cases and negative cases, and therefore LNDD's method is not a reliable method. Exhibit 40, USADA 1229.
- 5. At LNDD, this lack of validation is particularly troublesome because its acceptance criteria for quality control standards is far more lenient than that for an athlete's sample. Internal quality control measures allow for one out of four controls to be measured inaccurately that is, out of the known and determined isotopic value (plus measure of uncertainty) and still allow the results of the samples associated with that quality control to be used to establish an AAF.
- 6. This is of particular concern in this case because in Sample 995474, the internal standard 5 alpha androstanol AC was out of the known isotopic value in four instances associated with the running of Sample A and Sample B, including, importantly, the blank urine of F3 Sample B. Ex. 24, USADA 0185 (Sample F1, Blank F2); Exhibit 25, USADA 0351 (Sample F1, Blank F3).
- Outside of the determined isotopic value because it is used only to calculate retention time misses the mark entirely. First, as stated below, that was not USADA's original contention. Second, and more importantly, the IRMS instrument measures what it measures whether or not the laboratory technicians use the internal standard for some other reason does not explain why the instrument *cannot* measure accurately the isotopic value of the internal standard. As not below, the stated reason of matrix interference does not hold true because the Blank F2 internal standard is out of specification and there is no matrix interference. Exhibit 26, USADA 161. This raises significant concern whether LNDD can measure any substance accurately by GC/C/IRMS.

### D. LNDD Had No Effective or Appropriate Quality Controls

- 1. The ISL requires quality control. ISL 5.4.7.3 states: "Analytical performance should be monitored by operating quality control schemes appropriate to the type and frequency of testing performed by the Laboratory. The range of quality control activities includes: positive and negative controls analyzed in the same analytical run as the Presumptive Adverse Analytical Finding Sample [and] the use of deuterated or other internal standards . . ."
- 2. LNDD's quality control scheme is not effective. LNDD's acceptability criteria for its quality control, which requires that only 3 out of 4 of the target substances of the Mix Cal Acetate and Mix Cal IRMS must be within determined isotopic value, makes no sense when considered as against its positivity criteria, which only requires that 1 out of 4 of the target metabolites be outside of the -3.8 per mil range. Exhibit 24, USADA 174; Exhibit 25, USADA 353. This is inconsistent with the ISL, which mandates that the quality control be "appropriate to the type and frequency of testing," a requirement that applies to the positivity criteria of the testing involved. There never has been an adequate explanation for this nonsensical approach. See CAS Transcript, 1480:11–1481:18.
- 3. Further, the quality control scheme is not effective because LNDD manually integrates the quality controls, including the Mix Cal Acetate. Manual integration allows for subjective adjustment of peak start and stop and background, which can have a substantial impact on the final isotopic value, and may cause the final isotopic value to change. *See* LNDD SOP M-DP-31, at Exhibit 112, LNDD 606 (manual integration).
- a. Both Frelat and Mongongu concede that manual processing can substantially alter the isotopic ratio. CAS Tr. at 690:13-18, 845:15-19.
- b. LNDD failed to record and document the manual processing of its quality controls so no record exists of what changes were made to the peak start and stop and to the background points, all of which impact the final isotopic value. CAS Tr. at 690:13-698:5, 845:15-851:11. As a result, the exact parameters and values obtained by manual integration cannot be reproduced.
- c. Further, Mongongu admitted manually processing the Mix Cal Acetate because it was not "correct" with one of the other B samples. AAA Tr. at 589:14-17.
- 4. Most importantly, LNDD failed to determine the isotopic value of the internal standard, 5 alpha androstanol AC, within the correct isotopic value, plus or minus 0.5, which renders the test results of CIR test for Sample 995474 invalid. In the Sample A and Sample B runs, the Isoprime1 instrument failed to determine the isotopic value of the internal standard within the measurement of uncertainty on four (4) separate occasions as follows: Sample A (F1 Sample and F2 Blank Urine), Exhibit 24, USADA 0185, and Sample B (F1 Sample and F3 Blank Urine), Exhibit 25, USADA 351. See Meier-Augenstein Presentation at Slides 52, 54; AAA Closing Presentation at Slides 39, 40, 134, 136.
- 5. Prior to any testimony in this case, USADA asserted in response to discovery requests about quality controls that "Sample 995474 was verified by the use of a known internal standard each time Sample 995474 was analyzed." USADA's Response to Second Request Ex.

- C at 7-9. This internal standard was identified as 5 alpha-androstanol acetate, and LNDD's discovery response identified pages that showed the internal standard as being measured in the sample fractions, not just the mix cal acetate. Id. The discovery response states that "one can determine that the . . . instrument [was] performing properly when the instrument provides data on the internal standards . . . within the range that is acceptable, for example for signal strength or measured value. Id.
- 6. LNDD's assertion was restated by Dr. Brenna at the AAA hearing, who, on direct examination, testified that "that standard [the internal standard] is further checked to determine the instrument is running properly during analysis of every particular sample. And then there were standards run after the sets of analytes. So there were standards at each level." AAA transcript RT 237:12-19.
- 7. After cross-examination of Dr. Brenna, in which it was established that LNDD failed to determine the internal standard within the measure of uncertainty of its determined isotopic value, the witnesses in this case, including the experts in the CAS appeal (Dr. Brenna, Dr. Matthews, Dr. Ayotte, Claire Frelat and Cynthia Mongongu), testified that the internal standard was *not* used as a quality control in the sample runs, but rather only as a relative retention time marker. Rebuttal Declaration of Dr. Brenna at ¶¶ 7-8, Declaration of Dr. Matthews at 13, Declaration of Dr. Ayotte at ¶ 23, Declaration of Frelat at 9, Declaration of Mongongu at 4. This testimony is not credible for the following reasons:
- a. Dr. Brenna provided inconsistent testimony on the issue of the internal standard. During cross-examination at the AAA hearing, Dr. Brenna was asked whether he realized that the internal standard was out of isotopic measure. He testified that "I was aware that some of them were a bit outside . . . ." AAA Transcript RT 313:22–314:5. At the CAS hearing, as noted above, Dr. Brenna, testified that he believed that the internal standard was *not* used as a quality control, and that the reason why was that he learned that some of the values were out of expected range "And it has been pointed out that the delta values for some of the internal standards were out of the plus or minus .5, as I've said." CAS Tr. at 967:3-6. Further, he testified that he did a "spot check" and saw that "the ones that I looked at were fine." CAS Tr. at 966:22–967:6.
- b. All of the witnesses' testimony is in direct conflict with the discovery response and Dr. Brenna's testimony, all of which was delivered before Mr. Landis established that LNDD failed to accurately determine the isotopic value of the internal standard in 4 of the fractions in Sample A and Sample B.
- c. Nowhere in the discovery responses does LNDD indicate that the internal standard is used as a relative retention time marker.
- d. Whether LNDD used the internal standard as a relative retention time marker or not, there is no explanation for failing to accurately determine the isotopic value of the internal standard, aside from poor chromatography and instrument failure and unreliability.
- e. Nor does the excuse that matrix interference and poor chromatography which is limited to the "front half" of the chromatogram explain away the internal standard

failing to be measured within the determined isotopic value. As shown in the chromatogram for the Sample A blank urine F2, Exhibit 24 USADA 164, LNDD failed to accurately measure the isotopic value of the internal standard even where the chromatogram shows no matrix interference or poor chromatography around the internal standard, as testified to by Dr. Brenna. CAS Tr. 974:17-977:19.

- f. Further, the new contention that the isotopic value of the internal standard does not matter defies common sense because there is no explanation for why the internal standard values are reported on the IRMS results page, which is Exhibit 24, USADA 185 and Exhibit 25 USADA 352, if their isotopic values did not matter.
- g. Further, the experts' testimony that LNDD does not use the internal standard as a quality control and only as a relative retention time marker utterly lacks credibility because USADA, through its chief science officer, Dr. Larry Bowers, told at least one of its witnesses, Dr. Matthews, prior to his testimony, that the internal standard is not used as an isotopic standard within the samples, contrary to USADA's own discovery responses earlier served on Mr. Landis. CAS Transcript 1103:3-25.

### E. The Isoprime1 Was Not Linear

- 1. Mr. Landis's opening appeal brief set forth detailed arguments regarding linearity, all of which are adopted here.
- 2. Linearity is the ability of an IRMS instrument to accurately quantify the isotopic ratio of each testosterone metabolite and endogenous reference compound in different samples regardless of their concentration. Linearity is critically important to the accuracy and reliability of an IRMS instrument because it ensures that the instrument will measure the isotopic ratio of a target analyte accurately in samples whether there is a large amount of the analyte present or a small amount. It also insures that small contaminant peaks will be measured more accurately and will be less likely to cause interferences.
- 3. Indeed, ensuring the linearity of the IsoPrime instrument is of such a critical importance that the IsoPrime manual that it states that the linearity of the instrument should be checked before each run. Ex. GDC00522, IsoPrime Manual Section 6, Page 31(??), "Checking the System"). USADA's experts, Dr. Brenna and Dr. Matthews, who state that linearity is not a problem when analyzing carbon, do not have experience working with the IsoPrime instrument and are not aware of its tendency to fall in and out of linearity. *See* CAS Tr. at 1084:15-20; 1107:23-25; Davis Decl. at ¶ 52.
- 4. Without even analyzing whether the individual linearity test are within specification, LNDD violated the ISL by not following its Standard Operating Procedures ("SOP") that dictates the linearity runs must be performed once per month. *See* Ex. 26, LNDD0161-0187. Leaving aside the August 2006 linearity run which, as is established below, is a forgery, LNDD's linearity testing dates were: (1) June 26, 2006, roughly one month before the Stage 17 A Sample was tested (Ex. 26, LNDD0313, 0315, 0317), (2) July 31, 2006, roughly one week after Mr. Landis's A Sample was tested (Ex. 26, LNDD0320, 0322, 0324) and (3) September 25, 2006, roughly a month-and-one-half after Mr. Landis's B Sample was tested

- (Ex. 26, LNDD0327, 0329, 0331) (Ex. GDC00522, IsoPrime Manual Section 6, Page 31, "Checking the System"). By not actually performing a linearity test in August 2006, LNDD violated their SOP and, in turn, the ISL.
- 5. LNDD's SOP contains a linearity acceptance criteria that is contrary to the IsoPrime manual. The manual requires the linearity test to be performed over the full range of 1 nanoamp to 10 nanoamps; whereas, LNDD's SOP states that the linearity should be performed over a range of 2 nanoamps to 9.5 nanoamps. Exhibit 26, LNDD0161-0187; (Ex. GDC00522, IsoPrime Manual Section 6, Page 31, "Checking the System"). LNDD's SOP's acceptance criteria of 0.7‰ between the greatest isotopic value and the smallest isotopic value is substantially more lenient than the 0.3‰ standard stated in the manual (GDC 522 at page 17), other documents produced by the IsoPrime manufacture (GDC 1397, GDC 1410) and even a paper co-authored by Dr. Jacques de Ceaurriz (Exhibit 26, LNDD0210).
- 6. Using the manufactures specifications, the IsoPrime instrument is not linear. Davis Decl. at ¶¶ 56-58.
- 7. Dr. Jumeau's testimony that the linearity specifications in the manual, the other documents produced by the IsoPrime manufacturer, and the paper co-authored by Dr. de Ceaurriz should be disregarded is simply nonsensical and without any support. Despite being shown both the manual and another document from the IsoPrime instrument manufacturer listing 0.3% as the acceptance criteria for the IsoPrime instrument, Dr. Jumeau simply refused to admit, without citing any rational, that these documents applied to the IsoPrime 1 machine. CAS Tr. at 1187:2-1200:11. The closest Dr. Jumeau came to providing a reasoned explanation for her outright dismissal of the 0.3% acceptance criteria was that one part of the manual conflicted with another portion of the manual, and that based on pure speculation, the 0.3% standard applies to the IsoPrime JB series, not the JA series. CAS Tr. at 1193:12-15; 1196:11-1197:3. The steadfastness with which Dr. Jumeau disregards the 0.3% is simply disproportionate to the reasons for which she states this information should be disregarded. Indeed, Dr. Jumeau stated that her position about the 0.3% would not be altered even if Dr. de Ceaurriz wrote in a paper that LNDD uses as linearity acceptance criteria of 0.3%, which he did. CAS Tr. at 1204 at 8-16, see Exhibit 26, LNDD 210.
- 8. Dr. Jumeau further disregarded the manual's requirement that the linearity be tested over the entire range. CAS Tr. at 1210:11-1213:7. Despite stating that she essentially wrote the linearity section of the manual, she disagrees with its statement in the manual that it is essential that the full range must be tested because if the laboratory does not use the full range there is no need to ensure that the instrument is linear over the full range. CAS Tr. at 1212:5-20. This position is illogical because if it were true that she believed, as the supposed drafter of the manual, that linearity must only be tested over the peak range of the laboratories target peaks, she would not have drafted the manual to say that the linearity test must be performed over the entire range.

# F. LNDD's Chromatography Was Poor and LNDD Improperly Manually Processed IRMS Test Results

- 1. Good chromatography is critical to accurate isotopic results. See ISL 5.4.4.2.1 (Confirmation methods for Non-threshold Substances must be validated. Examples of factors relevant to determining if the method is fit for the purpose are: Matrix interferences. The method should avoid interference in the detection of Prohibited Substances or their Metabolites or Markers by components of the Sample Matrix.).
- 2. Matrix interference and poor chromatography can result in dramatic swings in isotopic values. *See* AAA Tr. 1425:7-1426:7, Decl. Dr. Goodman at 43-44, Meier-Augenstein Presentation at Slides 28-30.

Exhibit 120 (a demonstrative exhibit that USADA's counsel asked Dr. Meier-Augenstein to prepare, showing that even a small coeluting peak could have more than a -2 per mil effect on the target peak, where the isotopic value of the smaller peak was a hypothetical -70 per mil).

3. The critical importance of maintaining good chromatography with GC/C/IRMS when analyzing samples with matrix interference and coeluting peaks is supported by a peer-reviewed paper co-authored by Dr. Goodman and Dr. Brenna. *See* Goodman and Brenna, Curve fitting for restoration of accuracy for overlapping peaks in gas chromatography/combustion isotopic ratio mass spectrometry, Anal. Chem. 66, 1294-1301 (1994) at GDC1561-1568. That paper states: "Specific requirements for auxiliary preparation devices for GCC/IRMS results in a large number of connectors between the chromatography column and the detector, which influence peak shape and generally reduce chromatographic efficiency. Resolution is also limited by the restriction of He as a carrier gas, compared with H2 . . . For these reasons, chromatography in GCC/IRMS tends to be more subject to overlaps than conventional GC." *Id.* at 1294.

In that same paper, Drs. Goodman and Brenna conducted a systematic investigation of the effects of overlap on isotope ratio using conventional peak detect algorithms: "Overlapping peaks detected by conventional algorithms are systematically distorted in isotope ratio even for closely matched compounds, though high precision is maintained. Further, small trailing peaks can significantly affect the apparent isotope ratio of the major peak." *Id.* at 300.

- 4. LNDD's laboratory technicians have admitted that there was poor chromatography in some of the sample fractions of Sample 995474. *See* Testimony of C. Mongongu, at AAA Tr. 618:17-619:14.
- 5. LNDD technicians testified that more manual integration is necessary when poor chromatography is present. See CAS Tr. at 689:10-22, see, e.g., AAA Tr. of R. at 743:15-744:5.
- 6. C. Frelat and C. Mongongu both testified that they manually integrated substantial portions of Sample A and Sample B tests, including quality controls, *See* CAS Tr. at 690:4-7; 694:7-14.

- 7. USADA's own expert witnesses have admitted to poor chromatography in at least some of the chromatograms:
- a. Dr. Catlin, testified that chromatography was very important and that the chromatography on some of the chromatograms used to support the adverse analytical finding were poor. See AAA Tr. 1213:8-18. In every case he was shown an LNDD chromatogram at the AAA hearing, Dr. Catlin expressed that he found the chromatography lacking. See AAA 1228:10-13 and 1230:17-24 (Using an "A, B, C system" Dr. Catlin graded the LNDD chromatograms as either a C or a C-). In contrast, when shown the chromatogram produced at the UCLA laboratory (Exhibit GDC1362) he noted that it's chromatography was "pretty good." AAA Tr. 1241:15-17.

Dr. Catlin was not invited back as a witness in the CAS proceeding.

- b. Dr. Matthews, in coming to his conclusions that the AAF was supportable in this case, reviewed the chromatograms of only the Fraction 3 samples and blanks. CAS Tr. 1143:21-1144:24. Even when reviewing only these few chromatograms, however, Dr. Mathews noted that the chromatography in some parts of the chromatogram was poor. CAS Tr. 1145:5-16 and 1151:5-9.
- 8. The poor chromatography is demonstrated by the widely varying reprocessing results. If the chromatography was good, than the method used by LNDD to determine isotopic value should have resulted in consistent values, at least within LNDD's stated measurement of uncertainty of 0.8 per mil. However, this was not the case. <u>Using the same manual integration</u>, <u>LNDD was unable to reproduce the determined isotopic values within the 0.8 measurement of uncertainty as follows:</u>
- a. In the A Sample, when the operator (Ms. Mongongu) manually processed 5A-P during the EDF reprocessing, she was 0.81 per mil different from her original manual processing.
- b. In the B Sample, when the operator (Ms. Frelat) manually processed E-11K, A-11K and 5A-P during the EDF reprocessing, she was 1.67, 1.90 and 0.8 per mil different, respectively, from her original manual processing.
  - c. All of these values can be found at Exhibit GDC 1362.
- 9. Most disturbingly, the blank urine, using automatic subtraction, was nearly determined to be an Adverse Analytic Finding as follows:
- a. The blank urine run in the B analysis when using automatic processing had a delta-delta value for 5A-P of -3.45. See GDC 1362.
- 10. The testimony of the USADA experts at the CAS hearing that the Sample B chromatography is good is not credible.
- a. USADA's experts, in rendering blanket opinions of the high quality of the chromatography in this case, have not attempted to use any analytic tools (aside from visual

inspection) to define that quality. *See* e.g. Goodman, Hardware Modifications to an Isotope Ratio Mass Spectrometer Continuous-Flow Interface Yielding Improved Signal, Resolution, and Maintenance, Anal. Chem, 70, 833-37 (1998) (using the analytic Trennzahl calculation to define the quality of chromatography and its reliability), GDC1556-1560. When asked about this analytic tool, Dr. Ayotte did not even know what it was. *See* Test. of Dr. Ayotte, CAS Tr. at 1320:14-21.

b. Many of these experts are biased, and their testimony is unreliable. *See* Bias Section, *infra*.

### 11. Manual Processing, as used in this case, renders the IRMS results unreliable.

- a. Manual processing, as it was intended to be used on the IsoPrime1, is a diagnostic tool and after using that tool to diagnose and fix problems to your method, the samples would be re-run. See CAS Tr. at 561:13-564:13, 1008:2-25. Dr. Brenna suggested that it would only be acceptable to use results that had been manually processed if the change in delta value was not significant to the test parameters. Tr. 1008:15-21. As noted above, the LNDD operators when manually processing results often get wildly varying results. See GDC 1350. Such wildly varying results caused even Dr. Brenna concern when confronted with them for the first time in the AAA hearing. AAA Tr. 351:22-352:18.
- b. Manual processing is entirely subjective. *See* CAS Tr. at 592:4-593:16, 937:12-25, 938:2-20. This is confirmed by the testimony of the operators at the AAA hearing. See AAA Tr. 453:6-11 (Ms. Mongongu) and 734:14-735:3 (Ms. Frelat). Thus, at LNDD, determination of what is and is not a proper background point and what is and is not an appropriate start and end of a peak is done not by the objective algorithms designed by chromatography experts, but is instead done using the subjective opinions of technicians with as little as 4 months experience.
- c. Manual processing, as used in this case, did not involve any record keeping related to the start and stop of peaks, and adjustments to background subtraction, all of which have a material impact on the final isotopic value, and therefore violates the ISL. *See* ISL 5.4.4.1.4 and ISL 5.2.6.1 (requiring that the laboratory document procedures to ensure a coordinated record related to each analyzed sample). CAS Tr. at 869:11-19.
- d. Manual processing, as used in the IsoPrime1 instrument, can not fix poor chromatography. CAS Tr. at 598:4-18; Decl. of Dr. Keith Goodman at p. 52.
- e. The use of manual processing is especially troubling as it applies to LNDD's testing of Sample 995474 due to the procedures and mindset employed by Claire Frelat in this case.

# G. The LNDD Procedure USADA to Test Sample 995474 Violates the Core Principles of ISL 5.2.4.3.2.2.

- 1. The ISL prohibits the same operator from performing the A and B sample analytical tests. See ISL 5.2.4.3.2.2. There are several obvious reasons why the ISL includes this rule, the most obvious reason being that the ISL requires the B analytical test to be absolutely independent of the A analytical test. Without the B sample being independent, the corroborative benefit of the B sample is belied.
- 2. Ms. Frelat testified that she was not an independent operator when she performed the B sample when she stated that when she performs the B analysis, her goal is to "confirm the first analysis which had given a positive result." CAS Tr. at 914:5-7. In trying to explain what she meant at the AAA proceeding when she stated that 1.5 or 1.6 permil is a significant difference to her when comparing the reprocessing results, Ms. Frelat stated she got confused and that the 1.5 or 1.6 permil significant difference is when she compares the A sample test results from the B sample test results. Ms. Frelat testified that "at the end of the analysis, at the end of the test when the results come out, if I see that there are differences, if there is a difference in the isotopic values, then I think something must have happened." CAS Tr. at 908:18-909:4.
- 3. Further, the structure of LNDD's reporting structure does not support an independent analysis on the B sample. Ms. Frelat reports to Ms. Mongongu in the laboratory organizational chart. Therefore, when Ms. Frelat performs the B sample analysis with the goal of confirming the A sample analysis, she is in other words trying to confirm her superior's previous analytical test. If for some reason the B analysis does not match the A analysis, Ms. Frelat would essentially be establishing that he supervisor incorrectly performed the original analysis. To make matters even worse, in this case, Mr. Mongongu was also the confirming scientist for the B sample analysis. CAS Tr. at 916:15-917:13.
- 4. This improper belief that the goal of the B sample is to confirm the A analysis is further exacerbated by the fact that LNDD engages in manual processing. In performing her analysis, Ms. Frelat has the ability to manipulate and alter the results so that the B results match the A. While Ms. Frelat may not have the A sample test results in front of her, she can see the isotopic values from her test sample and if, for example, the 5-alpha minus the P-diol did not result in a delta-delta value larger than negative three, she can manually process the results to obtain a positive delta-delta value.

### H. LNDD Failed to Use the Same Column as Required by Its SOP

- 1. The failure to use the same columns as required in LNDD's SOP M-An 52 is an ISL violation because it violates its SOP.
- 2. The document package states that different columns were used by LNDD. Appellant's Brief, at 37-41, Exhibit 24 USADA 0124, Exhibit 25, USADA 0303.
- 3. The evidence admitted during the CAS hearing did nothing to establish that the same column was in fact used. Moreover, the evidence indicated an attempt to deceive Mr. Landis and the CAS tribunal with a fraudulent document. USADA relies upon the testimony of Mr. Lepetit, Ms. Mongongu and Ms. Frelat. However, none of these witnesses remembers the

column being changed, they assume that it was because GC/MS maintenance log at Exhibit 142, LNDD 2004 – 05 reflected that change. CAS Tr. 720: 2 – 19, 729:7 – 730:19, 819:20 – 821:10.

- 4. However, this document is fraud. Troublingly, LNDD has a demonstrated a willingness to create a document to substantiate its argument that the same column was used.
- a. Exhibit 142, LNDD 2004-05 purports to be a maintenance log for the GC/MS instrument. As Ms. Frelat testified, the maintenance log, according to LNDD's established laboratory procedures, was contemporaneously prepared. CAS Tr. 815: 23 816:17. It contains an entry that indicates that the column was changed, consistent with the story of LNDD that the same column was inserted into the GC/MS instrument.
- b. However, this document contains entries all written in the same handwriting, with the date order of the entries transposed immediately above the column change entry, which should not have been able to occur because Ms. Frelat testified that it was contemporaneously prepared. *See* Bias Section, *infra*. Contrary to the evidence, Mr. Young in his closing attempted to explain the inexplicable transposition of the entries by claiming that the document was not contemporaneously created. CAS Tr. 1471:4-22
- c. This attempt at defrauding the Panel and Mr. Landis is critical for several reasons. First, it should result in an adverse credibility finding against LNDD, Ms. Frelat and USADA. Second, the Panel should thereby then be entitled to rely, and only rely, on the LNDD documentation package that indicates that two different columns were used.
- d. The critical importance of whether two different columns were used or not is that, if two different columns were used, then it explains why the LNDD asserted method(s) of identification of testosterone metabolites *cannot work* because it relies on comparing peaks and peak pattern matching, which assumes that the elution order of the compounds is the same on both GC/MS and GC/C/IRMS. Appellant's Brief at 37, Decl. of Dr. Goodman at  $\P$  93 97.
- e. Indeed, one piece of evidence that supports that different columns were used is the gross difference between the retention times and relative retention times between the GC/MS and GC/C/IRMS phases as shown by Dr. Meier-Augenstein's summary of retention times and relative retention times. GDC 1356.
- 5. USADA also relies upon Dr. Brenna's testimony and his testimony about a study he performed using the two different columns at issue. Dr. Brenna's testimony and testimony about his study should be given no weight because he provided no substantiation for his conclusion. CAS Tr. at 1002:13-17.
- a. Brenna first states that if two different columns were used, then the operator would immediately notice because the order of the peaks would be different, and it would be immediately noticeable based upon the results of the IRMS test. Decl. of Dr. Brenna at 15-17.
- b. In an effort to further bolster his argument, Brenna then states (entirely inconsistently) that he ran a test with these particular two different columns, and the elution order

was unchanged, thereby contradicting his first assertion. Rebuttal Decl. of Dr. Brenna at  $\P 18 - 19$ .

# I. LNDD Failed to Properly Train and Supervise Its Laboratory Technicians and They Were Incompetent

- 1. Mr. Landis incorporates all of the facts contained in his Proposed Findings of Fact submitted following the AAA hearing, at pages 53 56.
- 2. In addition, USADA called Dr. Brenna to testify that Mr. Landis' argument about lifting rings is meritless. In so doing, Dr. Brenna testified that "there are data in the doc packs indicating that the lift rings on the Isoprime1 didn't have any effect." See CAS Tr. 1087: 9-15. There were no lifting rings on the IsoPrime1 the lifting rings were on the IsoPrime2. See Exhibit GDC 734, AAA Tr. 1784:3 1786:17, Decl. of Dr. Davis, ¶ 80 81.

### J. LNDD Failed to Comply With the ISL When It Deleted Data

Mr. Landis incorporates all of the facts contained in his Proposed Findings of Fact submitted following the AAA hearing, at pages 41-46, see also Appellant's Brief at 63-73, see also AAA Tr. 365:14-376:5, 575:10-601:7, 705:17-714:24, CAS Tr. 876:7-879:17. In particular note that Cynthia Mongongu admitted to deleting data related to the Mix Cal Acetate on one of seven other B Sample test because it was "incorrect." AAA Tr. 589:14-17.

# K. LNDD Failed to Maintain Chain of Custody Pursuant to ISL 3.2, WADA TD2003LCOC and TD 2003 LDOC

- 1. The opening brief contains detailed reference to citations to the applicable WADA technical documents and a detailed description of breaks in the chain of custody.
- 2. In particular, at the CAS hearing, additional facts were learned, in particular, those centered on Exhibit 103, LNDD 1590, 1591 and Exhibit 24, USADA 0006.
- a. LNDD 1590 and 1591 were only provided to Mr. Landis as exhibits attached to USADA's AAA reply brief, as an attempt to establish continuous chain of custody based upon underlying documents after conceding that the document in the document package was only a "summary sheet." USADA Pre-Hearing Reply Brief at 19.
- b. LNDD 1590 and 1591 are conflicting documents because they describe the A Sample bottle coming out of the CH.FR.1 at different times by different operators.
- c. LNDD 1590 states that Operator 44 removed the B Sample from CH.FR.1 at 7:25 a.m. LNDD 1591 states that Operator 42 removed the B Sample from the CH.FR.1 at 7:30 a.m.
- d. In Garcia's Reply Declaration dated March 12, 2008, she stated that "she made two mistakes" that LNDD 1591 should have read Operator 42 and 7:25 a.m. She asserted that LNDD 1590 is the correct document and should be relied upon.

- e. Ms. Garcia repeatedly denied knowing about her Reply Declaration, either because her memory is so poor or because she did not write it or see it before being questioned about it on March 24. First and foremost, she denied that she wrote the Reply Declaration in response to at least three separate questions. *See* CAS Tr. 1241:4-1242:25. She only admitted remembering the declaration after having it read to her in her entirety by Mr. Paulsson, and after USADA's counsel prompted her numerous times about it. *See* CAS Tr. at 1246:6-1248:22.
- f. Even after having the declaration read to her in its entirety, Ms. Garcia would not admit to an independent knowledge of any fact. In particular, in response to a question about how she obtained the A Sample bottle, she stated "No I don't because obviously two years is too long . . . " CAS Tr. 1251:9-20. Further, and most importantly, she had no memory and did not testify to how she knows that 1590 is correct and 1591 is incorrect. 1253:12-1254:10. Because Ms. Garcia has no such independent memory, she can not resolve any difference between LNDD 1590 and 1591.
- g. This problem is compounded by the fact that Operator 42 (Laurent Martin) was present in the building with Operator 44 (Jean Antoine Martin) at the time that the transfer took place. CAS Tr. 725:4-15.

## L. LNDD Failed to Comply With the ISL In Making Its Forensic Corrections

Mr. Landis incorporates all of the facts contained in his Proposed Findings of Fact submitted following the AAA hearing, at pages 51-53, see also Appellant's Brief at 73 - 74, Decl. of Dr. Goldberger, at  $\P\P 100 - 115$ .

### M. Dr. Botre's Supervision of the Reprocessing and Retesting Process

### 1. The Retesting Procedure

- a. Mr. Landis provided seven urine samples during the 2006 Tour in addition to Sample 995474: Stage 2 (Sample 995642 on July 3), Stage 9 (Sample 994203 on July 11), Stage 11 (Sample 994277 on July 13), Stage 12 (Sample 994276 on July 14), Stage 15 (Sample 994075 on July 18), Stage 19 (Sample 994080 on July 22), and Stage 20 (Sample 994171 on July 23). See Ex. 41, USADA0412, 0419, 0426, 0433, 0440, 0447, 0458, 0465.
- b. Each of these seven other samples were tested at LNDD during the 2006 Tour and none of these other samples displayed an AAF in the test of the A Sample. *See* Ex. 41, USADA0415, 0422, 0429, 0436, 0443, 0461, 0468.
- c. During the litigation before the AAA, USADA requested that the AAA Panel authorize it to have B samples of these seven other samples tested for the presence of testosterone. Mr. Landis strenuously objected to the further testing as it was against the USADA protocol, the WADA Code and the UCI rules to perform testing on a B sample when the A sample resulted in a negative test. Mr. Landis further objected to having this testing performed at LNDD due to the inherent bias LNDD has because it is essentially a party to this litigation, and Mr. Landis had made explicit accusations of incompetence and misconduct by the laboratory in the testing of his Stage 17 sample. See Mr. Landis' Motion in Limine re Exclusion of Re-Testing Results during AAA proceeding; Interlocutory Order at 2-6.

- d. Following extensive briefing, the AAA Panel found that despite the inherent conflict, USADA could have LNDD test each of the other seven B samples. The retesting began at LNDD on April 16, 2007. Representatives from both parties attended the retesting, but as is described in great detail in Mr. Landis's Motion in Limine to Exclude the Retesting Results filed in the AAA proceeding, were not permitted to observe the entire testing procedure, and in fact, Mr. Landis's expert, Paul Scott, was excluded from the entire laboratory on the last days of testing. See id.
- e. The testing of Mr. Landis's seven other B samples was performed on the IsoPrime 2 instrument. Mr. Landis did not request that the retesting be performed on the IsoPrime 2 instrument; indeed, Mr. Landis was not aware that LNDD had a second GC/C/IRMS instrument. The results of the retesting are summarized at Exhibit GDC01363.
- f. During the AAA proceeding, USADA placed significant weight on the results from seven other B sample tests. However, in this proceeding USADA and its expert witnesses have all but abandoned these results as part of their case.
- g. The reason for USADA downplaying the results of these seven other B sample tests is because these results are just as unreliable and inaccurate as Mr. Landis's Stage 17 result. Similar to the Stage 17 sample test, the chromatography was poor. In fact, during the AAA hearing, some of USADA's expert witnesses testified to the poor quality of these chromatograms. See, e.g., AAA Tr. at 1213:8-18. But, most importantly, log files from the IsoPrime 2 instrument establish that during the testing of these seven other B samples, LNDD routinely re-ran quality controls and overwrote existing data during the testing process. CAS Tr. at 876:7-879:17; AAA Tr. at 365:14-376:5, 575:10-601:7, 705:17-714:24.
- h. Additionally, as described by Dr. John Amory, and as noted above, when the results of the seven other B sample tests, their original T/E test results, and the Stage 17 A and B sample T/E and GC/C/IRMS test results, the total picture is contrary to the known science of testosterone metabolism. *See* discussion of testosterone metabolism, *infra*.

## 2. The Reprocessing of the Electronic Data Files

- a. At the start of this litigation, Mr. Landis requested several categories of documents from USADA. USADA refused to produce the documents requested. As part of his discovery requests, Mr. Landis requested the Electronic Data Files ("EDFs") from the IsoPrime 1 instrument. After litigating this discovery dispute, the AAA Panel in a March 23, 2007 letter entitled Ruling on Second Request for Documents and in Procedural Order No. 2 ordered that LNDD make available the EDFs from Sample 995474. However, because USADA's attorneys argued that Mr. Landis's attorneys would manipulate the data in these files if produced, the AAA Panel ordered that a Panel appoint an independent expert.
- b. In Procedural Order Number 2, the AAA Panel wrote that "[t]o facilitate the discovery process and to obviate any possible battle of experts on each side the Panel is to appoint their own expert. . . . The expert will be requested by the Panel, the Parties and their experts to run various tests on the Electronic Data Files (EDF) of LNDD." The procedural order does not authorize or notify the parties that this Panel appointed expert was going to opine or

provide any analysis whatsoever with regard to the EDFs other than facilitating their removal and performing the analysis.

- c. The discovery order and the Procedural Order Number 2 were not issued until the end of March 23, 2007, approximately one and one-half months before the scheduled hearing date of May 13, 2007. As a result of the Panel requiring a Panel-appointed expert before the EDFs could be analyzed and the proximity to the hearing date, Mr. Landis immediately sought to find a suitable expert. The parties, however, were not able to mutually agree upon an expert to be appointed, and the AAA Panel in early April 2007, just over a month before the hearing date and only weeks before Mr. Landis's hearing brief was due to be filed, suggested the appointment of Dr. Botre, the WADA Laboratory Director for the Italian laboratory.
- d. Immediately after the AAA Panel suggested Dr. Botre be appointed the AAA Panel expert, Mr. Landis immediately objected to his appointment. In a letter dated April 13, 2008, Mr. Landis agreed to have a conference call with the AAA Panel, USADA, and Dr. Botre, but noted that it objected to Dr. Botre because (1) Dr. Botre's resume did not list any experience with the CIR test method, (2) as a WADA laboratory director, Dr. Botre was subject to the WADA Code of Ethics, Section 3.3, which prohibited Dr. Botre from engaging "in testing or providing expert testimony that would call into questions the integrity of the individual or the validity of work performed in the anti-doping program," and (3) Dr. Botre does not appear to have the skills to remove the EDFs from the IsoPrime computer system. March 13, 2007 Letter from Maurice Suh to the AAA Panel.
- e. On April 16, 2007, the AAA Panel notified the parties that Dr. Botre, in addition to being a WADA laboratory director, sat on the WADA Laboratory Working Group with USADA's Chief Science Officer, Larry Bowers. (The same Larry Bowers who told Dr. Matthews to testify contrary to USADA's discovery responses.)
- f. On April 18, 2007, three weeks before the trial and a little over a week before Mr. Landis's Pre-Hearing brief was due on April 26, 2008, the parties, the AAA Panel and Dr. Botre had a conference call to discuss Dr. Botre's qualifications.
- g. As Mr. Landis repeatedly argued in the discovery proceedings, obtaining the EDFs were critical to his defense. With three weeks before the hearing date, Mr. Landis faced a Hobson's choice, either accept Dr. Botre as the Panel-appointed expert and obtain the EDFs, or reject Dr. Botre as the expert and risk not obtaining the EDFs before the hearing. Faced with this choice, Mr. Landis withdrew his objection, due to the need for the evidence. Mr. Landis was not aware that Dr. Botre was going to issue a report opining on issues such a manual processing and so forth.
- h. On April 26, 2007, Dr. Botre and representatives for both parties arrived at LNDD. When they arrived at LNDD, they were told that: (1) the EDFs from the IsoPrime1 (the instrument used to test Sample 995474) had already been copied to an archive CD and (2) the original information on the IsoPrime1 hard-drive had been erased. A further discussion of the erasing of the IsoPrime 1 hard drive is found in Dr. Botre's Report.

- i. On May 4, 2007, nine days before the AAA hearing, Dr. Botre and representatives for both USADA and Mr. Landis arrived at LNDD. Pursuant to directions provided by Mr. Landis' representatives, LNDD technicians performed a series of operations on the EDFs. Because LNDD technicians did not know how to transfer data from the CD onto the computer operating the IsoPrime1, Dr. Davis performed this part of the procedure. *See* Dr. Botre's Report.
- j. As described at the trial, there were several operations performed using the EDFs: (1) LNDD's attempt to reproduce the original test results using the same processes used to determine those results, i.e., manual processing the results, (2) delta-delta values were calculated using the automatic background subtraction embedded within the software program, (3) delta-delta values were calculated with the automatic background subtraction disabled and (4) delta-delta values were calculated using the Masslynx software loaded onto the IsoPrime2. The chart showing the results of the reprocessing is Exhibit GDC01350. See Dr. Botre's Report.
- k. In USADA's closing argument, significant time was spent reading the . Botrè report to the Panel. The Botre report, however, should not be given any weight by this Panel for the following reasons:
- i. Dr. Botre's opinions and conclusions about the manual processing were clearly flawed. Dr. Botre concludes that manual processing "appears" to be scientifically sound based on the results of the reprocessing. See Dr. Botre Report at ¶ 7.11. In other words, Dr. Botre assumed that, because the blank urine values that resulted in a nearly positive test result using the automatic processing were converted into the expected results using manual processing, LNDD's manual processing made the results more reliable and accurate. However, and critically, an equally likely conclusion one can draw from the reprocessing results is that the conversion of the nearly positive blank urine results using automatic subtraction into the expected negative results using manual processing is that manual processing can be used to artificially manipulate the results (in this case a quality control) to show that the machine is working properly when it is indeed not working properly. This is also consistent with Ms. Frelat's testimony where manual processing of the B sample is conducted in order to reproduce the results of the A sample.
- ii. The lack of reliability in Dr. Botre's conclusions in his report is also shown by considering his conclusions with respect to the log files. In paragraph 8.7 of his report, Dr. Botre notes that "the time intervals between the single instrumental runs are consistent with the total times of the assays . . . ." This allegedly "objective and independent" conclusion disregards and fails to account for the undisputed fact that LNDD re-ran quality control portions of the sample runs and deleted the original data obtained by overwriting the file name. See CAS Tr. at 876:7-879:17; AAA Tr. at 365:14-376:5, 575:10-601:7, 705:17-714:24. Either Dr. Botre was not qualified to review these log files and did not notice these errors or he observed these errors but withheld them from his report, regardless of what the reason for the failure to include the re-running of quality controls and deletion of data in his report establishes the incompleteness of his conclusions and their lack of reliability.
- iii. When Dr. Botre decided in his report to make opinions and conclusions about the laboratory, under the WADA Code of Ethics, Dr. Botre could not have set

forth an opinion or conclusion that questioned the validity of LNDD's testing. Under the WADA Code of Ethics, the only conclusion and opinion he could reach was that the laboratory processes were acceptable.

- iv. The parties were given no notification that Dr. Botre was going to provide a report that went beyond merely stating facts. Dr. Botre improperly set forth opinions and conclusions he made about the laboratory processes. When Mr. Landis chose not to object to Dr. Botre as the AAA Panel-appointed expert, Dr. Botre had the limited role of facilitating the removal and analysis of the EDFs.
- v. This hearing is a de novo hearing and the Panel is not bound by the findings of the AAA Panel in its majority decision, likewise, the Panel is not bound by the report of the AAA Panel's expert. This Panel has been presented with documents and testimony supporting Mr. Landis's arguments about the deficiencies in LNDD's CIR testing method and has heard the testimony and arguments of USADA in response. This Panel is capable, and is required under CAS Rules, to make its own independent factual and legal findings. For example, this Panel has seen that some of the delta-delta values that were reported by LNDD differ drastically from some of the delta-delta values during the reprocessing using the sample manual processing technique. That Dr. Botre concluded that manual processing is sufficient is meaningless, as this Panel on its own can conclude based on the same evidence whether it is scientifically valid.
- vi. In light of the time constraints, Mr. Landis was provided with no reasonable choice with respect to whether Dr. Botre should be appointed the Panel's expert. An objection to the appointment of Dr. Botre would have prevented Mr. Landis from obtaining the critical evidence he need to present a defense. With the considerable bias Dr. Botre simply by being a WADA laboratory director, had there been sufficient time to object to Dr. Botre and still obtain the EDFs, Mr. Landis would have maintained his objection to Dr. Botre.
- l. During USADA closing argument, it noted that despite having the opportunity to cross-examine Dr. Botre about his report, Mr. Landis chose not to do so. But no weight should be afforded to USADA's argument because a choice to cross examine the Panel's expert who will help decide the case is not much of a choice. As noted above, Mr. Landis disagrees with the assumption and conclusions made by Dr. Botre in his report. By the time of the hearing, Dr. Botre was the Panel's expert and part of the deliberative process in deciding the outcome of the case. Potentially discrediting Dr. Botre in a public hearing by subjecting him to cross-examination with respect to the obvious deficiencies in his report and his inherent bias as a WADA laboratory director would provide little benefit because after being discredited and publicly embarrassed, he was going to assist the arbitrators in the deliberative process.

# N. Dr. DeBoer's Presence at a Portion of the Sample B Test Does Not Constitute a Waiver of Claim on Appeal

- 1. Dr. DeBoer attended the Sample B testing as Mr. Landis's representative.
- 2. There is no "waiver" arising from Dr. DeBoer's attendance at the Sample B testing of the issues and arguments encompassed within this appeal:

- a. Dr. DeBoer did not attend any procedure associated with the A Sample CIR test.
- b. There is no precedent for the proposition that the attending expert must determine the laboratory science errors in every case or somehow a waiver of that issue may result.
- c. The issues contained within this appeal are highly complex in nature, and often require background documents that were not available to Dr. DeBoer. He cannot fairly have been expected to discover them all in a few days.
- d. Dr. DeBoer recognized that the T/E test failed to meet the "minimal WADA requirements" for identification and therefore his official conclusion was "non-conclusive." See Exhibit 25, USADA 368. Dr. DeBoer did not specifically mention the SIM requirement that ultimately resulted in the overturning of the T/E finding, nor did he specify what problems existed with compound identification in the T/E test, nor did he conclude that an ISL violation had occurred. At no time did the AAA Panel or USADA assert that this lack of specificity was tantamount to a waiver.
- e. Dr. DeBoer was not able to see documentation regarding the IRMS analysis, and concluded that he could "not give an adequate evaluation of GC/C/IRMS analysis of the respective sample." See Exhibit 25, USADA 369. Similarly, in a case of this complexity and reliance upon documents, his conclusion should not result in any kind of waiver of claim.
- f. Moreover, Claire Frelat testified that Dr. DeBoer did not see the entire CIR test procedure because he went to discuss the lack of documentation with Dr. Ceaurriz. *See* Test. of Frelat. CAS Tr. at 911:17-912:7.
- g. No adverse inference should be drawn from his lack of presence at the CAS proceeding. Dr. DeBoer did not have the IRMS expertise that Mr. Landis's other experts possessed, and Mr. Landis' budget did not allow for it.

# O. Test Results Do Not Correspond With Known Science of Metabolism of Testosterone

- 1. Mr. Landis incorporates by reference the arguments contained in his Appellate Brief establishing that the test results are not consistent with the known science of testosterone metabolism.
- 2. Both the initial declarations and rebuttal declarations of Dr. Shackleton and Dr. Clark attempt to discredit Dr. John Amory's statement when the total picture, including the Stage 17 test results, the test results from the seven other B samples, and the respective T/E ratios for all of these samples are considered, the test results are not consistent with known science. But instead of looking at the total picture, these declarations look at one data point in the whole picture, such as the difference between the delta-delta value for the 5-Alpha P-diol and 5-Beta P-diol, and argue that this occurrence is consistent with known science. Even if the Panel were to accept the statements of USADA's witnesses, which Dr. Amory in his rebuttal declaration and cross-examination largely discredits, there is still no evidence that contradicts Dr. Armory's

conclusion that the when all of the test results are considered, the test results are not consistent with the known science of testosterone.

3. As Dr. Amory stated in his testimony, to be consistent with the known science of testosterone metabolism, one would expect "to see the T/E ratio go up in a high-mode individual and we'd like to see the metabolites both go down and be significantly suppressed during testosterone administration." CAS 454:22-455:9. When the results set forth in GDC1363 are analyzed, it is evidence that this did not occur here.

# P. The Presence and Importance of Bias, False Statements, Fraudulent Documents and Credibility of Witnesses

#### 1. False Documents

a. From the beginning of this proceeding, Mr. Landis requested that USADA and LNDD produce documents to support the anti-doping rule violation charge against him. USADA strenuously objected to the production of these documents, hiding behind LNDD's alleged accreditation, which as discussed above, LNDD did not actually have for the CIR test method performed on Mr. Landis's samples. Forced to produce documents to support the bald assertions made about the reliability of LNDD's test results, LNDD produced at least four fraudulent documents:

### b. August 2006 Linearity Study

- i. LNDDs SOP requires that LNDD perform a linearity testing once a month. See Exhibit 112, SOP I-N-29, LNDD 0547, section 4.2.6.2. By failing to produce a linearity test result for August 2006, the AAA Panel found that LNDD did not comply with its own SOP. AAA Majority Award at 218.
- ii. Just three weeks before the hearing in this proceeding, USADA moved this Panel for the introduction of the August 2006 test, which is Exhibit 155. USADA Submission to Panel of February 27, 2008. LNDD 2020 because it was recently located by LNDD.
- iii. LNDD's rather convenient discovery of the linearity document is contrary to USADA's discovery responses. Mr. Landis requested that LNDD produce all linearity tests performed around the period in which Mr. Landis's Sample was tested. Second Request for Documents at C9. In response, LNDD produced the linearity tests for June, July and September of 2006. Exhibit 26, LNDD0313, LNDD0320, LNDD0327. It was then confirmed by USADA in a later discovery letter that there were no linearity tests performed in August 2006. Letter from Holme Roberts & Owen, LLP to the AAA Panel, dated March 30, 2007 at Page 11.
- iv. Ms. Frelat, despite allegedly being the technician who performed the August linearity test, was never consulted about whether an August linearity test was performed and, if so, where it would be located. CAS Tr. at 884:2-12. Indeed, Frelat was not involved in the discovery process at all and was not consulted before the discovery responses were issued. CAS Tr. at 884:14-886:12.

- v. The August 2006 linearity document is fraudulent because:
- A) All the other linearity tests produced by USADA have file names and batch names that match the date on which the linearity test was performed. For example, in June, the batch and file names are 260606. See e.g., Exhibit 26, LNDD0313. The August linearity test does not use the date for the batch and file name, rather, the batch and file name are "Stab 3." Compare Exhibit 155, LNDD 2020, with Exhibit 26, LNDD 0313, 0320 and 0327.
- B) The printouts/screenshot of the files stored on the IsoPrime 1 hard drive, retrieved during the supervision of Dr. Botre, during the relevant period do not contain a folder with the name "Stab 3." See GDC 875. (The complete list of all harddrive screenshots is GDC00871 to GDC00908.)
- C) Frelat's declaration states that "LNDD staff found the printed data from the August 2006 linearity test." *See* Frelat Decl. at 5. On cross-examination, however, despite only finding the linearity test approximately one month before the hearing, Frelat testified that she thinks that she recalls finding the August 2006 linearity test in the archives with Dr. Bussion. CAS Tr. at 880:11-25. She then says she was not sure if it was Dr. Buisson. In response to the Panel's questioning, Ms. Frelat stated that the reason why she wrote LNDD staff instead of writing "I" found the study was because it was "shorter." CAS Tr. at 919:15-920:4.
- D) The August 2006 linearity test was not discovered in an obscure location, but was allegedly discovered where it would have been expected to be found using LNDD's normal file management system. Ms. Frelat testified that the linearity test was found in a box labeled with IsoPrime 1 and August 2006. CAS Tr. at 882:4-883:3. Frelat further testified that she found that the June, July, and September linearity tests in boxes with similar labeling as the August 2006 linearity test; i.e., IsoPrime 1 and the month and year in which the linearity test was conducted. CAS Tr. 883:10-25.
- vi. Mr. Landis's allegations that this document was fraudulent went unanswered during the hearing.

### c. GC/MS Instrument Maintenance Log

- i. In its Appeal Brief, Mr. Landis asserted that the document package establishes that LNDD used an incorrect column in the GC/MS instrument when performing the CIR test on his samples. *See* Appeal Brief at pp. 37-41; *see also*, Exhibit 24, USADA 124, and Exhibit 25, USADA0303. The failure to use the right column was in violation of LNDD's SOP and could have significantly altered the results of the CIR test.
- ii. In its Response Appeal Brief, USADA contended that while the document package was incorrect, the correct column was used. To support this assertion, LNDD attached a newly produced maintenance log that it posited showed that the column was changed in April 2006 and the correct column was installed. See USADA's Response Appeal Brief at p. 45; Exhibit 142, LNDD 2005.

- iii. The maintenance log was a contemporaneous document in which each entry would be made after the servicing occurred. CAS Tr. at 815:23-817:3. As a contemporaneous document, the entries are supposed to be in chronological order. CAS Tr. at 815:23 to 816:17.
- iv. The maintenance log is fraudulent because the entries in the document are not in chronological order. The entry labeled as sequence 5 was performed on January 30, 2006, whereas, the entry entered below it, sequence 6, was performed on January 20, 2006. See Exhibit 142, LNDD 2005.
- v. The LNDD laboratory technician who is listed as having entered these entries on the document, Ms. Frelat, has no explanation for why the entries were not in chronological order or why the document was not created contemporaneously. Indeed, Ms. Frelat testified that she has no recollection of anything on form and that she "would prefer to say that we see what is on the form. I don't remember. I just can see what's written here." 817:23-819:13.
- vi. Mr. Young, when questioned on this point by Mr. Rivkin, chooses to attempt to mislead the panel, directly contradicting the testimony of Ms. Frelat. Mr. Rivkin asks, "If it is contemporaneous, if it's that day, how would that happen?" Tr. 1471:14-16. Initially, Mr. Young attempts to deceive the panel by suggesting that the entries on the document, contrary to the clear testimony of Ms. Frelat, were in fact, not created contemporaneously. See Tr. at 815:23-816:10, 816:11-17. That the two entries in January were likely created at the same time and the lines were mixed. Tr. 1471:17-22. Then, possibly realizing his contradiction, he falls back on a USADA standard and suggests that the entries simply suggests that "one of those dates was a mistake." Tr. 1471:22-23. These explanations are laughable and provide further evidence that the document is a fraud created after the fact to solve another problem in USADA's theory of the case.

### d. Fraudulent Reference Solution Document

- i. During the AAA proceeding, the validity of the T/E test performed by LNDD was at issue. From the documents produced in the document package, Mr. Landis argued that there were several problems with the concentration of the seven solutions listed on the Exhibit 24, USADA 200. To further investigate these problems, Mr. Landis had requested the reference solution preparation documents. In response, in connection with a production of hundreds of other documents, USADA produced what is now Exhibit 26, LNDD440.
- ii. The reference solution document produced by USADA is not what it was held out to be, the original contemporaneous reference standard solution preparation document. The reference solution preparation document is clearly not the original document because: (1) the handwriting is the same even though multiple operators should have prepared different reference solutions, (2) most importantly, the document in the upper most right-half portion of the chart has two instances when the date of 06-03-07 was altered to reflect the date of 06-03-06. The document was supposed to have been created in 2006, and it is highly unlikely that someone in 2006 mistakenly wrote 2007.

iii. USADA did not in a cover letter or in any other document identify Mr. Landis that the reference standard solution chart was not the original document. Indeed, it was not until USADA Response Appeal brief did USADA concede that the document was not the original. USADA's Response Appeal Brief at 10.

### e. Fraudulent Myriam Garcia's Rebuttal Declaration

- i. USADA submitted to this Panel two declarations on behalf of Myriam Garcia. On direct examination, Ms. Garcia has no recollection of drafting her rebuttal declaration that was signed a little over a week before her testimony before the Panel. On direct when asked if Ms. Garcia submitted two declarations, she responded, "No, only one statement." CAS Tr. at 1241:4-7. After USADA's counsel informed Ms. Garcia that there were two declarations in the record from her, USADA's counsel once again asked if she recalled submitting the second declaration, to which she responded that she did not remember drafting the second declaration. CAS Tr. at 1241:18-1242:5.
- ii. After the Panel ruled that it was best to read Ms. Garcia her declaration to determine whether she recalled signing it, USADA's counsel improperly instructed Ms. Garcia as follows: "Ms. Garcia, we have in front of us *your March 12 statement* in French in addition to your March 5 statement in French. Mr. Paulsson is going to read you parts of *your second declaration* to see if you can refresh *your recollection*." CAS Tr. at 1246:6-12. Only after (1) this instruction from USADA's counsel and (2) Mr. Paulsson reading Ms. Garcia her alleged rebuttal declaration did Ms. Garcia affirm that she signed a witness declaration to this affect. CAS Tr. at 1248:24-1249:3.
- iii. In her alleged rebuttal declaration, Ms. Garcia stated that she made two mistakes in drafting Exhibit 103, LNDD 1591. However, on cross-examination, Ms. Garcia said that she had no recollection of the events of that day and that the only basis for why she thought she made an error on the document was because there was a conflicting document. CAS Tr. at 1251:21-1253:23.
- iv. It is completely implausible on March 24, 2008 that Ms. Garcia could remember a statement she signed and submitted on March 5, 2008 but could not remember, even after substantial prodding by USADA's counsel, that she had signed and submitted a second statement in this case on March 12, 2008.

### 2. False and Misleading Statements

- a. Throughout this litigation, in briefs, in testimony, and in discovery responses USADA and LNDD has made several false and misleading statements. Each one of these false and misleading statements was made with respect to a critical factual point or scientific point in this case.
- b. USADA's false statements began in its discovery responses and its Pre-Hearing and Pre-Hearing Reply Brief:
- c. USADA falsely stated in the pre-hearing briefs that the "... Mix Cal Acetate, Blank Urine, and Mix Cal IRMS controls run in the same sequence minutes before,

during and minutes after Respondent's sample produced the expected analytical results." USADA Pre-Trial Reply Brief ¶ 27, see also, USADA Pre-Hearing Brief at p. 37. There was a five hours and fourteen minutes gap between the last sample fraction and the second Mix Cal Acetate in the A sample, and a four hour thirty-nine minute gap in-between the running of the first Mix Cal Acetate and the first blank urine fraction of the B sample. See Exhibit 24. The order is on USADA 0155, the times are on USADA 0166 and USADA 0183; Exhibit 25. The order is on USADA 0331, the times are on USADA 0360, USADA 0347.

- d. Based on the discovery response, USADA considered the internal standard as a quality control. With this understanding, USADA falsely stated in its pre-trial Reply brief that "[b]ecause the IRMS instrument was accurate in measuring all of the controls, the results for Respondent's samples . . . must be accurate." USADA Reply Brief at ¶ 27. And USADA also stated that ". . . LNDD's results for Respondent's A and B samples must have been accurate because all of the controls run at the same time can be proven to be accurate." USADA Brief at ¶ 144. As Appellant established at the hearing before the AAA, and at this hearing, the internal standard, 5 alpha-androstenol AC, was not accurately measured in the sample fractions and the blank urine fractions. The acceptable range for the internal standard is 02.96 to -30.96. See USADA 0354. The standard failed in the 'A' sample F1 fraction and in the 'B' sample F3 fraction. See USADA 0161, USADA 0346. Additionally, USADA, through their Science Director Larry Bowers, instructed its expert witness, Dr. Mathews, that the internal standard was not used as an isotopic quality control in direct contravention to their prior briefs and discovery response. CAS Tr. 1102:17-1103:25.
- e. USADA's pre-hearing brief incorrectly states that "Respondent's sample is *positive by any criteria*." Appellant's sample would not have been considered positive by the positivity criteria at the UCLA laboratory. See GDC 451. Catlin so testified at:
  - "Q. (By Mr. Suh): If you would obtain the same results, leaving aside a moment whether or not they were accurate . . . you would not declare these results as an adverse analytical finding when you were head of the UCLA laboratory.
  - A. [T]hose criteria, if they're applied to this case, would find it negative."

#### AAA Tr. at 1220:18.

- f. In its Pre-Hearing Reply Brief, USADA falsely states that "[w]hen WADA has established a positivity criteria, they [WADA Laboratories] are not expected (let alone required) to conduct their own studies to validate their criteria." USADA Reply Brief at ¶ 6. This statement was directly contradicted by USADA's own witness, Dr. Ayotte when she testified that a laboratory should validate its positivity criteria. See AAA Tr. at 856:13-857:18. Also, ISL 5.4.4.2.1 states that confirmation methods for threshold substances must be validated.
- g. When asked for all documents that relate to the creation and accuracy of the background subtraction method used by LNDD in the IRMS test, LNDD responded that the "Background subtraction is embedded in the instrument software, which is proprietary to the instrument manufacturer. *LNDD has no separate documentation.*" LNDD Response to 2nd Request for Production #C.10. This statement is false because it is undisputed that LNDD

manually manipulates the background points and has a SOP that describes this process. See Exhibit 112, LNDD 0603-0609.

- h. Similarly, through the discovery process, LNDD was asked to explain how it performed and applied background subtraction, LNDD again responded that "Background Subtraction is embedded in the instrument software, which is proprietary to the instrument manufacturer. LNDD has no separate documentation." LNDD Response to Interrogatory #8. It is undisputed that this statement is simply incorrect. LNDD manually removed and added background points during the processing of Appellant's sample. Therefore, LNDD performed background subtraction by more than relying on the embedded software in the instrument.
- i. USADA's statement that "[w]hen the instrument is operating properly a green light is displayed on the instrument. If the operating pressure become too high, the light turns yellow as a warning followed by red and instrument shutdown." USADA Brief at ¶ 106, USADA Exhibit 32. The light USADA referred does not in fact change color or signify that the operating pressure is sufficient; the light USADA refers to is a power light. See Davis's testimony at AAA Tr. 1787:6-1789:2.
- j. USADA Reply Brief also falsely stated that "[t]here is no WADA requirement to document the location of a bottle sample." USADA Reply Brief at ¶ 8. This statement is clearly contradicted by the statement in WADA Technical Document 2003LCOC which repeatedly states that a laboratory must document the location and movement of the sample in the laboratory and indeed, specially states that "[a] chain of custody is required for both "A" and "B" Sample bottles . . . . " GDC0233.
- k. LNDD reported the andro-11keto delta-delta value of -3.51‰ as positive. Exhibit 25, USADA 0352. However, according to LNDD's own SOP, a delta-delta value between -3.0‰ and -3.8‰ should be reported as unclassifiable. LNDD0617.
- 1. The false statements continued throughout the AAA proceeding and during this CAS Appeal. Because many of the false and misleading statements are dependant on evidence introduced during the AAA proceeding and during the CAS proceeding, the false and misleading statements are included below:
- m. In direct response to the Panel's question about the weight it should give Mr. Landis's argument that the GC/MS maintenance log was a forgery, USADA's counsel stated in his closing that no weight should be given to it because it was not a contemporaneous document. CAS Tr. at 1471:17-22. This response directly contradicts Ms. Frelat's testimony that the document was a contemporaneous document. CAS Tr. at 815:23-816:10, 816:11-17.
- n. USADA's counsel falsely stated in his opening that "the lab applies uncertainty before they call it a positive." CAS Tr. at 188:15-17. While this may be what LNDD's SOP requires, in reporting the results for Mr. Landis's "B" sample, the laboratory reported the Andro 11keto value of -3.51‰ as a positive, despite it not being more negative than -3.8‰. Exhibit 25, USADA 352.

- o. Despite Mr. Landis raising the contradiction in the measurement of uncertainty section of the May 2006 accreditation with the December 2006 accreditation during the cross-examination of Dr. Ayotte in the AAA proceeding, USADA's counsel during opening statement stated that Mr. Landis raised this point for the first time in Dr. Goldberger's declaration. Indeed, USADA's counsel went so far as to say USADA was "shocked" and "scrambled to talk to COFRAC . . . . " AAA Tr. at 878:7-15; CAS Tr. at 189:14–190:8.
- p. USADA's expert witnesses testify, and USADA's counsel argued in his opening statement, that because of the carbon composition of the target compounds, the peak sizes from the GC/MS portion of the CIR test and from the GC/C/IRMS portion of the CIR test would be same. CAS Tr. at 232:7:18; Brenna Decl. at 14-15, Matthews Decl. at ¶ 5-10, Jameou Decl. at ¶ 14-15. The falsity of this statement can be seen by comparing the GC/MS chromatogram at Exhibit 91, LNDD1362 compared with the GC/C/IRMS chromatogram at Exhibit 91, LNDD 1362. In the middle of the GC/MS chromatogram, there is a set of three small peaks, but in the GC/C/IRMS chromatogram, one of the three small peaks is now a relatively large peak (this peak was later identified as the 11-ketoetio peak.
- q. Ms. Mongongu testified that the reason why the IsoPrime 2 machine was not used to run Mr. Landis's samples was because at the time his samples were run, the machine had not been validated yet. CAS Tr. at 757:2-10. However, before Mr. Landis's samples were run, LNDD had in fact reported two samples run on the IsoPrime 2 machine as positive. See Exhibit 110, LNDD 1748-55, 1797; CAS Tr. at 821:11-824:18.
- r. Dr. Brenna said that LNDD did not use the internal standard as a quality control because "they don't keep track of the isotope ratio of the standard either . . . ." CAS Tr. at 979:13-15. LNDD does in fact keep track of the isotopic values of the internal standard on the CIR test results page, see Exhibit 24, USADA 185 and Exhibit 25, USADA 351.
- s. In USADA's opening statement, USADA's counsel in describing the requirements of WADA TD2003LCOC combined the two individual requirements of the LCOC (1) that the name or initial of the person in possession of the sample bottle must be on each chain of custody sheet, and (2) the complete name and signature of the person must appear in the document at least once when he stated that "And finally, the name or initials, and that links to this, 'The individuals complete signature/name should . . . appear in the document at least once." CAS Tr. at 219:18-22, TD2003LCOC. After muddling the TD2003LCOC requirements, USADA's counsel implied that LNDD's chain of custody documentation was compliant because it included "either the initials or *operator code* of the operator." CAS Tr. at 219:23-220:2. That the documents contain an operator code and not initials is in violation of TD2003LCOC when the actual requirements are considered.
- t. In this appeal, Brenna testified that he believed the internal standard was a quality control because he "had done a spot check on their delta values [and] . . . the ones that I looked at were fine." CAS Tr. at 967:22-968:3. During his AAA testimony, however, after it was pointed out that several of the internal standard values were not within specification, Dr. Brenna testified that he "was aware that some of them were a bit outside." AAA Tr. at 314:3-5.

- u. Dr. Brenna, Dr. Jameou, and Dr. Matthews assert that the GC/MS retention times and relative retention times of the target compounds cannot be compared with the GC/C/IRMS retention times and relative retention times of the target compounds. In direct contradiction, Dr. Ayotte testified that at her laboratory it "compares[s] the retention times and we do make sure that the peaks eluting on the GC/C/IRMS is what has been identified by GC/MS. So we use the comparison of course." CAS Tr. at 1289:13-17.
- v. USADA's counsel stated in his opening statement that "Dr. Brenna tried an experiment using the two different columns and he could tell from that experiment that it had to be the correct column in both instruments." CAS Tr. at 201:9-14. This statement falsely characterizes Dr. Brenna's testimony in his declaration in which he stated that "[t]o confirm [his] experience that the order of elution would not change, [he] performed a simple experiment . . . . Indeed, the steroids do elute in the same order on both columns." Brenna Rebuttal Decl. at ¶ 19.
- w. In USADA's opening statement, USADA's counsel stated that "[w]hat you have when you go through these documents is the ability to identify every single individual who touched the bottles in order." CAS Tr. 217:15-19. However, there are conflicting documents about who possessed the "A" sample bottle on July 21, 2006 because LNDD 1590 stated that Operator 44 possessed the sample bottle and LNDD 1591 stated that Operator 42 possessed the sample bottle. Compare Exhibit 103, LNDD1590 with LNDD1591.
- x. Dr. Ayotte testified that based on her review of the documents, she was able to track the movement of the sample bottle while in the laboratory. However, such a task is impossible in light of the conflicting documents at Exhibit 103, LNDD 1590 and 1591.
- y. Ms. Frelat testified that she manually integrated the internal standard because it was a peak with which she was concerned, CAS Tr. 847:5-848:2, 864:20-24, but then when she was asked why she was concerned about integrating the peak if the isotopic value of the internal standard in the sample is not used a quality control, Ms. Frelat responded that it was "like a reflex." CAS Tr. at 864:6-865:24.

### 3. Bias and Credibility

### a. Dr. Matthews

i. The determination of whether the internal standard added to each sample and blank urine fraction is used as a quality control is of critical importance in this case. USADA's expert, Dr. Matthews submitted a declaration in which he stated that the internal standard was not used as a quality control. See Matthews Decl. at 13. When cross examined on his support for this conclusion, Dr. Matthews stated that the only support for this potentially case dispositive point was Larry Bowers, the Chief Science Officer for USADA, the prosecuting agency. CAS Tr. at 1102:17-1103:25. Dr. Matthews did not confirm this statement with anyone at the laboratory or review any document to corroborate what Larry Bowers told him.

### b. Dr. Brenna

i. Brenna is currently receiving a grant from USADA worth \$1.2 million. CAS Tr. at 955:23-956:18. This grant represents nearly 10% of the grant money Dr.

Brenna has received in the last 18 years. CAS Tr. at 960:4-961:4. In addition to already receiving a grant, Dr. Brenna had discussions with Larry Bowers, Chief Science Officer of USADA, about three weeks before his testimony in this case about receiving a new grant from USADA. CAS Tr. at 957:10-958:10.

- ii. In an attempt to explain why his testimony has changed regarding whether the internal standard added to each sample and blank urine fraction is a quality control, Mr. Brenna said that his testimony before the AAA Panel was supported by an "unwarranted" but, at the time rather convenient and helpful, "assumption." CAS Tr. at 969:2-3. Interestingly, when Dr. Brenna was cross-examined in this appeal about why he believes the internal standard is *not* a quality control, Dr. Brenna stated that he is "assuming that based on my experience." CAS Tr. at 981:19-21; see also, CAS Tr. at 982:9-13. In sum, at the AAA hearing, when it was beneficial for the internal standard to be a quality control, Dr. Brenna "assumed" it was, but then during the CAS proceedings, when it was beneficial for the internal standard not be a quality control, Dr. Brenna "assumed" it was not.
- stated that the internal standard is a quality control, Dr. Brenna refused to admit that it would cause him concern about his testimony that the internal standard was not a quality control. CAS Tr. at 984:18-985:16. When pressed, Dr. Brenna said that because the discovery response says measured value, he would interpret the response as stating that the internal standard is a quality control. Dr. Brenna stated that "I interpret measured value not as the retention time which he could be referring to, but as to delta value. . . . but if he has said this is used as a quality control for our delta value and if those are out then we toss the run, then that would be in contradiction." Question by Panel: "To what you understand?" Answer by Brenna: "That's right" CAS Tr. at 987:6-23, 987:24-988:2.
- iv. Dr. Brenna during his re-cross-examination testified that while he did not know what effect the lifting rings had on the IsoPrime 2 instrument, he saw data that showed the lifting rings on the IsoPrime 1 instrument had no effect on the analysis. CAS Tr. at 1087:9-15 ("There are data in the doc packs indicating that the lift rings on the IsoPrime 1 didn't have any effect."). Mr. Landis has never argued that LNDD improperly left the lifting rings on the IsoPrime 1, and in fact, LNDD did not have lifting on the Isoprime 1; Mr. Landis's argument has always been that the lifting rings were on IsoPrime 2. Although there were no lifting rings on IsoPrime 1, Dr. Brenna testified confidently that there was data in the document packet that showed the lifting rings, which did not exist, had no effect. Once again, Dr. Brenna testifies to facts about which he has no personal information because his testimony, if believed, would appear helpful to USADA. Unfortunately, yet again, for Dr. Brenna, his facts simply do not exist.
- v. Dr. Brenna in the AAA proceeding stated that the target peaks in the GC/C/IRMS chromatogram are identified because they have retention times that match the peaks in the GC/MS chromatograms for the same fraction. AAA Tr. at 225:18-22. In the CAS proceeding, Dr. Brenna changed his testimony and now says that the retention times of the GC/MS peaks should not match the peaks in the GC/C/IRMS chromatograms and that identification occurred by matching the peak patterns in the GC/MS and the GC/C/IRMS chromatograms. Brenna Decl. at ¶ 12-13. When this contradiction was presented to Dr. Brenna

on cross-examination, Dr. Brenna stated that these different processes "seem to be descriptions of very similar processes." CAS Tr. at 1000:10-19. This is yet another instance of Dr. Brenna unwilling to concede the obvious contradiction in his testimony.

- vi. Dr. Brenna testified that he did not expect any validation studies to have been conducted by LNDD with respect to their positivity criteria. CAS Tr. at 1017:23-1019:4. This is inconsistent with the testimony of Dr. Ayotte before the AAA Panel in which she testified that despite WADA issuing a suggested positivity criteria, the laboratory should validate the positivity criteria with respect to their particular method. AAA Tr. at 856:13-857:18.
- vii. Despite the obvious problems in having quality controls with an acceptance criteria of 3 out of 4 target compounds, but a positivity criteria of 1 out of 4 target compounds, Dr. Brenna testified that he did not believe a laboratory had to validate this schema to ensure accurate and reliable results were being obtained. CAS Tr. at 1019:21-1020:9.
- viii. When Dr. Brenna was asked whether if he recalls any documents in which the target compounds were identified in the blank urine pool, Dr. Brenna responded that he "didn't make a specific note of that, [he] assume[d] that if they did blank urine - if [he] saw a blank urine analysis that that would be the practice for it. CAS Tr. at 1023:24-1024:4.
- ix. Dr. Brenna testified in his Rebuttal Declaration that "[u]pon inspection of chromatograms it is clear to anyone skilled in GCC-IRMS that the 5α-androstanol acetate chromatography reference standard delta value is measured as outside the +/- .5 permil value because of unresolved interfering substances. Rebuttal Declaration at ¶ 7. Yet, at the AAA hearing, Dr. Brenna testified that he spent considerable time reviewing the chromatograms in this case (indeed, based on his review he made several conclusions that the chromatograms were of good quality) and yet, while he presents himself to be skilled in the CIR test, still testified that the internal standard was a quality control. See AAA Tr. at 306:2-309:24. Dr. Brenna's most recent statements are actually in contradiction to his own conclusions drawn nine months earlier. Since he now realizes his earlier testimony concerning the robustness of LNDD's quality control measures was in error, he changes his testimony in an attempt to benefit USADA.
- x. Dr. Brenna testified that the manual integration was a mechanical process, but there a significant differences between some of the reported delta-delta values and the reprocessed delta-delta values when this supposedly "mechanical" process was used. CAS Tr. at 1077:16-20; GDC 1350.

### c. Dr. Ayotte

i. As a WADA Laboratory Director, Dr. Ayotte has an inherent conflict between taking an oath to tell the truth and the requirements of the WADA Code of Ethics, Sections 3.3 and 3.4, both of which prohibit providing expert testimony or testing services in defense of an athlete in an anti-doping case. *See* Ex. 8, at Annex B, Sections 3.3 and 3.4.

- ii. Dr. Ayotte has also previously publicly stated that "[w]hen rich athletes and American lawyers fight against the validity of tests and controls, we better be creative!" GDC01354.
- iii. In defending her testimony before the AAA Panel that she was comfortable with the T/E test performed by LNDD, Dr. Ayotte testified in this proceeding that obtaining three diagnostic ions was only recommended by the ISL and the technical document and that LNDD's failure to do this, or at least produce evidence of compliance, it was not a violation. AAA Tr. at 826:11-14, CAS Tr. at 1291:22-1292:24 ("I view it as not in line with what the ISL and the technical document is *recommending*."). According to Dr. Ayotte, the ISL and technical documents no longer provide requirements, they merely provide recommendations. But after further examination, Dr. Ayotte admitted LNDD's T/E test was in violation of the ISL and technical documents. CAS Tr. at 1295:18-20.
- iv. When Dr. Ayotte testified before the AAA Panel that she was comfortable with the T/E test results, she knew "that [LNDD] had not followed the ISL and the technical documents," but instead of being forthcoming and entirely truthful, Dr. Ayotte chose not to inform the Panel that she knew that LNDD's T/E test was in violation of the ISL and technical documents. CAS Tr. at 1297:8-10.
- v. When Dr. Ayotte testified at the AAA hearing, she indicated that accredited method EC24C was the method used by LNDD for the T/E ratio. AAA Tr. 831:12-15. As we now know, this is not true. In fact, the method used was the unaccredited EC24D. When confronted with this fact in Dr. Goldberger's declaration, Dr. Ayotte responded that it was her opinion that EC24D did not need to be accredited because it was a "complement" to EC24C. Ayotte Resp. Decl. at para. 43. Once again, Dr. Ayotte testified to something she knew to be untrue because she felt that her obfuscating testimony was more valuable to USADA's case than simply admitting the truth and addressing the problem with the explanation she now gives.
- vi. When Dr. Ayotte prepared her declaration in this case she wholesale adopted the AAA panel's statement that documents existed that allowed her to trace the movement of the A and B bottle the entire time. Specifically she "was able from the different documents provided by the laboratory, to follow who had possession of the bottles..." Ayotte Declaration at para. 19. This was proven impossible given the contradiction between LNDD1590 and LNDD1591. When confronted with this fact in Dr. Goldberger's Declaration, Dr. Ayotte responded that she knew this contradiction all along. Ayotte Resp. Declaration at para. 28. Rather than acknowledge the deficiency and attempt to explain it, Dr. Ayotte chose to hide it in the hopes that no one would notice.

### 4. Changing Stories

- a. Lastly, USADA entire evidentiary plan has been shifted when it is has been confronted with evidence proving that its litigation strategy or story is false. The three best examples are the wholesale shifts in testimony of the three following critical issues areas:
  - i. Chain of Custody, Opening Presentation, Slides 98-135, CAS Tr. 135:18-155:15.

- ii. Peak Identification, Opening Presentation, Slides 52-81, CAS Tr. 89:2-114:11.
- iii. Quality Control, Opening Presentation, Slides 24-51, CAS Tr. at 72:1-87:22.

### Q. The Sanction Imposed on Mr. Landis Should Be Shortened, Not Lengthened

- 1. Mr. Landis Voluntarily Accepted His Sanction the Date He Was Fired From the Phonak Team, August 5, 2006
- a. The AAA Panel imposed a two-year sanction upon Mr. Landis. However, the Panel ruled that because Mr. Landis had "voluntarily accepted" his suspension on January 30, 2007, UCI Article 275 required that his period of ineligibility should begin to run on that date.<sup>5</sup>
- b. Article 275 provides that "Any period during which provisional measures pursuant to articles 217 through 223 were imposed or voluntarily accepted "...shall be credited against the total period of Ineligibility to be served...." As the CAS Panel deciding the appeal in the Tyler Hamilton case clearly held, Article 275 "is read to allow for the voluntary acceptance of a suspension...by the UCI Rider himself." If the rider does take action to voluntarily accept his suspension, Article 275 mandates that he be credited for all of the time that suspension was voluntarily accepted.
- c. Mr. Landis *first* voluntarily accepted his suspension when he was fired by the Phonak team on August 5, 2006.<sup>8</sup> It is undisputed that Mr. Landis did not compete at all from the date he was fired on August 5, 2006, through the January 30, 2007 date that the AAA Panel accepted as his voluntary acceptance. Mr. Landis's intent to not compete was confirmed when he chose not to renew his USA Cycling license when it came up for renewal in December,

<sup>&</sup>lt;sup>5</sup> AAA Panel Decision, September 20, 2007, at Paragraph 320(6), page 83.

<sup>&</sup>lt;sup>6</sup> UCI Anti-Doping Rule, Art. 275 (2008), emphasis added. Article 275 was amended by the UCI on June 26, 2007, but the quoted language remained unchanged. Moreover, CAS precedent clearly holds that new regulations do not apply retroactively to fact situations occurring prior to their entry into force, unless the new regulations are more favorable to the athlete. See, e.g., CAS Advisory Opinion requested by Comitato Olimpico Nazionale Italiano, 2005/C/841 at Paragraphs 51-53 (citing cases).

<sup>&</sup>lt;sup>7</sup> Hamilton v. USADA, CAS 2005/A/884, Paragraph 96.

<sup>&</sup>lt;sup>8</sup> AAA Hearing, Tr. Of R. at 1311.16-1312.2. See Hamilton v. USADA, CAS 2005/A/884, Paragraph 96.

2007.9 Mr. Landis has not competed in a single sanctioned event since he was fired by the Phonak team on August 5, 2006.<sup>10</sup> Mr. Landis has, in fact, turned down lucrative offers to compete, awaiting the formal outcome of this process.<sup>11</sup>

d. The CAS Panel considering the *Hamilton* and *Millar* cases must concluded that the voluntary acceptance of a suspension begins when a rider is fired from his team. <sup>12,13</sup>. In the event that this Panel concludes that the AAF should be upheld, it should hold that Mr. Landis's period of ineligibility began on August 5, 2006, not January 30, 2007 or September 20, 2007.

# 2. <u>Mr. Landis Has Not Competed in a USA Cycling-Sanctioned Event Since</u> Receiving Notification of the LNDD's Positive Test Result

- a. USADA has asked this Panel to further extend Mr. Landis's sanction, because in August 2007 he rode in the Leadville 100, an event USADA claims was sanctioned by USA Cycling.
- b. The evidence is to the contrary. It is uncontroverted that the Leadville 100 is local cycling event organized as a fundraiser for the city of Leadville, Colorado; its organizer, Ken Chlouber, is a Colorado state senator representing Leadville. Neither Mr. Landis nor any other rider was required to present a cycling license in order to participate in that event; Mr. Landis did not even possess a current USA Cycling license at the time he rode in the Leadville 100 in August 2007. It is also undisputed that no prize money was awarded, no USA Cycling points were awarded, and the standard USA Cycling categories were not employed. It is also uncontroverted that prior to riding in the Leadville 100, Mr. Landis informed the organizers that

<sup>&</sup>lt;sup>9</sup> See Declaration of Floyd Landis, March 7, 2008, Paragraph 36 [hereinafter, "Landis Declaration"]. Note: there is a typographical error in this paragraph. The date "August 2006" should read "August 2007."

<sup>10</sup> Id. at Paragraphs 33-41; CAS Appeal, Landis v. USADA 2007/A/1394, Tr. of R., 362:22-364:18.

<sup>11</sup> CAS Appeal, Landis v. USADA, CAS 2007/A/1394, Tr. of R., 362:22-364:18.

<sup>12</sup> CAS 2005/A/884 at Paragraph 96, 98.

<sup>13</sup> Millar v. UCI, CAS 2004/A/707, Paragraphs 53-54.

<sup>14</sup> Landis Declaration at Paragraph 35.

<sup>15</sup> Id. at Paragraph 36.

<sup>16</sup> *Id*.

he could not race in a sanctioned race, and was assured by them that a) the event was not sanctioned; and b) the organizers had contacted USA Cycling personnel – including USA Cycling Chief Operating Officer Sean Petty – concerning the matter and were assured that there were no problems with Mr. Landis's participation.<sup>17</sup>

c. Mr. Landis took no actions in contravention of his voluntary acceptance of suspension. He took reasonable steps to ensure that he did not race in a sanctioned race. He is an experienced cyclist, and recognized that the Leadville 100 bore none of the indicia of a sanctioned race-riders did not need a license to compete, there were no points awarded, standard race categories were not used, and no prize money was awarded. While he was not privy to any paperwork the organizers may have filed with USA Cycling, he obtained assurances from the race organizers that the race was not sanctioned, and he relied on those representations. Moreover, Mr. Landis was told by the organizers that USA Cycling personnel had been informed of his intent to participate and raised no concern. He was present during the telephone conversation between USA Cycling Chief Operating Officer, Sean Petty and race organizer Ken Chlouber, and understood Petty to tell Mr. Chlouber that "there was no issue." None of these actions are inconsistent with Mr. Landis's voluntary acceptance of his suspension. USADA's request for an extension of the sanction imposed should be denied.

# R. USADA's Unethical Behavior Should Result in It Being Ordered to Pay Mr. Landis's Costs of Appeal

1. From the outset of this case, Mr. Landis has had to fight to obtain crucial discovery, he has faced discovery abuse, <sup>16</sup> and he has been confronted with fabricated evidence. <sup>19</sup> USADA has tendered witnesses who were completely unable to remember submitting entire declarations, <sup>18</sup> witnesses who purposefully obfuscated the truth in their declarations, <sup>19</sup> and expert witnesses whose substantive testimony was spoon-fed to them by USADA's own scientific director, Larry Bowers. With respect to the substance of the case, USADA's explanation of the steps taken by LNDD when it analyzed Mr. Landis's Stage 17 samples changed each time Mr. Landis pointed out a flaw in the analysis, causing Mr. Landis to reformulate his challenge to meet the ever-evolving story of how LNDD conducted its IRMS testing. All of these improper tactics have drastically increased the cost and complexity of Mr. Landis's defense and wasted the time and resources of both Mr. Landis and this Panel.

<sup>&</sup>lt;sup>17</sup> *Id.* at Paragraph 37-8; CAS Hearing, *Landis v. USADA*, CAS 2007/A/1394, Tr. of R., 362:22-363:20.

<sup>18</sup> Id.

<sup>19</sup> See Dissenting Opinion, Arbitrator Chris Campbell, September 20, 2007 at 11, ¶30; Motion to Strike Untimely Exhibits and Related Testimony at 11-12 (linearity document); 21-22 (reference solution log).

2. The general rule is that once the Appellant has paid the Court Office Fee, CAS appeals are free, with each party advancing the cost of its own witnesses and litigation expenses.<sup>20</sup> At the close of the appeal, however, the CAS Panel has the discretion to "decide which party shall bear [the costs] or in what proportion the parties shall share them, taking into account the outcome of the proceedings, as well as the conduct and financial resources of the parties."<sup>21</sup> This is a case in which USADA's should be compelled to bear the costs of Mr. Landis's appeal as a sanction for its litigation misconduct. Appellants urge this Panel to should exercise the discretion granted in CAS Rule 65.3, and order USADA to pay the costs of Mr. Landis's appeal.

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Respectfully submitted,

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<sup>&</sup>lt;sup>20</sup> CAS Rules 65.1, 65.2, 65.3.

<sup>&</sup>lt;sup>21</sup> CAS Rule 65.3.