303-866-0200

4/19/2008 12:06:13 AM PAGE 1/051 Fax Server



## Holme Roberts & Owen LLP

Attorneys at Law

90 South Cascade Avenue, Suite 1300 Colorado Springs, Colorado 80903-1615 tel 719.473.3800 fax 719.633.1518 www.hro.com

To: Maurice Suh

Company: Gibson Dunn & Crutcher

Fax: 9-1-213-229-6260

Phone:

From: Marcella Aud Fax: (719) 633-1518 Phone: (719) 381 8439

E-mail: Marcella.Aud@hro.com

### NOTES:

Date and time of transmission: Saturday, April 19, 2008 12:05:52 AM

Number of pages including this cover sheet: 51

CONFIDENTIALITY NOTE: The information contained in this facsimile transmittal sheet and in any document(s) that follow is for the exclusive use of the addressee and may contain confidential, privileged and nondisclosable information. If the recipient of this facsimile is not the addressee, or a person responsible for delivering this facsimile to the addressee, such recipient is strictly prohibited from reading, photocopying, distributing or otherwise using this facsimile transmission or its contents in any way. If the recipient has received this facsimile transmission in error, please call us immediately and return the facsimile transmission to us via the postal service. Thank you.

DENVER	BOULDER	COLORADO SPRINGS	LONDON
			_
LOS ANGELES	MUNICH	SALT LAKE CITY	SAN FRANCISCO

IN THE COURT OF ARBITRATION FOR SPORT

Fax Server

## 303-866-0200 4/19/2008 1:

FLOYD LANDIS	)	
Appellant,	)	
V.	)	CAS 2007/A/1394
UNITED STATES ANTI-DOPING AGENCY	)	
Respondent.	)	

#### <u>UNITED STATES ANTI-DOPING AGENCY'S POST-HEARING BRIEF</u>

The United States Anti-Doping Agency ("USADA") respectfully submits this Post-Hearing Brief.

#### I. Introduction

Having reached the end of two hearings in this matter, Appellant's arguments have been exhaustively reviewed. Yet despite the resources and efforts expended, Appellant's defenses remain unpersuasive and scientifically meritless. With the exception of the "column" and "accreditation" issues, Appellant has raised no new defenses which were not before the AAA Panel. In its 84-page Arbitration Award ("AAA Decision"), the AAA Panel, with the assistance of its independent scientific expert, Dr. Botrè, thoroughly explained that none of Appellant's myriad attacks undercut the reliability of LNDD's IRMS findings. The AAA Decision described Appellant's primary arguments as "scientifically totally unacceptable and fundamentally flawed." AAA Decision at ¶189. Based on the evidence presented on appeal, this Panel should reach the same conclusion.<sup>1</sup>

\_

<sup>&</sup>lt;sup>1</sup> Pursuant to the Panel's instructions, USADA sent a proposed list of issues for post-hearing briefs to Appellant. Rather than working on a joint list of issues as suggested by Respondent's counsel, see CAS Tr. at 1498:10-16, Appellant submitted his own list of issues. Both letters are attached for the Panel's convenience, with references in this document to both lists.

# II. Burden of Proof<sup>2</sup>

303-866-0200

The controlling law on burden of proof in this case is set out in USADA's Response Brief at 12-13. In summary, Appellant's defenses are simply not relevant unless he can establish a violation of the International Standard for Laboratories ("ISL"). Even then, his defenses fail if USADA demonstrates that the violation did not cause the adverse analytical finding ("AAF").

The scientific evidence establishes that this is not a close case. The delta-delta difference between 5alpha-Pdiol in Appellant's A Sample was -6.14‰ and B Sample was -6.39‰. Considering the WADA positivity criteria of 3.0‰ and LNDD's measure of uncertainty of  $\pm 0.8\%$ , any difference over 3.8 is an AAF. Appellant has failed to offer any defense – let alone an ISL violation – that would explain a 5alpha-Pdiol delta-delta difference of more than 6.

In an attempt to discredit LNDD and the WADA system, Appellant has repeatedly maligned the presumption in the World Code and UCI's Rules that LNDD's procedures were performed correctly. In this case, with its extensive discovery, voluminous briefing and lengthy hearings, virtually every detail involved with LNDD's analyses, procedures and methods was scrutinized in exacting, unprecedented detail. Not only has Appellant failed to rebut the presumption, the Panel has been presented with overwhelming evidence supporting the presumption and the inescapable conclusion that Appellant tested positive. Indeed, Dr Matthews, who routinely reviews National Institutes of Health grant applications with a skeptical eye, testified that he reviewed LNDD's documentation using the same approach:

You look to see what's wrong with them [the A and B documentation packages], you know because you know there's got to be stuff wrong and what you're going to do is you're going to find what's wrong. And in going through the doc packs, you know, I can find things like the front end of this chromatogram that doesn't look so great. But as you start to get down to the meat of the issue and you keep your eye focused on what's leading to the adverse events, and you do your own

\_

<sup>&</sup>lt;sup>2</sup> USADA Issue #1; Appellant Issue #1. See also AAA Decision at ¶¶148-157.

calculations, taking this raw data and then redoing it yourself and looking at it this way and looking at it that way, it all keeps stacking up to the same conclusion, that the minus 6-ish per mil in the 5-alpha Adiol is a real measurement with real uncertainties that are limited well beyond the scope of the minus 3 cutoff.

CAS Tr. at 1156:3-24 (emphasis added). See also Ayotte, CAS Tr. at 1351:15-23.

### III. Credibility of Witnesses<sup>3</sup>

The Panel will judge for itself the credibility of the witnesses and the written and live testimony they offered, but USADA believes its witness testimony was credible, objective and reliable - virtues that all or almost all of Appellant's witness testimony lacked.

(a) Interpretation of the ISL. Dr. Ayotte (as head of the Montreal laboratory), and Dr. Schänzer (as head of the Cologne laboratory) are the experts in this case with the most appropriate experience to interpret and determine whether LNDD complied with the ISL. Each operated WADA-accredited laboratories under the ISL since the ISL's inception. As a member of WADA's laboratory committee, Dr. Ayotte reviewed the ISL before it was adopted and, as set forth in her witness statement, participated in drafting various portions of the ISL and its Technical Documents. See Ayotte Stmt. at ¶4-6; Ayotte Testimony, AAA Tr. at 198:11-801:13. Dr. Ayotte's opinion is that none of the claims raised by Appellant represents a violation of the ISL. See Ayotte Stmt. at ¶9-24. The ISL experience of Drs. Ayotte and Schänzer contrasts markedly with the total lack of any ISL experience of any Appellant expert. Yet their testimony is ultimately unreliable not because of their unfamiliarity with the ISL but rather because their testimony in many instances contradicts the plain meaning of the relevant documents. It is also revealing that Dr. de Boer, Appellant's expert witness at the B Sample analysis, and the former director at the WADA-accredited laboratory in Lisbon, never identified any ISL departure relating to IRMS in his report of the B Sample analysis.

<sup>&</sup>lt;sup>3</sup> USADA Issue #2; Appellant Issue #6. See also AAA Decision at ¶¶312-319.

- (b) IRMS Analysis. There is no comparison between the substantive expertise of USADA's IRMS experts and Appellant's IRMS experts. Dr. Matthews was a part of the group that invented the IRMS technique. See Matthews Stmt. at 1. Ms. Jumeau wrote the software and the relevant portions of the operating manuals for the Isochrom and IsoPrime instruments. See Jumeau Stmt. at 2-4. Dr. Brenna is internationally recognized for his research contributions to GC/C/IRMS. See Brenna Stmt. at 1-2. In contrast, Appellant's expert, Dr. Goodman, worked in IRMS after obtaining his Ph.D. under Dr. Brenna's supervision, but does not currently work in the IRMS field. See CAS Tr. at 624:25-625:14. None of USADA's IRMS experts has any doubt that LNDD's analytical results finding exogenous testosterone or its metabolites in Appellant's sample are reliable. See, e.g., Ayotte Stmt. at ¶9; Brenna Stmt. at 2-3, 24; Jumeau Stmt. at 8; Matthews Stmt. at 3; Schänzer, AAA Tr. at 1127:18-1128:6, 1149:18-1150:3; Catlin, AAA Tr. at 1192:25-1193:11.
- (c) Steroid Metabolism. Dr. Shackleton, whom Appellant declined to cross-examine, has published more than 200 articles in the area, including a study tracking testosterone metabolites using IRMS. See Shackleton Stmt. at 1-2; Shackleton Rebuttal at 1-3. Dr. Clark, whom Appellant also declined to cross-examine, has over 20 years experience in the field of steroid metabolism. He is a former president of the American Andrology Association. Unlike Dr. Amory, who looked at only two cases involving the analysis of steroids in urine before becoming involved as an expert for Appellant, Dr. Clark has reviewed the steroid profiles of more than 20 athletes to evaluate whether or not doping has occurred. See Clark Stmt. at 2. Both Dr. Shackleton and Dr. Clark conclude that Appellant's Stage 17 analytical results can only be explained by the use of exogenous testosterone or its precursors, a conclusion which they

found not inconsistent with the pattern of Appellant's analytical results throughout the rest of the Tour. See Shackleton Stmt. at 2-5; Shackleton, AAA Tr. at 155:22-156:5; Clark Stmt. at 2.

(d) Scientific Opinion vs. Advocacy. The role of experts in this case is to provide an unbiased scientific evaluation to assist the Panel in reaching a correct determination.<sup>4</sup> Appellant's experts crossed the line, acting for the most part as advocates for Appellant's cause and not as scientists objectively assisting the Panel in the search for the truth. This advocacy manifested itself in many ways, including Appellant's expert witness statements uniformly parroting that "to uphold an anti-doping sanction on the evidence in this case is morally and ethically wrong" (see Goldberger Stmt. at \$\quad 26\$; Amory Stmt. at \$\quad 18\$; Davis Stmt. at \$\quad 12\$; and Goodman Stmt. at ¶5), language Dr. Goldberger admitted was drafted by Appellant's counsel. See CAS Tr. at 300:22-301:9. Dr. Davis's expert statement goes beyond technical opinions to include unfounded and irresponsible accusations of lies and cover-up. See, e.g., Davis Stmt. at ¶4. Dr. Goodman went so far as to incorporate verbatim entire sections of the brief prepared by Appellant's counsel months before he became involved in the case. See Annotated Copy of Dr. Goodman's Statement at ¶¶47-110; CAS Tr. at 621:16-622:4; 628:6-632:25. See also Goodman Stmt. at ¶20, 56 (two express responses to what was apparently drafting by "Maurice").

The AAA Panel saw and heard Dr. Meier-Augenstein in person, yet rejected each of his arguments and concluded that he had "misdirected himself in his testimony before the Panel." AAA Decision at ¶182. The AAA Panel rejected Appellant's other criticisms of LNDD's IRMS

<sup>4</sup> In the AAA Hearing, Appellant attempted to attack Dr. Ayotte's credibility by suggesting that because her laboratory does things the same way, she had no choice but to defend LNDD's

practices. Her response was telling: that her opinion is "coming from experience. If I'm telling you it is okay, it is sound in principle, scientific principle, it is not based on who did something wrong or not." AAA Tr. at 913:3-7.

7/051

procedures in similarly strong language on key points, such as metabolite identification, describing them as "unsound," "without any reasonable scientific basis," and "scientifically totally unacceptable and fundamentally flawed." <u>Id.</u> at ¶¶188-89.

(e) <u>Dr. Francesco Botrè</u>. The AAA Panel stated in its Interlocutory Award of March 17, 2007, that it would appoint its own expert to determine whether LNDD's methodologies were flawed. <u>See</u> Ex. 147 at ¶19. On its own, the AAA Panel selected Dr. Francesco Botrè, the director of the WADA-accredited laboratory in Rome. There is no question, despite what Appellant's counsel argued in closing, that the Panel's selection of Dr. Botrè was approved by both parties. <u>See</u> USADA's Response Br. at 11-12. Dr. Botrè managed the collection of electronic data files and their subsequent reprocessing and issued his report at Ex. 114, in which Dr. Botrè concluded that LNDD's methodologies were sound. Dr. Botrè also sat through the entire nine-day hearing in Malibu and assisted the AAA Panel in their deliberations.

### IV. Accreditation<sup>5</sup>

The evidence presented in this case establishes that LNDD's IRMS method was accredited by COFRAC as of May 1, 2006, with a 0.8% uncertainty. See, e.g., Ex. 26 at LNDD0098. ISL § 7.0, which describes the procedures to be followed where an athlete challenges an AAF in a hearing, expressly states that:

The <u>Laboratory</u> is not required to provide any documentation not specifically included in the <u>Laboratory Documentation Package</u>. Therefore, the <u>Laboratory</u> is not required to support an *Adverse Analytical Finding* by producing, either to the <u>Testing Authority</u> or in response to discovery requests related to the hearing, standard operating procedures, general quality management documents (e.g., ISO compliance documents) or any documents not specifically required by Technical Document on Laboratory Documentation Packages.

<sup>&</sup>lt;sup>5</sup> USADA Issue #6; Appellant Issue #2.

<u>See</u> Ex. 8 (emphasis added). The complaints by Appellant that LNDD's document production has been selective<sup>6</sup> and that they had not seen all of LNDD's method validation documentation, are simply inconsistent with the ISL. This is the first time that LNDD (or any other WADA-accredited laboratory) has produced such a tremendous volume of documents. <u>See</u> Ayotte Stmt. at ¶8.

Appellant's only witness to support his claims that LNDD is not accredited and that its methods were not properly considered in the accreditation process is Dr. Goldberger.

Dr. Goldberger has no experience with accreditation under the ISL. CAS Tr. at 277:12-278:8.

More revealing of his lack of competency on the accreditation issue in this case is his total lack of experience with laboratory accreditation pursuant to ISO Document 17025, which is applicable to laboratories worldwide, not just laboratories in the WADA system. Id.

Contrary to Dr. Goldberger's statements about the extremely narrow review conducted by the accrediting body (COFRAC in this case), the COFRAC audit and accreditation documents specifically state that LNDD's methods and procedures were audited against ISO17025, the ISL, the Prohibited List, Technical Document 2004EAAS (IRMS Positivity Criteria), Technical Document 2003LCOC (Chain of Custody), Technical Document 2003LDOC (Documentation Packages), and Technical Document 2003IDCR (Metabolite Identification). See Ex. 26 at LNDD0396. Moreover, Mr. Leguy, the person responsible for accreditation of biological and

-

<sup>&</sup>lt;sup>6</sup> In response to Appellant's Issue #6.a: LNDD produced more than 2000 pages of documentation, in addition to the documentation packages, describing its analytical methods and the use of those methods in response to Appellant's requests and directions from the AAA Panel. The Panel and the parties went through an extended process of narrowing and refining the additional information that Appellant sought. Finally, in response to a direct request from the AAA Panel, Appellant acknowledged that, but for four specific issues, he received all of the documents which he had requested and which LNDD had been directed to produce. See Ex. 136, 2007 Corr. ISO compliance documents are not required to be produced in hearings where an AAF is challenged is because under the World Code and ISL, method validation is to be addressed in accreditation, not adjudication.

medical laboratories for COFRAC, confirmed that "[i]n advance of that audit, COFRAC received from [LNDD] and reviewed all appropriate information for the validation of method EC 31 including but not limited to SOP M-AN-52 and the validation study establishing uncertainty for the method at 0.8 mil." See Statement of Robin Leguy dated March 14, 2008 (the "Leguy Stmt.") (attached to USADA's Motion in Limine to Exclude Evidence in Violation of CAS Rule 56 (Mar 14, 2008)). Mr. Leguy was not cross-examined on his statement.

Mr. Leguy's statement is corroborated by the testimony of Cynthia Mongongu, Claire Frelat and Corinne Buisson, all of whom confirmed that the SOP for sample preparation and GC/MS and IRMS analysis, along with a method validation report, were sent to the COFRAC auditor in advance, and that the COFRAC auditor congratulated the LNDD staff on the method validation report. The COFRAC auditor spent an entire day at LNDD and observed Ms. Frelat prepare samples, identify analytes by GC/MS and IRMS, and manually adjust baseline and peak integration on chromatograms. He specifically went over the points of the ISL (including WADA Technical Documents TD2003IDCR, TD2004EAAS and TD2003LCOC, and ISO17025) one by one, to verify the conformity of LNDD's analytical procedure with their requirements. See Buisson Stmt. at 10; Mongongu Stmt. at 7; Frelat Stmt. at 2-3.

Further, Dr. Goldberger's argument that LNDD's IRMS method was not accredited because the accreditation document does not specifically list sub-method M-AN-52 and that the applicable measure of uncertainty should be 20%, not  $\pm 0.8\%$ , is put to rest by the statement of Mr. Leguy.<sup>7</sup>

<sup>&</sup>lt;sup>7</sup> Even using 20% uncertainty, Appellant's sample would still have been declared positive (6.14 delta-delta units  $\pm 20\% = 4.91$  delta-delta units.) <u>See also</u> Ayotte Stmt. at ¶26.

## V. Dr. de Boer's Observation of the B Sample analysis<sup>8</sup>

As allowed by the ISL, Appellant had his expert, Dr. de Boer, present to observe the entire B Sample analysis. Dr. de Boer also received the A Sample documentation package when he arrived at LNDD. See Ex. 25 at USADA0368-0369; Frelat Stmt. at 3. The fact that Appellant has never offered the testimony of Dr. de Boer in this case is telling, given Dr. de Boer's expertise in this field and that he was an eyewitness to the procedures that Appellant now claims were unreliable, even fraudulent or the subject of a cover-up. See CAS Tr. at 911:4-913:4. Dr. de Boer's report provides no support for the basic premises of Appellant's current attack on LNDD's findings, including those related to chain of custody, manual integration, identification of analytes<sup>9</sup>, poor chromatography, manipulation of results, deletion of data, delays in injections, use of the IsoPrime1 instrument or its OS/2 software and the other grounds alleged. Most revealing, and in direct refutation of Appellant's harangue to this Panel about the alleged incompetence of the LNDD technicians, Dr. de Boer's "impression... regarding the analytical performance of the B sample analysis was that the LNDD worked in a transparent and professional way and according to transparent and professional procedures." Ex. 26 at USADA0368. 10

. . . . .

<sup>&</sup>lt;sup>8</sup> USADA Issue #3; Appellant Issue #9.

<sup>&</sup>lt;sup>9</sup> The fact that Dr. de Boer specifically asked for and received the mass spectra data for the analytes in question establishes that he was interested in confirming the identity of the analyte peaks at issue. See Frelat Testimony, Tr. at 948:24.

<sup>&</sup>lt;sup>10</sup> Dr. de Boer's only reservations to LNDD's B Sample analysis were that he did not see the documentation regarding the validation of ±0.8% uncertainty of the GC/C/IRMS method or the historical data of blank urine pool number four. Even though not required to be provided to athletes under the ISL, both documents were produced to Appellant during discovery. See Ex. 26 at LNDD0451-0460 and LNDD0308-0311. The uncertainty validation study was reviewed by COFRAC and incorporated into the accreditation document, confirming its reliability. See Buisson Stmt. at 6; Ex. 26 at LNDD0381-0431; and Leguy Stmt. The historical data for blank urine pool number four are consistent with the delta values for the blank urine analyzed

May 2007 Electronic Data File Reprocessing<sup>11</sup>

Fax Server

#### 303-866-0200

VI.

Based on Appellant's discovery demands, on May 4-5, 2007, the original electronic data files ("EDFs") for Appellant's Stage 17 Sample were reprocessed at LNDD under Dr. Botrè's supervision. The EDFs were reprocessed on the IsoPrime 2 instrument, operating with the newer MassLynx software and on the original IsoPrime 1 instrument, where Ms. Frelat and Ms. Mongongu applied the same manual integration process used in the original analysis of the Sample. At Dr. Davis's request, the EDFs were also reprocessed on the IsoPrime 1 instrument using the "automatic" integration performed by the OS/2 software and with no background subtraction at all. The reprocessing that took place puts to rest many of Appellant's arguments. For example:

Allegedly poor chromatography. In response to questions from the Panel,
Dr. Davis testified that the reprocessing results should be ignored because the quality of the
underlying chromatography was poor. See CAS Tr. at 935-939, in particular 939:9. Dr. Davis's
answers to the Panel are inconsistent with the Affidavit he filed when Appellant initially
requested the AAA Panel to permit the reprocessing. See Ex. 131 at 6, ¶(e) and (f). There is no
suggestion in that Affidavit that original chromatograms were too poor to do any meaningful
reprocessing on MassLynx. Dr. Davis had reviewed the LNDD documentation packages
containing the original chromatograms before submitting his Affidavit. See id. at ¶15,16

contemporaneously with Appellant's Stage 17 Sample. See Ex. 24 at USADA0186; Ex. 25 at USADA0352; and Ex. 26 at LNDD0311.

<sup>&</sup>lt;sup>11</sup> USADA Issue #5; Appellant Issue #8. See also AAA Decision at ¶53-55; 135-142, 250.

<sup>&</sup>lt;sup>12</sup> Appellant made various claims below alleging irregularities in the copying of the EDFs. These claims were dismissed by Dr. Botrè (Botrè Report, Ex. 114 at USADA 1467, at ¶9.1).

<sup>&</sup>lt;sup>13</sup> Both Dr. Botrè and Dr. Brenna, who was also present at the reprocessing, have expressed opinions that the two reprocessing methods suggested by Dr. Davis made no sense. <u>See, e.g.,</u> Ex. 114 (Report of Dr. Botrè) at §§7.1, 7.6; Brenna, AAA Tr. at 285:6-286:16.

(references to the LNDD documentation package). The original chromatograms found in the documentation package did not change from the time of Dr. Davis's Affidavit to his testimony and response to the Panel. What changed was the fact that Dr. Davis did not get the EDF reprocessing results he had hoped for. See also Dr. Davis Testimony, CAS Tr. at 939:24-943:21.<sup>14</sup>

- (b) Destruction of Data. Dr. Goodman claims in his witness statement that the original data on the Stage 17 controls "are forever lost, as LNDD destroyed those records." See Goodman Stmt. at ¶138. Appellant's experts have also complained that the chromatograms or two over one traces of the original data were too small to interpret. As became apparent during the course of the hearing, all of the original data was preserved in the EDFs and was available to be viewed during the reprocessing. Dr. Davis could have asked to zoom in on and have printed any portion of any chromatogram which was of interest to him, but he did not make any such requests. See Davis Testimony, CAS Tr. at 580:6-588:20; 950:22-951:9; AAA Tr. at 1888:20-1896:3.
- (c) Claim that the allegedly <sup>13</sup>C-depleted value of the baseline could have caused the delta value of Appellant's 5alpha and Pdiol peaks to be more negative. When the EDFs were reprocessed with no baseline subtraction (meaning the entire value of the baseline was included in calculating the delta value of the peaks), the delta-delta difference between 5alpha and Pdiol was actually somewhat smaller (A Sample: -5.55‰, B Sample: -5.58‰) than the results reported when LNDD followed its SOP. See GDC1350. Thus, the allegedly improper inclusion of some

<sup>&</sup>lt;sup>14</sup> In response to further questions from the Panel, Dr. Davis admitted that his witness statement provides no mention of any concern about how the allegedly poor original chromatography supposedly would prevent reliable results if MassLynx software was used in the reprocessing.

part of the baseline in the peaks during manual integration could not have caused Appellant's AAF.

(d) <u>Manual Integration</u>. Dr. Botrè concluded, based on his supervision of the reprocessing and the results obtained, that: "[t]he manual subtraction of the background performed by the Paris laboratory, apart from being covered by their internal Standard Operating Procedures, appears to be a scientifically sound process, aimed to improve the quality of the signal and, therefore, the reliability of the obtained results and not to alter the results of the analysis." See Ex. 114 at USADA1645, ¶7.1.1.

Appellant contends that the variances found in the reprocessing results render the original results unreliable. The examples offered by Appellant are easily explained. Dr. Botrè points out that the delta-delta difference between 5alpha and Pdiol, which was greater than three in the automatic reprocessing of the B Sample blank urine, is good evidence that manual integration improves the results obtained by automatic reprocessing. The differences in Appellant's Sample between the 5alpha-Pdiol delta-delta values as originally reported and when the EDFs were reprocessed again manually are within LNDD's ±0.8% measure of uncertainty. Dr. Botrè also explains that the bottom right number on GDC01350 (B Sample blank urine analyzed on MassLynx) should be disregarded because the instrument software did not appear to process correctly. See Botrè Report, Ex. 114 at USADA1642, ¶6.16. The only delta value on manual reprocessing which appears to be off involves the 11-keto endogenous reference compound in the B Sample used as an endogenous reference compound for Andro and Etio metabolites, and does not involve the critical 5alpha-Pdiol delta-delta measurement. See Ayotte Rebuttal at ¶13. That apparent mistake is not surprising given the artificial pressure on Ms. Frelat of reprocessing the EDFs with four experts looking over her shoulder. See Jumeau Rebuttal at 4.

303-866-0200

Dr. Botrè's supervision and participation in the reprocessing of the EDFs led him to conclude that "the reprocessed data, regardless of the variability of individual results show that in all cases, the difference of the  $\Delta$  values between pregnandiol and 5-alpha-diol is greater than three, for both the "A" and "B" Samples. Also taking into account the stated value of measurement uncertainty value (0.8%)." See Ex. 114 at USADA1647, ¶9.2. Moreover, Dr. Botrè also noted that "the difference of delta values between pregnandiol and 5-alpha-diol is maximal if the EDFs are reprocessed by the new instrument (IsoPrime 2 using MassLynx software), both on the "A" and "B" Samples." Id. at USADA1645, ¶7.10(b).

The parties were advised by the AAA Panel at the beginning of the AAA Hearing that they would have an opportunity to question Dr. Botrè about his conclusions at the end of the hearing. Nine days later, when the Appellant was offered this opportunity, he elected not to question Dr. Botrè or seek further explanation from him. See AAA Tr. at 1955:1-12.

## VII. Appellant's Allegations of False Statements, Fraud, and Cover-ups<sup>15</sup>

Appellant is quick to make allegations of fraud, deceit and cover-up, which were also made before and flatly rejected by the AAA Panel as being "without foundation." See AAA Decision at ¶257. USADA urges this Panel to reach the same conclusion.

As mentioned previously, the Panel requested the parties confer to identify a common set of issues for the post-trial briefing. The Panel also admonished Appellant to be specific in regard to his allegations of falsehoods, fraud and cover-up. USADA therefore asked Appellant to identify in advance the allegedly false statements, fraudulent documents, and cover-up actions that he intended to continue to maintain, so that the issues could be narrowed and the briefing could be focused on specifics, thereby allowing the Panel to hear both sides on each issue. See

<sup>&</sup>lt;sup>15</sup> USADA Issue #16; Appellant Issue #6.

CAS Tr. at 1494:15-1499:10. Unfortunately, Appellant refused. See Attachment 2 at 4. Unable to realize the hoped-for efficiencies the Panel's request and admonition were envisioned to achieve, USADA has had to spend considerable time and effort to comb through Appellant's Appeal Brief, witness statements, opening and closing arguments and the trial transcript and attempt to discern the specific claims and bases that Appellant may persist in maintaining in support of its fraud theme.

(a) Allegedly fraudulently reference solution preparation log for the T/E ratio test.

The T/E analysis is no longer at issue in this case, so this aspect of Appellant's fraud claim has no substantive relevance. The claim regarding this document was raised for the first time in the AAA proceeding by Appellant's counsel in closing argument, giving USADA no opportunity to respond. See USADA Response Br. at 10; see also Ex. 26 at LNDD0440. The person who filled out the document, Agnes Gaillard, explained in her witness statement to this Panel that the document was not fraudulent, it was simply recopied. See Gaillard Stmt. at 2. The original document was also produced by USADA as Exhibit 37 at LNDD2006 (with related documents LNDD2007-2008 at Ex. 138). Appellant insisted that Ms. Gaillard be present at the AAA Hearing in Malibu but chose not to call her as a witness. Ms. Gaillard was also asked to be available by phone for cross-examination during the recent hearing, which she agreed to do over the Easter holidays. Again, Ms. Gaillard was not called for cross-examination. Instead, Appellant's counsel left the issue of whether the document was fraudulent for his closing argument. See CAS Tr. at 1437:9-1439:17. If finding the truth were Appellant's objective, counsel would have cross-examined Ms. Gaillard to address whatever questions he may now raise in his post-trial brief.

4/19/2008 12:06:13 AM PAGE 16/0

Fax Server

- (b) Complaint that LNDD was attempting to cover-up the fact that it conducted manual integration on Appellant's Sample. LNDD had no secret to keep in this regard, since Dr de Boer was specifically asked by Ms. Frelat during the B Sample analysis whether he wanted to watch her perform the manual integration of the sample. See Frelat Testimony, CAS Tr. at 911:4-913:5. Dr. Davis has known all along that the manual integration function was an essential and regularly used component of the OS/2 software. Indeed, he used the software to demonstrate to the Panel how manual integration works, and he testified that you "virtually always have to do [manual integration] on the OS/2 system." See CAS Tr. at 532:8-24. Under these circumstances, LNDD had no reason to believe that Appellant would be surprised by the fact that LNDD had performed manual integration in analyzing his sample. In response to Appellant's discovery request concerning the creation and accuracy of the background subtraction method used by LNDD, LNDD did not understand this request to address the issue of manual integration, but rather the computer algorithm used by the instrument to subtract background and generate delta values once the location of the background had been properly set. See USADA's Response to Respondent's Second Request for Production of Documents, Ex. B (LNDD Response to Request C10) at 10. Contrary to Appellant's repeated attempts to characterize these responses as false, LNDD's responses are factually consistent and accurate.
- (c) <u>Use of the IsoPrime 1 to analyze Appellant's Stage 17 Sample and IsoPrime 2 to analyze Appellant's other seven Tour Samples in April 2007</u>. The inference of nefarious intent behind LNDD's decision to use the older IsoPrime1 instrument to analyze Appellant's Stage 17 Sample and the newer IsoPrime 2 instrument in April of 2007 to analyze his other Tour Samples, as alleged by Dr. Davis, CAS Tr. at 604:8-605:3, was put to rest by the unchallenged testimony of LNDD witnesses. Ms. Mongongu explained that the IsoPrime 1 instrument was used for the

303-866-0200

Fax Server

Stage 17 Sample analyses because the IsoPrime 2 instrument had not been validated at that time.

See CAS Tr. at 757:2-10; see also Frelat, CAS Tr. at 824:19-826:2. Ms Mongongu further explained that the April 2007 analyses of the other Tour Samples were performed on the IsoPrime 2 instrument, which by that time had been validated, in response to the claim by Appellant's team that the IsoPrime 1 instrument and its OS/2 software were obsolete and unable to generate reliable results. See CAS Tr. at 789:12-793:8; Ex. 114, ¶6(e) and (f).

- Alleged Deletion of Data. Dr. Davis claims in his witness statement that the batch processing data in the documentation package show that LNDD deleted data to hide the fact that its instruments were not operating properly. See Davis Stmt. at ¶89. For Appellant's Stage 17 Sample, no data were deleted or "cherry-picked." See, e.g., Frelat Rebuttal at 2; Mongongu Rebuttal at 4. The differences in values referenced by Dr. Davis are explained simply by the fact that one set of data reflects values prior to manual integration while the other set reflects values generated after manual adjustments. See USADA Response Br. at 60-61; Mongongu Stmt. at 13-14; Frelat Stmt. at 4-5; Jumeau Stmt. at 11-12. With respect to the log files from the April 2007 analyses of Appellant's other Tour Samples, Ms. Frelat explained the entirely legitimate circumstances why certain controls were re-injected and their previous files overwritten and that no file containing complete data for any control was overwritten. See CAS Tr. at 874:21-879:17.
- (e) <u>August linearity test</u>. LNDD told Appellant prior to the AAA Hearing that the August linearity file had been lost. Appellant's Supp. Pre-Trial Brief at 5. Ms. Frelat later found it in a different box. See CAS Tr. at 844:14-24; 919:9-14; and 919:15-920:9.
- (f) <u>GC/MS maintenance log relating to installation of the new column</u>. The fact that a different column name was identified in the GC/MS method file in the documentation package was not raised during the first hearing and was presented for the first time in Appellant's Appeal

Brief. The exhibits provided by LNDD showing that the correct column was installed did not become relevant until Appellant raised the different column issue for this first time in this CAS hearing. In his attempt to persuade the Panel of his illogical claim that different columns were in the GC/MS and IRMS instruments LNDD used to analyze his Stage 17 B Sample, Appellant claims the maintenance log document, Ex. 142, reflecting that a new column was placed in the GC/MS instrument in April of 2006, is fraudulent. The alleged fraudulent nature is premised on the lack of consistent order in several of the log's entries on the second page. However, the related arguments of a fraudulent maintenance log document and the use of the wrong column are refuted by the consistent and un-rebutted testimony of the only witnesses with personal knowledge who testified on the subject, Gerard Le Petit, the outside maintenance service provider; Ms Mongongu, Ms. Frelat; and Ms. Buisson. See LePetit Stmt. and Testimony; Mongongu Stmt. at 4-5; Buisson Stmt. at 8; Frelat Testimony, CAS Tr. at 909:8-19.

and B Sample injection sequences are explained in USADA's Response Br. at 58-60 and in the testimony of Ms. Mongongu and Ms. Frelat. See Mongongu Stmt. at 11; AAA Tr. at 591:5-601:3; Frelat Stmt. at 4; AAA Tr. at 719:19-721:15. Ms. Frelat and Ms. Mongongu both make clear that no additional controls were injected during these delays. See id.; Mongongu Stmt. at 11-12. Appellant has adduced no evidence to refute the explanations given by Ms. Mongongu and Ms. Frelat. Further, Appellant's own expert, Dr. de Boer, watched the B Sample analysis and raised no concern about any delay between injections. See Frelat Testimony, CAS Tr. at 912:11-16. See also Matthews Stmt. at 13-14 (the delays would not have affected results).

Fax Server

## VIII. Controls<sup>16</sup>

303-866-0200

The controls used by LNDD to verify that the instruments are working properly are described in detail in USADA's Response Brief at 29-35 and in Corinne Buisson's Statement at 4-5. Appellant's arguments regarding the efficacy of LNDD's controls are largely recycled (in some cases verbatim from the arguments he made to the AAA Panel, which that Panel rejected). See USADA's Response Br. at 56; AAA Decision starting at ¶190. As Appellant has elected to continue to pursue these arguments, each is addressed briefly below.

(a) Mix Cal IRMS and Mix Cal Acetate acceptance criteria. The acceptance criteria for Mix Cal IRMS is described in detail in USADA's Response Brief at 31-33.<sup>17</sup> See also Buisson Stmt. at 4-5. LNDD's documentation package includes standard forms for the acceptance of performance of both the Mix Cal IRMS and Mix Cal Acetate. See, e.g., Ex. 25 at USADA0353-0354. (There are no similar acceptance criteria for the measured delta values of the internal standard.) In this case, the measurements for all four of the Mix Cal IRMS alkanes and all four Mix Cal Acetate steroids were within the 0.5% criteria. See also Jumeau Rebuttal at 12.<sup>19</sup>

<sup>16</sup> USADA Issue #11; Appellant Issue #3.a. See also AAA Decision at ¶¶190-231.

<sup>&</sup>lt;sup>17</sup> As counsel for USADA noted in closing, comparing this 3 out of 4 acceptance criteria with WADA's one metabolite positivity criteria is like comparing an apple to a brick. CAS Tr. at 1479:8-24.

<sup>&</sup>lt;sup>18</sup> The Eurofins value, which is certified by Eurofins to be within  $\pm 0.3$  delta units, is a reference measurement specification. LNDD's  $\pm 0.5$  delta units value is a measure of the appropriate variation for any particular measurement. As Dr. Matthews pointed out, the Eurofins  $\pm 0.3$  delta units is irrelevant for purposes of LNDD's measurements. See CAS Tr. at 1123:13-1128:2.

Dr. Goodman indicates that with 118 injections over a four-day period, he was able to achieve a standard deviation between measurements of <0.2‰. See Goodman Stmt. at ¶35. However, based on Ex. 26 at LNDD0448-0450, when LNDD analyzed its Mix Cal Acetate control 75 times from May to October, the standard deviation was also <0.2‰. See CAS Tr. at 1370:19-1371:5; Ayotte Stmt. at ¶14; Rebuttal at ¶¶9, 10; See also Brenna Rebuttal at ¶¶10-11.

(b) Manual Integration of Controls. 20 Neither Drs. Brenna (CAS Tr. at 1080), Matthews (CAS Tr. at 1115) nor Ayotte (CAS Tr. at 1323) were concerned that LNDD sometimes manually integrates the Mix Cal IRMS and Mix Cal Acetate controls. When asked about manually integrating controls, Dr. Matthews responded that he personally believes that in many respects, manual integration is superior. See CAS Tr. at 1115:7-20. Dr. Ayotte explained that her laboratory sometimes also uses manual integration to correct the results obtained automatically by the computer for controls like the Mix Cal Acetate. "You may have to adjust a start and stop of the peak even if you are having a single peak in a pure solvent." See Ayotte Testimony, CAS Tr. at 1323:4-7.

If Dr. Davis had a real concern with LNDD's manual integration of controls, he could have obtained the original delta values (before manual integration) for all of the controls during the EDF reprocessing to see what difference manual integration might have made. The fact that he did not bother to obtain the original Mix Cal IRMS results highlights the lack of significance of this argument. Ms. Jumeau demonstrates in her witness statement that with two slight exceptions (0.53 and 0.58 involving the 11-keto analyte), all of the Mix Cal Acetate controls were within  $\pm 0.5$  of the Eurofins value even before being manually integrated. See Jumeau Rebuttal at 12.

(c) <u>Positive and negative controls.</u> Dr. Goodman argues that LNDD's controls do not satisfy Article 5.4.7.3 of the ISL. That Article requires a quality control scheme appropriate to the type and frequency of testing performed by the laboratory. The Article then describes a "range" of quality control activities that includes in the list of examples "positive and negative controls" analyzed in the same run as the presumptive AAF sample. In its audit and

<sup>&</sup>lt;sup>20</sup> Appellant Issue #3.a.iv.

As noted by Dr. Ayotte, LNDD's blank urine is also an effective negative control. See Ayotte Rebuttal at ¶14. Blank urine pool four was collected from a single volunteer known not to have taken any prohibited substance. When samples from blank urine pool number four have been analyzed historically and in connection with Appellant's Sample, the delta-delta values reported have always been negative. They have also been highly consistent. See Ayotte Rebuttal at ¶14. Ms. Jumeau concludes that the blank urine worked well to demonstrate that the analytical system, together with the data processing software would return a negative finding in the absence of exogenous testosterone. See Jumeau Stmt. at 7. See also Mongongu at 5-6; Buisson at 5-7.

303-866-0200

## IX. 5alpha Androstanol Acetate Internal Standard<sup>21</sup>

Although he has not identified an applicable ISL requirement, Appellant claims that the fact that the measured delta values for the internal standard, 5alpha androstanol, were more than  $\pm 0.5\%$  units different than the Eurofins value on four of the 12 occasions when the internal standard was used in Appellant's Sample or the corresponding blank urine casts doubt on the reliability of the instrument performance. This issue can be analyzed in two parts. First, does LNDD have an established acceptance criteria for 5alpha androstanol when used as an internal standard? Second, whether or not LNDD has such an acceptance criteria, do the internal standard results cast doubt on the reliability of the 5alpha and Pdiol delta values upon which this AAF is based? <sup>22</sup>

A review of the documentation package makes clear that LNDD has not established any acceptance criteria for 5alpha androstanol when used as an internal standard. LNDD does have acceptance criteria for the Mix Cal IRMS and the Mix Cal Acetate controls. For each of these controls, there is a standard LNDD form on which the operator fills in the delta values for these controls and then confirms ("oui" or "non"), indicating whether or not the reported delta values satisfy the acceptance criteria. The conclusion that the results either conform or do not conform

<sup>&</sup>lt;sup>21</sup> Appellant Issue #3.a.ii. <u>See also AAA Decision at ¶192-201.</u>

<sup>&</sup>lt;sup>22</sup> USADA expects that Appellant will argue that LNDD acknowledged in its Response to Production of Documents that LNDD measured the delta value of the internal standard as a quality control. This is neither what LNDD said nor intended. The answer in question responds to a general request by Appellant relating to both GC/MS and GC/C/IRMS analysis. "Signal strength or measured value" are given as "examples" of how data from the internal standard and the positive and negative controls can be used. For example, in the T/E ratio analysis of Appellant's Sample, the first attempt at confirmation was rejected because it was apparent from the signal strength of the internal standard that it was not within an acceptable range. Hypothetically, in the case of the internal standard used in the IRMS analysis, the "signal strength" of the 5alpha androstanol could be too weak to be acceptable and clearly the retention times for the internal standard are "measured values," which are used in both the GC/MS part of the IRMS analysis and the GC/C/IRMS part of the IRMS analysis.

to the acceptance criteria is then signed and dated by both the operator and the operator's supervisor. See Ex. 24, USADA174-175 and Ex. 25, USADA0353-0354. As Dr. Ayotte noted, these forms establishing whether or not the Mix Cal IRMS and Mix Cal Acetate results satisfy LNDD's three of four <±0.5‰ acceptance criteria are part of LNDD's overall quality system. The fact that there is no comparable form for the delta value of 5alpha androstanol when used as an internal standard makes clear that LNDD does not have any acceptance criteria for those measurements. See CAS Tr. at 1373:12-1379:16.

Cynthia Mongongu, Claire Frelat and Corinne Buisson have all been completely consistent in their testimony, both before the AAA Panel and in this case, that the internal standard is used as a quality control for retention time, not delta value. See AAA Tr. at 433:20-435:21; Buisson Stmt. at 7; Frelat Stmt. at 2; Mongongu Stmt. at 3-4.

All of the witnesses, including the LNDD operators and Dr. Matthews (CAS Tr. at 1104:3-14), Dr. Brenna (<u>id</u>. at 1038:20-1039-13) and Dr. Ayotte (<u>id</u>. at 1373:12-1379:16), were clear that they have never seen any LNDD document that establishes a delta value acceptance criteria for 5alpha androstanol when used as an internal standard. Further, there is no ISL requirement that an internal standard be used as a quality control for delta value measurement. Dr. Ayotte stated that her laboratory also uses 5alpha androstanol as an internal standard for retention time, not delta value. <u>See</u> AAA Tr. at 810:23-812:8. As Dr. Ayotte further noted, if you wanted to use an internal standard as a delta value quality control, you would select a substance which elutes in the 1200 to 1700 second portion of the chromatogram, where there is less interference. See CAS Tr. at 1347.

In answer to the second question, Drs. Ayotte, Matthews, Brenna and Schänzer are all very clear in their opinions that whether or not LNDD considered the reported delta values of

5alpha androstanol, used as the internal standard, the results reported do not cast doubt on the reliability of the measured delta values for 5alpha and Pdiol. For example, Dr. Schänzer explained that the variation in the internal standard would be bigger because it elutes early in the chromatogram and is "more influenced by the biological background," and that Cologne obtains similar variations in its internal reference. See Schänzer, AAA Tr. at 1129:6-1131:21. As Drs. Matthews, Brenna and Ayotte point out, the information in the first part of the chromatogram where the internal standard elutes is unnecessary to come to a conclusion about the delta-delta values of 5alpha and Pdiol. As noted by Dr. Brenna, if someone in his lab brought him these delta values for the internal standard, he would say "[w]hy are you guys doing this?<sup>23</sup> It really doesn't tell us anything. ... So I don't see any harm in it . . . it doesn't bother me in the least that those numbers came out poorly, and I don't believe that they apply to the . . . parts of the chromatogram that are relevant in this case." CAS Tr. at 1078:20-1079:11; See id. at 1161, 1169-1170 (Matthews) and 1382 (Ayotte).

## X. Linearity<sup>24</sup>

LNDD's instrument was linear during the analysis of Appellant's samples. <u>See USADA</u> Response Br. at 62-64. In any event, the linearity of LNDD's IRMS instrument could not in any way have caused Appellant's AAF.

First, as Dr. Brenna points out and as the Panel below found, linearity is significant only when comparing small and large peaks. See AAA Decision at ¶219-223. Ms. Jumeau and Dr. Matthews concur in Dr. Brenna's opinion. See Jumeau at CAS Tr. at 1205:3-1206:25;

When Claire Frelat was asked on cross-examination why she bothered to manually integrate the internal standard peak, her response was "[f]or every peak of interest . . . I check the integration of the peaks. . . . It's like a reflex." CAS Tr. at 865:8-21.

<sup>&</sup>lt;sup>24</sup> USADA Issue #13; Appellant Issue #3.a.iii. <u>See also AAA Decision at ¶¶214-225</u>.

Fax Server

303-866-0200

Matthews Stmt. at 9. In this case, any instrument nonlinearity would have similarly affected the 5alpha and Pdiol peaks because they are approximately the same height. See Brenna at 17-18; Jumeau at 13, 17. Further, in the context of the 5alpha-Pdiol delta-delta difference in this case, Ms. Jumeau points out that it makes no difference to the AAF whether one uses the 0.3‰ specification which Dr. Davis recently pulled off the internet and is not even applicable to the IsoPrime 1 instrument or the 0.4‰ specification which Ms. Jumeau herself wrote in the operating manual used for the IsoPrime 1. In her words:

I remain incredulous at the importance that Mr. Landis's technical experts seem to give to the linear specification. Their position makes no sense when one considers that the error that any nonlinearity could have caused in the adverse analytical finding is 0.01 per mil if the instrument had showed all linearity tests to be within 0.3 per mil specification. The maximum error in the Adverse Analytical Finding would be only 0.03 per mil if all the linearity tests are within the 0.4 per mil specification. Jumeau Rebuttal at 13-16.

Ms. Jumeau further notes that the 0.7% linearity specification would impart a maximum error of 0.35%. Jumeau Rebuttal at 16.

There is no requirement in the ISL regarding how often linearity testing should be performed. As Ms. Jumeau notes, contrary to Dr. Davis's statement, there is also no requirement in the operating manual provided with the IsoPrime 1 instrument that in any way indicates that the laboratory should perform linearity checks before each run. See Jumeau Stmt. at 15. LNDD has established its own criteria for the frequency of linearity testing. See Ex. 112 at LNDD0547. That SOP states that linearity testing should take place on a monthly basis. Id.

The AAA Panel found a technical violation of LNDD's SOP when it did not perform linearity testing in August 2006. However, the AAA Panel correctly concluded that this failure to comply with the SOP did not cause the positive test for the reasons set forth above. AAA Decision at ¶217-219; 225. Even that technical violation was cured with the discovery of the August 2006 linearity tests. See Ex. 155; CAS Tr. at 920:5-9.

## XI. Manual Integration<sup>25</sup>

Dr. Goodman categorically states that manual processing is subjective and is not scientifically valid. Goodman Stmt. at ¶124, 132. As explained by Ms. Mongongu, Stmt. at 12 and Ms. Frelat, Stmt. at 4, and confirmed by Dr. Brenna, Stmt. at 23 and Ms. Jumeau, Stmt. at 21-24, LNDD's manual integration SOP (Ex. 112 at LNDD0603-0609) is not subjective. Rather, the technician mechanically follows the two over one trace and the corresponding numbers reflected on the computer screen to identify peak starts where the representative numbers begin to rise and peak stops where the numbers level out again. See, e.g., CAS Tr. at 684:4-687:11 (Mongongu); 901:19-905:4 (Frelat). Not only is this process dictated by an SOP which would have been reviewed by COFRAC, the COFRAC auditor personally watched Ms. Frelat perform manual integration during the audit process. See Buisson at 10; Frelat at 2-3; Mongongu at 7. If the manual integration process described in LNDD's SOP had been a violation of the ISL, COFRAC would have noted a deficiency. That did not occur. See Buisson at 10.

Further, Dr. Goodman's opinion that manual integration is scientifically inappropriate is diametrically opposed to the opinions of Ms. Jumeau, Dr. Brenna and Dr. Matthews.

Ms. Jumeau notes that she designed the OS/2 Manual Data Reprocessing facility to offer the operator the possibility to inspect the appropriateness of the default integration and processing parameters and to make adjustments "when the default parameters do not reflect reality . . . . The automatic software does not always make the best decision of where to locate peak starts and stops" See Jumeau Stmt. at 22-23. Ms. Jumeau states that she personally observed the LNDD technicians following their SOP and using the manual integration software correctly as a quality control when she watched them during reprocessing on May 3-4, 2007. See Jumeau Stmt. at 22-

<sup>&</sup>lt;sup>25</sup> USADA Issue #10; Appellant Issue #3.i. See also AAA Decision at ¶¶243-257.

Fax Server

24. See also Matthews Testimony, CAS Tr. at 1115:14-18. Dr. Brenna confirmed that when he observed Ms. Mongongu and Ms. Frelat performing manual integration, they followed the two over one trace as required by the SOP and that manual integration is an important quality control such that even in the most up-to-date, sophisticated computer algorithms that he writes, he builds in the opportunity for manual integration. See CAS Tr. at 1005.

Dr. Davis argues that the need for manual integration is evidence of poor chromatography. Again, USADA's experts disagree with him. As Dr. Ayotte stated, "[m]anual integration is not a symptom of bad lab processing or bad chromatography." See CAS Tr. at 1328:16-18. "So it's not a correction to a bad process. It is a correction to a decision of the computer." Id. at 1324:15-17. As Dr. Brenna notes, the fact that the OS/2 software is older and is less automated than more highly developed software does not make it less reliable, but simply means that more detailed quality control in the form of manual integration is required to insure robust results. See Brenna Stmt. at 23.

Dr. Davis attempted to demonstrate before the Panel that where peak starts and stops are located can have a significant effect on the resulting delta values. However, in response to a question from the Panel, it became apparent that Dr. Davis had to locate peak starts and stops in obviously ridiculous places in order to cause a change of even one delta value unit. Had Dr. Davis told the instrument to accept those values (which he could not do because he didn't bring a printer with him), an error message would have appeared on the screen because as Ms. Jumeau points out, "the software includes several 'safeguards'—algorithms that prevent the analyst from making significant errors of judgments in executing manual adjustments." See Jumeau Rebuttal at 2. Finally, as previously noted, the results from reprocessing of the EDFs makes Appellant's manual integration defense academic: "Based on the reprocessing results,

303-866-0200

28/051

there is no need to speculate on what the results would have been if the laboratory analysts had not manually corrected the data. We know what the result was—the sample was still positive." Brenna Rebuttal at ¶4.

#### Spirit of the same operator rule.<sup>26</sup> XII.

In its list of issues for post-hearing briefs, Appellant identifies the following issue:

LNDD's violation of the spirit of the "same operator" and confidentiality rules, as manifested by LNDD staff's improper attempts to ensure that the results of the "B" sample in fact "confirmed" the results of the "A" sample, and to ensure that the results of the "B" sample conducted by one technician "confirmed" the "A" sample results generated by that same technician's supervisor.

Attachment 2 at #4. This issue should be rejected by the Panel for two reasons. First, it has never been raised before at any time in this proceeding, let alone in the Appeal Brief, as required by CAS Rule R56. Second, the underlying premise, if we understand it, is inconsistent with the evidence in the case.

ISL 5.2.4.3.2.2 provides that a "different analyst must perform the 'B' analytical procedure. The same individual(s) that performed the 'A' analysis may perform instrument setup and performance checks and verify results." Ex. 8 (emphasis added) Ms. Mongongu's role in verifying Ms. Frelat's results is specifically permitted by the ISL. (Before the results were reported positive, they were also reviewed by the laboratory director.) See id.

It also appears that Appellant is suggesting that Ms. Frelat, in conducting the B Sample analysis of Appellant's sample, was trying to perform manual integration in a way that would cause the results of the A Sample analysis to be replicated. There is simply no evidence of this "fact." Indeed, there is no evidence that in performing manual integration, either Ms. Mongongu or Ms. Frelat were ever focused on the resulting delta values as opposed to the two over one

<sup>&</sup>lt;sup>26</sup> This issue was raised for the first time by Appellant as Issue #4.

trace in the process described in LNDD's SOP. Dr. Davis candidly admitted as much during the AAA Hearing: "I don't think they were trying to get the numbers. I think they were genuinely

could." AAA Tr. at 1843:13-17. Dr. Davis provided similar testimony before this Panel. <u>See</u>

just looking at the baseline and . . . trying to fit the lines and fit the piece the best way they

CAS Tr. at 577:11-578:2

Finally, there is no ISL requirement that the identity of the athlete remain confidential during the B Sample analysis. Frequently, the athlete attends the B Sample in person. In this case, Mr. Landis personally wrote a letter to LNDD advising the laboratory that Dr. de Boer would be his representative for the B Sample analysis of Sample 995474. Ex. 25 at USADA0239-0240.

### XIII. ISL Data Recording Requirements<sup>27</sup>

Appellant claims that LNDD violated ISL Articles 5.2.6.1 and 5.4.4.4.1.4 in not recording and preserving each step in the manual integration process. This is not a proper interpretation of the relevant ISL sections. See AAA Decision at ¶¶ 254-57; USADA Response Br. at 67-70. First, all original data were preserved in the EDFs. The results of manual integration thus can be reviewed, and if necessary compared to, the original results prior to manual integration. This is precisely what was done during the EDF reprocessing. In addition, the peak start and stop locations determined by manual integration can be seen by the red dashed lines on the IRMS chromatograms in the documentation package. See Jumeau Stmt. at 23; Davis, CAS Tr. at 542:14-19. If he had he truly been concerned about the locations of the start and stops of the relevant peaks during EDF reprocessing, Dr. Davis could have obtained zoom-in blowups of the chromatograms of each peak, clearly showing the location of the red dotted lines.

<sup>&</sup>lt;sup>27</sup> USADA Issue #10; Appellant Issue #3. <u>See also AAA Decision at ¶¶243-257.</u>

The relevant section of the ISL is Article 5.2.6, entitled "Documentation and Reporting." Article 5.2.6.1 states:

In the case of an Adverse Analytical Finding, the record must include the data necessary to support the conclusions reported (as set forth in the Technical Document, Laboratory Documentation Packages). In general, the records should be such that in the absence of the analyst, another competent analyst could evaluate what tests have been performed and interpret the data. 28 Ex. 8 (only the emphasis on language that is both underscored and italicized added).

The ISL Article provides "general" direction, not a specific requirement that all back-up analytical data which was or could have been generated be included in the laboratory documentation package. There is no question that based on the documentation package, a competent analyst could evaluate what tests were performed by LNDD and could interpret LNDD's data. In fact, that was Dr. de Boer's role when he obtained the A Sample documentation package at the beginning of the B Sample analysis and wrote his report following the B Sample analysis. None of the observations and requests for additional documentation made by Dr. de Boer had anything to do with the documentation of manual integration.

The section of Article 5.2 which deals specifically with analytical data is 5.2.6.4, which states that "where instrument analyses are conducted, the operating parameters for each run shall be recorded.." Those operating parameters include, for example, the temperature at injection, the volume at injection, the various temperature gradients used, and the operating pressure. All of these operating parameters are reported in LNDD's documentation package. See, e.g., Ex. 24, USADA 1053. There is no requirement in the ISL to provide the type of documentation that Appellant is demanding with respect to the backup for the manual integration delta value results.

Appellant's reliance on Article 5.4.4.4.1.4 is clearly misdirected. The title of this ISL

29

<sup>&</sup>lt;sup>28</sup> There is absolutely nothing in TD2003LDOC, Ex.11, which requires the production of all detailed back-up data at the level of identifying manual integration steps.

subsection is "Data and Computer Security." As Dr. Ayotte points out, "Article 5.4.4.4.1.4 applies to changes to reported data. When the laboratory technician is manually integrating baselines, the technician is creating data, not altering records and reports in the computer system." See Ayotte Stmt. at ¶22.

### (a) Peak Identification<sup>29</sup>

Appellant's Brief dedicates a large section to the argument that LNDD failed to properly identify the metabolites of interest in the GC/C/IRMS analysis of Appellant's samples because the retention times between GC/MS and GC/C/IRMS were not the same, the method files for GC/MS and GC/C/IRMS were different, and the columns in the instruments were not the same. USADA's Response Brief provided a detailed rebuttal of these arguments. See Response Br. at 35-55. Appellant has done nothing to materially advance his retention time argument since then. Indeed, the WADA Technical Document TD2003IDCR that featured so prominently in Appellant's analysis was rarely mentioned during the CAS hearing. 30

Dr. Davis conceded that, in order to have good chromatography in the area of interest on the IRMS chromatograms, it would be important to change the temperature program and flow rates. See CAS Tr. at 557. This was done at LNDD. See Buisson Stmt. at 4. Dr. Goodman also acknowledged that differences in temperature program will not change the order of elution of the analytes of interest. See Goodman Stmt. at ¶92.

<sup>&</sup>lt;sup>29</sup> USADA Issue #12; Appellant Issue #3.c.

<sup>&</sup>lt;sup>30</sup> Dr. Meier-Augenstein expressed dismay at the difference in the retention times for the internal standard for GC/MS and GC/C/IRMS. <u>See</u> AAA Tr. at 1417:5-1419:3. USADA noted that the SOP for IRMS analysis actually addresses this issue, instructing the analyst to ensure that the internal standard in GC/C/IRMS elutes at a specific, later retention time than it does in GC/MS. Response Br. at 47-50. This SOP (M-AN-41, <u>see</u>, <u>e.g.</u>, Ex. 24 at USADA0153) is specifically listed in LNDD's COFRAC accreditation. <u>See</u> Ex. 26 at LNDD0098 at "EC31." Appellant not contradicted this explanation or introduced evidence to rebut the testimony of Ms. Mongongu that, based on the validation she performed, adjusting the elution timing has no effect on the order of elution of the analytes. <u>See</u> Mongongu Stmt. at 5-6.

Fax Server

303-866-0200

Once his contentions regarding retention time were shown to be simply incorrect,
Appellant pursued the argument that LNDD and USADA's explanations have changed
throughout the case as to how peak identification is done in GC/C/IRMS. (Revealingly,
Appellant never bothered to even ask either Ms. Mongongu or Mr. Frelat about peak
identification during the AAA Hearing.) As is clear from the testimony, particularly that of
Ms. Buisson, Ms. Mongongu, and Ms. Frelat, the explanation LNDD and USADA have offered
has been consistently the same. The process is not mysterious—it is borne out by the A and B
documentation packages—and its scientific validity has been acknowledged by many of the
experts in this case, including Drs. Botrè, Ayotte, Brenna, Matthews, Schänzer, and Catlin.
Though the process is detailed, and its translation from French at times intricate, LNDD and
USADA have never tried to obfuscate the steps involved.

The foundation pieces to LNDD's method are covered by its ISO accreditation. During the accreditation process, the COFRAC auditor specifically watched Claire Frelat identify peaks using the peak matching methods described in her testimony. See Buisson Stmt. at 10; Frelat Stmt. at 2-3; Mongongu Stmt. at 7.

The process used by the LNDD technicians is described in their witness statements, <u>See</u> Buisson Stmt. at 8-9; Frelat Stmt. at 2-4; Mongongu Stmt. at 2-13, and summarized below. LNDD identified the peaks in Appellant's sample in GC/MS by comparing the retention times for the peaks against the retention times for known standards (Mix Acetate) in compliance with TD2003IDCR. It then analyzed the mass spectra of each of those peaks to establish their purity. The same process was followed for the peaks in the blank urine sample and LNDD obtained the same result that LNDD had found over the many months in which blank urine sample four had been used.

LNDD uses two different methods to identify the peaks in Appellant's IRMS chromatogram. LNDD confirmed the identity of the peaks of interest in Appellant's IRMS chromatogram by comparing the peak pattern in the IRMS chromatogram to the pattern of known peaks in the GC/MS chromatogram. For example, by comparing Fraction 3, IRMS chromatogram at USADA0173 with Fraction 3, GC/MS chromatogram at USADA0171.

Ms. Mongongu testified that, when she performs peak-matching between the GC/MS and IRMS chromatograms, she also has the relative retention times corresponding to both chromatograms in front of her so that she can establish peak order where two peaks are close together. See CAS

Tr. at 746. 31 This is a very different purpose than comparing retention times between instruments for purposes of TD2003IDCR, as Appellant has argued LNDD should have done.

LNDD also compared the IRMS retention times for the peaks of interest in the blank urine with the IRMS retention times for the peaks of interest in Appellant's sample. In all cases, these retention times matched within the criteria set forth in TD2003IDCR. This is documented on Exhibit 24 at 185 and Exhibit 25 at 0351. For example, the retention times for 5alpha (5 $\alpha$  diol) and Pdiol (5 $\beta$  Pdiol) in the blank urine ("blanc urinaire") and the sample ("echantillon") are found at the bottom of Ex. 24 at USADA0185. As reflected there, the retention times ("tr(s)")

\_

Appellant's counsel had both Ms. Mongongu and Ms. Frelat perform a peak identification exercise by comparing the GC/MS chromatogram at 1339 with the IRMS chromatogram at 1362. This is Fraction 1 of Appellant's Stage 9 Tour sample collected on July 11, 2006, which was negative on IRMS analysis. Counsel obviously chose this chromatogram because visually it is very hard to identify which of two peaks in the IRMS chromatogram is the internal standard. In spite of counsel's protestations that Ms. Mongongu only look at the chromatograms, Ms. Mongongu insisted on using all of the data that she would have had available when she made such a comparison in the laboratory, and she was readily able to identify that the second of the closely eluting peaks as the internal standard. Had Ms. Frelat done what she would have normally done in the laboratory and also looked at retention times, CAS Tr. at 899:25-901:18, instead of playing along with counsel's illustration, she too would have been able to identify the internal standard as the second eluting peak.

303-866-0200

for the 5alpha and Pdiol peaks in the blank urine (1337 seconds and 1652 seconds, respectively) are identical to the retention times for the same peaks in Appellant's sample.

Neither Dr. Matthews, Dr. Brenna, Ms. Jumeau, nor Dr. Ayotte had any trouble identifying the 5alpha and Pdiol peaks in Fraction 3 of Appellant's chromatograms. As Dr. Matthews points out, because the same sample vial is measured on both instruments, it should be very clear that there are no new substances in the GC/C/IRMS that were not analyzed in the GC/MS, and no substances which appeared as significant peaks in the GC/MS will have disappeared in the GC/C/IRMS. See Matthews Rebuttal at 2-3. Further, as noted by Dr. Matthews, Dr. Brenna and Ms. Jumeau, the Fraction 3 big peaks and small peaks in GC/MS continue to be big peaks and small peaks in GC/C/IRMS because all of the peaks of interest have a similar carbon composition. See Matthews Stmt. at 8; Brenna Stmt. at 14; Jumeau Stmt. at 14-15. Dr. Brenna stated: "Any expert who is familiar with analyzing steroids in IRMS can review the sequence and patterns of the peaks between GC/MS and GC/IRMS and readily identify the 5alpha and 5diol peaks." Brenna Stmt. at 14.

Both Dr. Brenna and Ms. Jumeau were also able to identify the 5alpha and Pdiol peaks in Fraction 3 of Appellant's Sample using the GC/IRMS retention times for the Mix Cal Acetate. As Ms. Jumeau stated,

We already know from the standard Mix Cal Acetate mixture that 5 betaandrostandiol (5beta diol), with a retention time of 1305 [seconds] is the second peak in the central set of four peaks. From the GC/MS trace, we know that the next large peak is 5alpha androstandiol (5alpha diol) and that the large isolated peak towards the end of the chromatogram is 5 beta prednandiol (Pdiol). I therefore identify the analyte eluting at a retention time of 1337 [seconds]-unambiguously as 5alpha androstandiol (5alpha diol) and the analyte eluting at the retention time of 1651 [seconds] unambiguously as 5 beta prednandiol (Pdiol).

Jumeau Stmt. at 14; see also, Brenna Stmt. at 14-15.

Finally, Dr. Brenna pointed out that although he would not expect LNDD to do this, he was able to prove mathematically that LNDD correctly identified the 5alpha and Pdiol peaks in the IRMS chromatogram. See Brenna Rebuttal at 3 at ¶13,14; CAS Tr. at 1054-1055.

#### XIV. GC/MS Column Issue<sup>32</sup>

303-866-0200

The fact that the LNDD documentation package shows an Agilent 19091S-433 column listed in the GC/MS instrument method file is a mistake which is easily explained and straightforward. As Ms. Buisson testified in her witness statement, LNDD has never purchased an Agilent 19091S-433 column. See Buisson Stmt. at 8. As Mr. Le Petit stated in both his witness statement and his live testimony, in order to perform a service call, he would have installed his own Agilent 19091S-433 column into the instrument. He then would have removed that column at the end of his service call to install the column used by the customer. Before leaving, he would have checked to make sure he had his Agilent 19091S-433 column with him. He would not have left his column at LNDD because he has only one column and that column represents one-third of his total service package. See CAS Tr. at 713:19-719:3. LNDD's service record reflects that in connection with Mr. Le Petit's service call, a new column was installed, conditioned, and put into service. Ex. 142. Ms. Buisson's testimony corroborates this explanation: if the wrong column was in the GC/MS instrument when athlete samples were analyzed, the retention times for the Mix Acetate standard, which contains reference standards for the six metabolites of interest and is run as a control in GC/MS to identify the peaks of interest, would not have produced the expected retention times in its operating program. See Buisson Stmt. at 8. Dr. Ayotte confirms Ms. Buisson's observation. See Ayotte Rebuttal at \$\gamma 1\$.

<sup>&</sup>lt;sup>32</sup> USADA Issue #18; Appellant Issue #3.d.

## XV. Chromatography<sup>33</sup>

Appellant claims that the results of 5alpha and Pdiol in Fraction 3 upon which his AAF is based are unreliable because of bad chromatography. Dr. Brenna, Ms. Jumeau, Dr. Matthews, Dr. Ayotte, and Dr. Schänzer all disagree. For example, Dr. Brenna states:

I am aware of Appellant's claims regarding *poor chromatography*, *sloping baselines*, and *differences in baseline isotopic ratios*. I disagree with these arguments. Having spent much of my professional career producing and reviewing GC/MS and GC/IRMS chromatograms, I believe that the chromatograms are reliable and support LNDD's conclusion that there was an AAF in this case. While the relevant chromatograms are those in the F3 sample, I am also comfortable with the chromatograms for his other samples. ...The scientific data in this case refutes the claims made by Appellant alleging unacceptable chromatography.

Brenna Stmt. at 19. See also Jumeau Stmt. at ¶ 20; Ayotte Rebuttal at ¶25; Ayotte, CAS Tr. 1347-1349; Schänzer, AAA Tr. at 1178:6-11. Moreover, it is clear that these experts have carefully considered their opinions bearing in mind the nature of the proceeding. For example, Dr. Matthews testified on cross-examination:

I'm very well aware of the gravity of this hearing and its effect on Mr. Landis. But I'm comfortable with what I've seen with regard to the F3 fractions, yes.

CAS Tr. at 1147:4-8.

Dr. Ayotte made clear on cross-examination, as she had in her witness statement (Ayotte Stmt. at ¶24) that §5.4.4.2.1 of the ISL requires the laboratory to develop methods that avoid matrix interference. The ISL does not make the existence of matrix interference in a particular chromatogram an ISL violation. She further stated that even if matrix interference made the reported results inaccurate, the interference would not be a violation of Article 5.4.4.2.1; rather it would be an ISL violation for reporting inaccurate results, and that is not the case here. CAS Tr. at 1308:5-1309:2. Finally, Dr. Ayotte makes clear that if there is not matrix interference in the

<sup>&</sup>lt;sup>33</sup> USADA Issue #9; Appellant Issue #3.b. See also AAA Decision at ¶¶232-242.

relevant portion of the chromatogram upon which a positive test is based, such as the second half of Fraction F3, matrix interference in the beginning of that chromatogram or in other chromatograms would not violate the ISL. CAS Tr. at 1317:9-1319:14. Dr. Brenna agreed, see CAS Tr. at 1042:8-19, as did Dr. Matthews:

From a practical point of view, almost every real sample has areas of a chromatogram that are not all that great. And the job of the chromatographer is to set up the method so that the area of interest is as clean and neat and tidy as possible . . . . Even though the front end does not look nice, I'm less concerned. In fact, one could start the analysis at 1200 seconds and we'd not see it at all. We could also start it earlier, the laboratory has set it up to do this way and it seems perfectly reasonable because in the area of interest, the peaks in this particular chromatogram look pretty good.

CAS Tr. at 1147:19-1154:16.

With respect to Appellant's "sloping baseline" allegation, Dr. Matthews also notes that in the area of interest in Fraction 3, the baseline is relatively unchanging. CAS Tr. at 1132:15-1135:21. Both Dr. Matthews and Ms. Jumeau also explain why the background in the Fraction 3 chromatograms is not significantly depleted, as claimed by Appellant. See id. at 1135:22-1141:6; Jumeau Rebuttal at 8. Dr. Brenna testified that the zero background analysis in reprocessing addresses the argument that the background in Fraction 3 could have had a very low delta value because, even when the entire background was included in the peaks, it did not significantly influence their delta values. CAS Tr. at 1033, 1034.

Finally, Dr. Brenna, Ms. Jumeau and Dr. Matthews all refute Dr. Meier-Augenstein's speculative claim, adopted by Dr. Goodman, that there could have been a small contaminant peak co-eluting with the 5alpha peak in Fraction 3 of the B Sample, which could have significantly impacted the 5alpha peaks' delta value. In response to questioning from the Panel, Dr. Goodman conceded that he did not really know whether there were any low-level contaminant peaks that were creating interference because "it wasn't an ideal way to look at the

data." See CAS Tr. at 613. Further, Dr. Brenna explained that in the data obtained during reprocessing, looking carefully at the 2:1 ratio trace, he could see baseline on both sides of the 5alpha peak, which told him that the peak was resolved and that there was no co-elution from the little contaminant peak. See CAS Tr. at 1037:7-23; see also Brenna Stmt. at 20-22. Ms. Jumeau also explained that the small contaminants on the chromatograms for Sample 995474 did not have an "exotic" isotopic values as speculated by Dr. Meier-Augenstein because if they had, it would have forced spectacular dips in the 2:1 traces far beyond the scale shown, and that did not occur. See CAS Tr. at 1207:2-1208:25. Ms. Jumeau's conclusion was that any contaminants present in Mr. Landis's sample fractions had isotopic values within the normal range found in nature and were too small to have any significant effect on the target analytes used to determine the AAF. See Jumeau Stmt. at 7-8. Dr. Matthews expressed a similar opinion on these points.

## XVI. Bottle Chain of Custody<sup>34</sup>

Appellant's expert on chain of custody was Dr. Goldberger. Although Dr. Goldberger is familiar with chain of custody issues in his own laboratory work, which is largely related to drunk driving cases and autopsies, he has no experience with the chain of custody requirements of the ISL. See CAS Tr. 277:24-278:8.

Dr. Goldberger states that the purpose of laboratory chain of custody is to "provide to the judge or arbitrator proof that the sample could not have been altered or tampered with." See Goldberger Stmt. at ¶35. Without getting into the details of the ISL, the Panel can be

<sup>&</sup>lt;sup>34</sup> USADA Issue #17; Appellant Issue #3.g. <u>See also AAA Decision at ¶¶258-279</u>. Appellant's list of issues, filed 12 days before the hearing, also identified <u>aliquot</u> chain of custody as an issue. However, because no issue with aliquot chain of custody was raised in the Appeal Brief, witness statements, or during the hearing, USADA requests that the Panel ignore any aliquot chain of custody argument submitted by Appellant.

comfortably satisfied that this purposes was fulfilled in this case because: 1) Appellant's counsel conceded in the AAA Hearing that the samples that were analyzed belonged to Appellant. AAA Tr. at 2054:11-13; and 2) It is not contested that from receipt at LNDD, Appellant's A and B Sample bottles remained inside the controlled area of the laboratory where only LNDD laboratory technicians and escorted guests would have had access to them. See Buisson Stmt. at 11-12.35 Thus, whether or not the Panel finds any technical chain of custody violation by LNDD, the Panel can be comfortably satisfied that no chain of custody issue could have caused Appellant's AAF.

The various arguments raised by Dr. Goldberger regarding chain of custody are addressed in USADA's Response Br. at 75-79 and in the witness statement of Ms. Buisson at 11, 12 and in her rebuttal at 1-5. It became clear during the hearing, however, that Dr. Goldberger was willing to overlook many of the chain of custody "requirements" described in his witness statement (for example, time of transfer and location within the laboratory) when he used the UCLA chain of custody form as "an example of proper chain of custody documentation." Goldberger Stmt. at ¶30; CAS Tr. at 282:24-291:11. Further, COFRAC, which specifically audited LNDD against TD2003LCOC (Ex. 26 at LNDD0396), found no chain of custody deficiencies. Dr. de Boer, who watched the bottle chain of custody for the B Sample, similarly found no chain of custody problems and in fact praised LNDD for its transparent procedures. See Ex. 25 at USADA0368.

<sup>35</sup> Chain of custody offers no protection against the extreme hypothetical of a rogue laboratory employee manipulating a sample. See USADA's Response Br. at 76 n. 35; Goldberger Stmt. at ¶ 37. However, no tampering could have occurred with respect to the B Sample because Dr. de Boer and the other witnesses were watching the B Sample analytical process. See Frelat Stmt. at 3.

The ISL requires only that a laboratory's documentation comply with the "concepts" found in the chain of custody Technical Document TD2003LCOC. ISL at 5.2.2.2. Thus, the concepts in the Technical Document are satisfied, for example, when on each LNDD chain of custody document, the operator with custody is identified by an operator code (instead of initials) and elsewhere in LNDD's documentation package, there is a section which identifies each operator by name and which contains each operator's signature. See Ex. 24, USADA0013-0020.

The AAA Panel found on the evidence before them that they were able to follow LNDD's bottle chain of custody as required by the ISL and Technical Document TD2003LCOC. See AAA Decision at ¶264. Dr. Ayotte testified that she was able to do the same. Ayotte Stmt. at ¶19. LNDD has provided substantial additional chain of custody evidence since the AAA Hearing, which includes an annotated map of the laboratory tracing the A and B Sample bottle locations, see Ex. 144, and importantly, the witness statements of each of the LNDD technicians who handled the A and B Sample bottles. (The last paragraph of TD2003LCOC specifically provides that "testimony" may be used to establish chain of custody. See Ex. 102.) These witness statements, together with the chain of custody documents, establish what person or refrigerator had custody of the bottles and the purpose, location and time of the custody. With the exception of L. Martin and M. Garcia, Appellant elected not to examine any of LNDD's chain of custody witnesses and thus their witness statements are uncontroverted. As to Mr. Martin and Ms. Garcia, Appellant failed to establish any break in the chain of custody, any departure from WADA chain of custody Technical Document, or any violation of the ISL.

Dr. Goldberger's witness statement and testimony in relation to chain of custody focused primarily on three documents: See Ex. T103, LNDD1590, 1591; and Ex. 24, USADA0006. LNDD1590 was written by Laurent Martin. It shows him taking the A bottle out of cold room

Fax Server

CH.FR1 at 7:25 a.m. on July 21, performing aliquotting for the EPO screen, and then transferring the bottle to Room 006 at 9:00 a.m. Mr. Martin personally performed each of the activities described in this document. See Martin Stmt. at 1-2 and testimony at CAS Tr. 722-726. LNDD 1591 was completed by Myriam Garcia. She personally performed each of the activities described on the bottom half of that document, including aliquotting for screens other than EPO, and returning the A Bottle to Refrigerator CH.FR1 at 10:00 a.m. See Garcia Stmt. at 1-2. On the top half of that form, however, she described activities which she did not personally perform and she did not describe these activities correctly—she wrote that it was Operator 42 (Jean Antoine Martin, not Laurent Martin) who took the Sample out of the refrigerator at 7:30 (not 7:25). Ms. Garcia's testimony on cross-examination was that as between the two documents, what Laurent Martin wrote would be correct since he was the person who actually performed the tasks. See CAS Tr. at 1253. Dr. Ayotte testified that it was apparent that what Myriam Garcia described on the top of LNDD1591 was someone else's action, and Dr. Ayotte testified that she relied on the entry of the person who actually took the bottles out of the refrigerator. See CAS Tr. at 1303-1304.

The other document upon which Dr. Goldberger focused his attention was USADA0006. This document is a log that reflects transfers of Appellant's A bottle in and out of Refrigerator CH.FR1. Mr. Martin and Ms Garcia explained that because their transfers in and out of CH.FR1 were documented on LNDD1590 and 1591, they were not repeated on USADA0006. See Martin, CAS Tr. at 724 and Garcia Stmt. at 1-2.

303-866-0200

# XVII. Allegations of Non-Forensic Corrections, Illegible French Handwriting, and Incorrect Sample Numbers<sup>36</sup>

Dr. Ayotte testified at the AAA Hearing and in her witness statement that she personally reviewed each of Appellant's non-forensic correction claims and alleged improper sample number arguments and concluded that none of them could have in any way caused Appellant's AAF. See AAA Tr. at 821:14-832:22; Ayotte Stmt. at ¶19. The AAA Panel reached the same conclusion. See AAA Decision at ¶260-290. Each of the documents identified in Appellant's witness statements is explained in a witness statement from the LNDD technician who completed the document. They are summarized as follows:

- USADA0288: See Cerpolini Rebuttal at 3.
- USADA0008: See id.
- USADA0009: See Buisson Rebuttal at 5.
- USADA0079: See Cariou Stmt. at 2.
- USADA0200: See Cerpolini Rebuttal at 5.
- USADA0228: A bar code with the number of Appellant's sample is correctly

printed in the middle of the page ("BUR995474"), so there is no

evident problem with numbering; and

• USADA0229: See Rahali Stmt. at 1. (USADA0024 is identical to USADA0229.)

## XVIII. Training of LNDD Technicians<sup>37</sup>

The witness statements of the LNDD IRMS personnel – Dr. Buisson, Ms. Mongongu, and Ms. Frelat – describe their experience and training. See Buisson Stmt. at 1-3; Frelat Stmt. at 1; Mongongu Stmt. at 1-2. Appellant's conclusion that Dr. Buisson, Ms. Mongongu and Ms. Frelat were poorly trained is inconsistent with the conclusion reached by Dr. de Boer, who

<sup>&</sup>lt;sup>36</sup> Appellant Issue #3.6. See also AAA Decision at ¶260-290.

<sup>&</sup>lt;sup>37</sup> Appellant Issue #3.f.

watched Ms. Frelat perform the B Sample analysis over three days and concluded that she "worked in a transparent and professional way." Ex. 25 at USADA0368. In addition, Dr. Ayotte testified that the IRMS analysis performed by the Paris laboratory is as reliable as any she has an opinion about. CAS Tr. at 1361:9-16.

Appellant's criticism of the training of LNDD's IRMS staff is largely anecdotal, and has been rebutted by other evidence. For example,

- Both Dr. Davis and Dr. Goodman say it was incompetent for LNDD to perform (a) analysis on the IsoPrime 2 with the lifting rings still attached, yet Dr. Goodman performed the majority of the work for his PhD thesis in Dr. Brenna's laboratory on an IRMS instrument with the lifting rings attached. See Ex. 156. Dr. Brenna's clear testimony was that the rings were removable. See CAS Tr. at 647:8-648:23; 1074:9-1075:20. In any event, lifting rings on the IsoPrime 2 instrument could not possibly have affected the Stage 17 results which were generated by the IsoPrime 1 instrument.
- (b) Dr. Davis argues that the fact that LNDD admitted that it did not have an operating manual is evidence of poor training and incompetence. See Davis Stmt. at ¶71. As was clearly explained in LNDD's response to discovery, LNDD did have the Isochrom manual, which was delivered with the instrument by the manufacturer. See USADA's Response to Respondent's Second Request for Documents, Ex. B at 9 (Response to Request C.4(c)) As Ms. Jumeau pointed out, there was no IsoPrime GC manual available at the time LNDD purchased its IsoPrime instrument. See CAS Tr. at 1181:23-25.
- Dr. Davis claims that the fact that the LNDD operators did not notice that the (c) wrong type of column was named in the GC/MS method file indicates that they were

incompetent. Yet evidently Dr. Davis (and for that matter, Dr. Meier-Augenstein) did not notice either, despite having spent many hours on the case. See CAS Tr. 588:21-589:17.

(d) Dr. Davis also says that it is his opinion, based on his observations during the reprocessing, that the LNDD technicians lacked training. See Davis Stmt. at ¶50. Ms. Jumeau, who was also present at the reprocessing, flatly rejects Dr. Davis's statement. See Jumeau Rebuttal at 3. Perhaps most importantly, the COFRAC assessor, who spent a day with LNDD's IRMS team and specifically watched Ms. Frelat prepare and analyze samples, concluded the staff was clearly very knowledgeable and demonstrated their competence. See Ex. 26, LNDD0396.

Further, as confirmed in examination of Ms. Frelat by the Panel, neither Appellant's A Sample nor B Sample was declared positive based on the analysis of one technician alone.

Rather, the analyst's conclusion was verified by the analyst's supervisor and approved by the laboratory director before the sample was reported positive. See CAS Tr. at 917-918.

### XIX. Steroid Metabolism<sup>38</sup>

Appellant contends that his Stage 17 positive test results should be disregarded because those results and the overall pattern of his eight Tour de France results are inconsistent with known steroid metabolism. Clearly, Appellant has the burden to establish this proposition by a balance of probability. <sup>39</sup> Appellant's only witness on steroid metabolism, Dr. Amory, in response to questions from the Panel, virtually conceded that this burden could not be met. Dr Amory acknowledged that the studies in this area contain limited data, and no data where a subject has been given a combination of methods of testosterone application (e.g., oral and gel) and different doses applied at irregular times. "We can only make the inferences that we can

<sup>&</sup>lt;sup>38</sup> USADA Issue #15; Appellant Issue #5.

<sup>&</sup>lt;sup>39</sup> Appellant has not even attempted to establish an ISL violation on this issue.

make based upon the data that we have . . . there's an absence of knowledge here that's frustrating." CAS Tr. at 499:16-20.

Dr. Amory also acknowledged that he has not personally studied urinary steroids and that his conclusions are based on his interpretation of the studies. Remarkably, the conclusions that Dr. Amory draws from some of these studies are inconsistent with the opinions of the very scientists who performed and authored the studies. See AAA Tr. at 1590:11-12.

Dr. Amory's opinion rests on the proposition that the 5alpha and 5beta metabolites always rise and fall together. "In normal circumstances, the differences between 5alpha and the 5beta delta-delta values would not exceed one, and only in rare cases would it rise as high as two." Amory Stmt. at ¶86.

Dr. Shackleton points out that Dr. Amory's assertion is not scientifically sound because the 5alpha and 5beta metabolites are formed by entirely different pathways under no common control. Therefore, he was not at all surprised at the difference between Appellant's 5alpha and 5beta delta-delta values. See Shackleton Stmt. at ¶1. Dr. Shackleton's opinion is borne out in the studies. Dr. Schänzer's testosterone gel study<sup>40</sup> concludes that the delta-delta differences between the 5beta metabolite and the endogenous reference compound are much smaller than the differences between the 5alpha metabolite and the endogenous reference compound. "These results once again indicate that testosterone is most probably converted mainly into 5-alpha-steroids after transdermal application, due to the high 5-alpha-reductase activities of the skin." See Exs. 34, 152. <sup>41</sup> Both of the subjects in Dr. Schänzer's study showed more depletion of the

<sup>&</sup>lt;sup>40</sup> There are two studies by Dr. Schänzer. The original study, Ex. 34, was referred to extensively by Dr. Amory in his AAA testimony. Data from the original study was subsequently published in a peer-reviewed journal. USADA Ex. 152. It appears that Appellant never gave Dr. Amory a copy of this published study. CAS Tr. at 430:2-18.

<sup>&</sup>lt;sup>41</sup> Both Dr. Shackleton and Dr. Clark concur with this opinion.

Fax Server

5alpha metabolite than the 5beta metabolite following testosterone gel administration. One subject (P9) showed a difference between 5alpha and 5beta of 3.3% units. See Clark Rebuttal at 16; see also Ex. 43 at USADA0802. Dr. Shackleton makes clear that significant differences between 5alpha and 5beta begin to appear in his study during the washout period, after testosterone injection. See Shackleton Stmt. at 4-5; Rebuttal at 1-4. For most of the subjects in the Shackleton study, there were times during the washout period where the difference between 5beta and Pdiol would have been positive (>3‰) and the difference between 5alpha and Pdiol would have been negative. See Ex. 40 at USADA1245, Figure 4. Similar delta-delta differences of 4.3‰ and 3.1‰ can be seen in the Aguilera and Catlin studies, as described by Dr. Clark. See Clark Stmt. at 17; Rebuttal at 15.

Dr. Shackleton also points out that some individuals are predisposed to convert testosterone into 5alpha and others into 5beta. See Shackleton Stmt. at 4. The opinions of Drs. Shackleton and Clark and the studies by Drs. Schänzer, Catlin, Shackleton and Maitre clearly demonstrate, consistent with the WADA positivity criteria, that an athlete can dope with testosterone and, depending on the method of testosterone application, his natural tendency to produce 5alpha and 5beta, and when his sample is collected after administration, he or she can have only one testosterone metabolite that exceeds WADA's three delta-delta unit positivity criteria.

Dr. Amory's opinion also rests on the proposition that a subject's T/E ratio will always go up and down with the values of testosterone metabolites. Amory Stmt. at ¶ 45. Contrary to Dr. Amory's conclusion, however, the T/E ratio scatter plots in the appendix to Dr. Schänzer's study clearly demonstrate that, even when a consistent dose of testosterone is applied every morning, an individual's T/E ratio can fluctuate from 7:1 to 1:1 on consecutive days of

administration. <u>See Clark Rebuttal at 1-12</u>. The lack of correlation between T/E ratio and the delta values of 5alpha and 5beta is also illustrated in the Shackleton study. <u>Compare Ex. 40 at USADA1247</u>, Table 2, with Figure 4 on USADA1245.

Comparing the pattern of Appellant's eight Tour analytical results, see GDC 01363, Dr. Amory expressed particular concern that a 5alpha-Pdiol delta-delta difference of greater than four was reported on the final two days of the Tour. It is not USADA's burden to establish what form of testosterone Appellant used, when he used it, or what dose he took to cause his Stage 17 AAF, or that his doping made sense. However, as Dr. Clark points out, if Appellant had used testosterone gel before the important time trial on July 22, it is not surprising that his 5alpha-Pdiol ratio would still be depleted after the ceremonial ride into Paris the next day. See Clark Stmt. at 4-5.

Dr. Amory conceded that physical stress reduces natural testosterone levels and he would not be surprised if that happened to riders during the Tour de France. CAS Tr. at 439. Whatever the reason, there is ample evidence that riders in the Tour de France and other stage races have chosen to dope with testosterone. See Exs. 98, 123, 149-151.

### XX. Appellant's Other Seven Tour de France Samples<sup>42</sup>

The significance of the analytical results of Appellant's other seven Tour samples is discussed in USADA's Response Brief at 86-89. Those arguments need not be repeated here. What is important is that Appellant's Stage 17 AAF was not a single aberrational laboratory result: Appellant was using exogenous testosterone at various times during the last ten days of the Tour. Although Appellant's other seven Tour samples screened negative using the T/E ratio

<sup>&</sup>lt;sup>42</sup> USADA Issue #4; Appellant Issue #7.

test, as Dr. Ayotte pointed out, an elevated T/E ratio is not a prerequisite to an AAF based on IRMS. See Ayotte Stmt. at ¶ 10.43

#### XXI. Sanction Start Date<sup>44</sup>

The AAA Panel effectively gave Appellant credit on the start date of his sanction based on his voluntary declaration of non-competition as of January 30, 2007. See AAA Decision at ¶320.6; USADA Response Br. at 89-90. Appellant violated that voluntary declaration when he competed in the USA Cycling sanctioned Leadville 100 Mountain Bike Race after the AAA Hearing was over but before the Panel's Decision. Appellant has not challenged this fact. Appellant should not have the benefit of his self-imposed non-competition declaration when he failed to honor it.

Appellant cannot argue that USA Cycling allowed him to participate in the Leadville race: until the AAA Decision finding that he committed an anti-doping rule violation, USA Cycling had no power to exclude him from competition. Having declined to cross-examine Sean Petty, Appellant cannot dispute that the Leadville 100 Race was USA Cycling-sanctioned. See Petty Stmt. at 1; Ex. 146 at USADA1694-1697.

As discussed during the CAS Hearing, this Panel has the authority to alter the sanction imposed for an anti-doping rule violation. Accordingly, the normal application of UCI Rule 275 should be imposed and Appellant's sanction should start on September 20, 2007, the date of the AAA Panel's decision. See USADA Response Br. at 89-90.

<sup>&</sup>lt;sup>43</sup> As noted in USADA's Response Brief, a number of CAS decisions have held that IRMS results can stand alone without support from T/E ratio analysis. See USADA Response Br. at 17-18, 23-24.

<sup>&</sup>lt;sup>44</sup> USADA Issue #7; Appellant Issue # 10. See also AAA Decision at ¶ 320.6.

#### XXII. Fees and Costs<sup>45</sup>

Under CAS Rule 65.3, the Panel has authority to make an award of fees and costs in this case. See, e.g., Olga Danilova v. IOC (CAS 2002/A/371); Michelle Smith de Bruin v. FINA (TAS 98/211).

Despite the Panel's instructions to the parties to limit the issues in this appeal, Appellant refused to do so. The length of the briefing and the hearing, and the number of USADA witnesses are all a result of Appellant's election to pursue myriad defenses regardless of their scientific merit.

Appellant's approach substantially increased the cost to USADA far beyond what would typically be expected in an IRMS case. The out of pocket costs for Respondent's side of this proceeding on appeal include, for example, transportation, hotel and meals in New York City for nine witnesses whom Appellant demanded be present in person for cross examination and then elected not to call them (approximately \$60,000); expert witness fees for Drs. Matthews, Brenna, Shackleton and Clark and Ms. Jumeau to address Appellant's myriad defenses (approximately \$33,000); and substantial attorneys fees. Appellant's strategy in this case was to do more than present a vigorous defense. Appellant targeted both LNDD and the system itself; as he described in his book, his "defense was to take down the French lab in an embarrassing way." CAS Tr. at 354:12-19.

If this type of defense conduct is allowed to go unchecked, the effectiveness of the whole anti-doping system will suffer. The message to anti-doping agencies would be clear: to bring a solid case against a famous athlete will be financially ruinous. While an athlete, regardless of

<sup>&</sup>lt;sup>45</sup> USADA Issue #8; Appellant Issue #11.

financial resources, should be entitled to pursue any legitimate defense, the defenses pursued by Appellant in this appeal have been scientifically baseless and an award of costs is appropriate.

#### XXIII. Conclusion

Based on the foregoing, as well as the record below and the evidence submitted in these proceedings, USADA respectfully requests that Mr. Landis's appeal be denied.

Dated this 18th day of April, 2008.

UNITED STATES ANTI-DOPING AGENCY

Richard R. Young

Daniel J. Dunn

Jennifer A. Sloan

Holme Roberts & Owen LLP

90 South Cascade Avenue, Suite 1300

Colorado Springs, CO 80903

Matthew S. Barnett Barnett & Barnett P.C. 830 Tenderfoot Hill Rd., Suite 350 Colorado Springs, CO 80906

Attorneys for the United States Anti-Doping Agency

#### **Table of Contents**

1.	Introduction	1
II.	Burden of Proof	2
III.	Credibility of Witnesses	3
IV.	Accreditation	6
V.	Dr. de Boer's Observation of the B Sample analysis	9
VI.	May 2007 Electronic Data File Reprocessing	. 10
VII.	Appellant's Allegations of False Statements, Fraud, and Cover-ups	. 13
VIII.	Controls	. 18
IX.	5alpha Androstanol Acetate Internal Standard	. 21
X.	Linearity	. 23
XI.	Manual Integration	. 25
XII.	Spirit of the same operator rule.	. 27
XIII.	ISL Data Recording Requirements	. 28
XIV.	GC/MS Column Issue	. 34
XV.	Chromatography	. 35
XVI.	Bottle Chain of Custody	. 37
XVII.	Allegations of Non-Forensic Corrections, Illegible French Handwriting, and Incorrect Sample Numbers	. 41
XVIII.	Training of LNDD Technicians	. 41
XIX.	Steroid Metabolism	. 43
XX.	Appellant's Other Seven Tour de France Samples	. 46
XXI.	Sanction Start Date	. 47
XXII.	Fees and Costs	. 48
XXIII.	Conclusion	. 49