Report

Independent Investigation

Analysis Samples from the 1999 Tour de France

Scholten c.s. Advocaten

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## 1 Executive summary

#### Mandate of the independent investigator

- 1.1 The independent investigation of all facts and circumstances regarding the analyses of the urine samples of the 1998 and 1999 Tours de France conducted by the French WADA-accredited laboratory, the 'Laboratoire Nationale De Dépistage Du Dopage' (hereinafter: the 'LNDD') in Châtenay-Malabry, France, was the result of allegations made in the newspaper article 'Armstrong's lie', published in the French newspaper L'Equipe on August 23, 2005, that the American cyclist and seven-time winner of the Tour de France, Lance Armstrong, had used the prohibited substance 'recombinant EPO' (hereinafter: 'r-EPO') during the 1999 Tour de France. According to the article, six urine samples of Armstrong from the 1999 Tour de France allegedly tested positive for r-EPO when analysed by the LNDD as part of ongoing research to further improve the existing detection method for r-EPO. In addition, it was alleged that six other urine samples, from six other riders, had also tested positive for r-EPO.
- 1.2 In the course of the subsequent public debate, it was suggested by the 'World Anti-Doping Agency' (hereinafter: 'WADA') - a foundation or agency founded to promote and coordinate at international level the fight against doping in sport in all forms<sup>1</sup> - that the 'Union Cycliste Internationale' (hereinafter: 'UCI'), the International Federation responsible for the sport of cycling, was slow to act and apparently more interested in finding out how confidential information had become public, instead of determining whether or not the findings of the LNDD were correct, i.e. whether Armstrong had indeed used the prohibited substance *r-EPO* when participating in the 1999 Tour de France. The UCI denied these suggestions and subsequently invited Mr. Emile N. Vrijman at that time practicing as an attorney specialised in sports law in Rotterdam, the Netherlands, to conduct an independent investigation. On October 6, 2005, the UCI issued a press release announcing its decision to ask Vrijman to conduct this independent investigation. On November 9, 2005, the UCI issued a 'Letter of Authority', specifying Vrijman's mandate and the conditions for conducting the independent investigation.

#### The members of independent investigator's team and its work

1.3 The team of the independent investigator consisted of:

– Emile N. Vrijman is attorney-at-law at Scholten c.s. advocaten in The Hague, the Netherlands and as such has been involved in a number of doping cases before the 'Court of Arbitration for Sport' (hereinafter: 'CAS') in Lausanne, Switzerland, as well as other national and international tribunals. Vrijman has been active

World Anti-Doping Agency (WADA), Constitutive Instrument of Foundation of the World Anti-Doping Agency, art. 4, par. 1, 'Object', Lausanne, Switzerland, April 11, 2005.

in the field of anti-doping for almost ten years as director of the 'Netherlands Centre for Doping Affairs' ('NeCeDo'), the national anti-doping organization in the Netherlands and has published extensively on anti-doping policies and legal issues concerning doping.

- Dr. Adriaan van der Veen is currently working as a scientist for the Dutch Metrology Laboratory, the 'Nederlands Meetinstituut' (hereinafter: 'NMi') in Delft, the Netherlands. Dr. Van der Veen is an expert regarding the application by laboratories in general and doping control laboratories in particular of the requirements as detailed in the international standard 'ISO/IEC 17025: 1999', 'General requirements for the competence of testing and calibration laboratories' (hereinafter: 'ISO/IEC 17025 international standard'). As such, he has been consulted as an expert-witness in a number of doping cases before CAS, as well as other national and international tribunals and has been the author of several scientific publications in peer-reviewed journals regarding the relationship between quality assurance and doping control, measurement uncertainty and the burden of proof in doping cases. Dr. Van der Veen has been responsible for the evaluation of all of the technical issues of the independent investigation concerning the measurements and related matters such as the application of procedural rules and implementation of requirements.
- Paul Scholten is an attorney-at-law for almost 30 years and as such one of the first attorneys in the Netherlands practising sports law. Paul Scholten has acted as attorney for the Amsterdam Football Club 'Ajax' and a large number of other sports organizations, as well as athletes. He is currently heading Scholten c.s. advocaten in The Hague, the Netherlands.

In the period between October 2005 and May 2006, the investigator team collected and reviewed all available information and documentation on file with the UCI, as well as information and documentation obtained upon request or through the investigator's team own research. As part of the review, various anti-doping rules and regulations have been examined and evaluated to determine their significance with regard to the inquiry itself. In addition, a large number of other relevant regulations, such as the French Anti-Doping law, other French legislation, the IOC Medical Code, as well as existing codes of good practise, such as the so-called 'Helsinki Accords', addressing issues like the ownership of biological samples, as well as the necessity of obtaining informed consent in cases involving scientific human biological material, have been examined and evaluated. This was also done with potential relevant technical and procedural rules, regulations and requirements, such as WADA's 'International Standard for Laboratories' (hereinafter: 'ISL') and 'Result Management Guidelines', as well as 'ISO/IEC 17025: 1999 - 'General requirements for the competence of testing and calibration laboratories' (hereinafter: 'ISO/IEC 17025 international standard').

## The Importance of Fighting Doping in Sports; The Importance of Proper Conduct by the Organisations and Authorities Involved

1.4 The 'International Olympic Committee' ('IOC') has recognized the importance of eliminating the use of performance enhancing substances in sport and its Olympic Charter requires the IOC *'to lead the fight against doping in sport'*<sup>2</sup>. The importance of conducting the fight against doping in sport and a campaign to identify performance enhancing substances and methods, to detect their use, and sanction those involved in the provision and use of these substances and/or methods cannot be overstated. According to the 2003 World Anti-Doping Code (hereinafter: *'WADA Code'*), anti-doping programs seek to preserve what is intrinsically valuable about sport.

'This intrinsic value is often referred to as 'the spirit of sport'; it is the essence of Olympism; it is how we play true. The spirit of sport is the celebration of the human spirit, body and mind, and is characterized by the following values:

- Ethics, fair play and honesty.
- Health.
- Excellence in performance.
- Character and education.
- Fun and joy.
- Teamwork.
- Dedication and commitment.
- Respect for rules and laws.
- Respect for self and other participants.
- Courage.

3

• Community and solidarity.

Doping is fundamentally contrary to the spirit of sport.'3

The independent investigator's commitment to the objectives of the fight against doping is well known and on public record.

- 1.5 In order to structure and harmonize the international fight against doping in sport,WADA was founded in 2003. Its objectives are:
  - 1. to promote and coordinate at international level the fight against doping in sport in all forms including through in and out-of-competition; to this end the Foundation will cooperate with intergovernmental organizations, governments, public authorities and other public and private bodies fighting against doping in sport, inter alia the International Olympic Committee (IOC), International Sports Federations (IF), National Olympic Committees (NOC) and the athletes; it will seek and obtain from all of the above the moral and political commitment to follow its recommendations;'
- 2 International Olympic Committee (IOC), Olympic Charter, Chapter I, 'Mission, Role of the IOC', Rule 2, Lausanne, Switzerland, September 1, 2004.
  - WADA, World Anti-Doping Code, 'INTRODUCTION', 'FUNDAMENTAL RATIONALE FOR THE WORLD ANTI-DOPING CODE', Lausanne, Switzerland, 2003, p. 3.

- 2. to reinforce at international level ethical principles for the practice of doping-free sport and to help protect the health of the athletes;'
- [...]
- '5. to develop, harmonize and unify scientific, sampling and technical standards and procedures with regard to analyses and equipment, including the homologation of laboratories, and to create a reference laboratory;
- 6. to promote harmonized rules, disciplinary procedures, sanctions and other means of combating doping in sport, and contribute to the unification thereof, taking into account the rights of the athletes;' <sup>4</sup>
- 1.6 Notwithstanding the many difficulties experienced in the fight against doping, the ideal of fair play nevertheless also applies to all of those involved in this fight. The IOC, the Council of Europe and CAS have always recognized that the ideal of fair play first and foremost requires fair rules and clear procedures<sup>5</sup>. The CAS Panel in the matter of USA Shooting & Quigley v. UIT, made the following remarks in this regard:

'The fight against doping is arduous and it may require strict rules. But the rule-makers and rule-appliers must begin by being strict themselves. Regulations that may affect the careers of dedicated athletes must be predictable. They must emanate from duly authorised bodies. They must be adopted in constitutionally proper ways. They should not be the product of an obscure process of accretion. Athletes and officials should not be confronted with a thicket of mutually qualifying or even contradictory rules that can be understood only on the basis of the de facto practice over the course of many years by a small group of insiders.'<sup>6</sup>

1.7 They further recognized that the ideal of fair play means that the fight against doping in sport must also be conducted in a manner consistent with the principles of natural justice and with respect for due process, while taking into account athletes' rights, professionalism, and ethics. This means that the applicable laws and regulations must be followed and applied in a consistent manner<sup>7</sup> and that athlete confidentiality, as required by those very same rules, must be honoured. This requires from those involved in doping control and results management, especially when in a position of responsibility and authority, to abide by the rules and to refrain from making

<sup>4</sup> Supra, at 1, p. 1.

According to the IOC's 1990 International Olympic Charter against doping in sport, it is the responsibility of sports organizations 'to have clear regulations and to conduct competition and out-of-competition controls' and to protect the rights of suspected persons by ensuring that the regulations 'are adequate and sufficient'. IOC, International Olympic Charter against doping in sport, Annex 6, par. 1.2 and par. 1.7, 'The responsibilities of sports organizations', Lausanne, Switzerland, 1990, p. 6.1. According to the 1989 Anti-Doping Convention of the Council of Europe, sports organizations should be encouraged to 'clarify and harmonize their respective rights, obligations and duties, in particular by harmonizing their [...] (d) disciplinary procedures, applying agreed international principles of natural justice and ensuring respect for the fundamental rights of suspected sportsmen and sportswomen; [...]'. See: Council of Europe, Anti-Doping Convention, art. 7.2 sub d, Strasburg, France, 1989.

<sup>6</sup> USA Shooting and Quigley v. UIT, May 23, 1995 (CAS 94/129).

Chagnaud v. FINA, April 1996 (CAS 95/141).

unfounded and unjustified allegations against athletes or commenting on them, especially in those cases which aren't covered by any applicable rules yet and sanctions cannot be issued. It might be so that sport, worldwide, can only be dopingfree if the trails of those who may be doping are followed as far as is necessary to expose their actions, this however, does not mean that the fact that in some cases it may not be possible to impose any sanctions, is only a secondary consideration to the discovery and exposure of doping. Because of the principles of natural justice and its respect for due process, the CAS Panel in USA Shooting & Quigley v. UIT found that -when asked to determine whether the definition of doping as laid down in the UIT Anti-Doping Regulations was one of strict liability or not- its sympathy for the principle of strict liability 'obviously' did not allow it to create such a rule where it did not exist. This is also true when wanting to discover and expose doping in cases where it may not be possible to impose any sanctions. As ASOIF President Dennis Oswald and IOC Athletes Commission President Sergey Bubka remarked in their letter to WADA President Dick Pound, dated October 6, 2005, that striving to determine the 'truth' in the interest of clean sport, while commendable, does come at a price. If this would mean that ethical, legal and regulatory standards have to be sacrificed to obtain a result, which leaves serious doubts as to the truth, they believe that this price should not be paid<sup>8</sup>.

1.8 The IOC, WADA, the UCI as well as all other IFs, NOCs, national sports governing bodies, 'National Anti-Doping Organizations' (hereinafter: 'NADO'), intergovernmental organizations, governments, public authorities and other public and private bodies fighting against doping in sport all require and expect athletes involved in international sports to comply with high standards of ethics and honesty, to honour the principle of fair play, to adhere to applicable rules and regulations and to believe that the current anti-doping program is meant to ensure their right to fair play and to protect their health. In order to achieve this, however it is absolutely essential that those responsible for, and those involved in, the system of doping control and results management hold themselves, their colleagues, and their conduct to the same high standards.

## Authority for retrospective testing or re-testing of urine samples for doping control purposes

1.9 Various sport officials, while commenting on the analyses of the urine samples from the 1998 and the 1999 Tours de France, have suggested that article 17 of the 2003 WADA Code, titled 'Statute of Limitations,' would authorize sports governing bodies to conduct 'retrospective testing', i.e. to go back in time and retest frozen urine and/or blood samples obtained up to eight (8) years ago<sup>9</sup>. The rationale for having such a rule is that it would allow WADA-accredited doping control laboratories to apply new

<sup>8</sup> 

Letter from Dennis Oswald, President, ASOIF and Sergey Bubka, President, IOC Athletes Commission, to Richard Pound, President, WADA (October 6, 2005).

Article 17 of the 2003 WADA Code states: 'No action may be commenced against an Athlete or Other Person for a violation of an anti-doping rule contained in the Code unless such action is commenced within eight years from the date the violation occurred.'

detection methods for certain *Prohibited Substances* that were not available at the time the urine samples had been collected. This however, is incorrect. All that article 17 actually says, is that it is possible to commence an action against an athlete or any other person for a violation of an anti-doping rule within a period of eight (8) years from the date the violation did occur and then only as far as 'non-analytical positives' are concerned, i.e. an admission of use by the athlete or documentary evidence of purchase and use of *Prohibited Substances*. Article 17, in other words, allows a sports governing body to respond whenever it receives a 'notitia criminis', i.e. whenever it has learned that a possible anti-doping rule violation might have occurred, from whatever source, as long as this is being done within a period of eight (8) from the date this possible anti-doping rule violation might have occurred<sup>10</sup>. It does not say anything about retesting urine samples within a period of eight (8) years from the date they were provided.

- 1.10 WADA and the IFs simply have never promulgated any rules that permit or even contemplate retrospective testing. But even if article 17 of the WADA Code was to authorize sports governing bodies to conduct 'retrospective testing' - quod non neither the WADA Code, nor the 'ISL' provide any procedural rules and regulations on how to conduct retrospective testing. The anti-doping rules and regulations that do exist require that testing be conducted promptly after the urine samples are received. They do not require that the urine samples or the doping control forms that might be used to identify which urine samples were given by which athletes, be kept for eight (8) years. In fact, WADA President, Dick Pound, told the media that the doping control forms in this matter should have been destroyed after two years. In addition, all of the doping control testing rules require that tests, which may yield 'Adverse Analytical Findings' be conducted on previously sealed urine and/or blood samples with an intact external and internal chain of custody. There is also the problem that most detection methods for Prohibited Substances have been validated only for the analysis of 'recent urine samples', i.e. urine samples that were obtained only a short time before being analysed. Adequate scientific information about the effects of longterm storage on the reliability of the analysis results obtained years after these urine samples were taken may not exist.
- 1.11 If the IOC, WADA, the UCI as well as all other IFs, NOCs, national sports governing bodies, NADOs, intergovernmental organizations, governments, public authorities and other public and private bodies fighting against doping in sport, believe that retrospective testing is necessary as another means to ensure doping-free sport worldwide, they need to think about the implementation of the necessary procedural rules and regulations allowing them to do so in a manner compatible with the current procedural rules and regulations for regular doping control testing, while providing the same protection of athletes' rights. Whether this might require that a 'C' sample should be obtained from athletes as well i.e. if the athlete's 'A' sample has tested negative in the past, years later a sealed 'B' and 'C' sample would be available for

<sup>10</sup> 

Supra, at 3, p. 46. See also: CAS, Advisory Opinion CONI, April 26, 2005, (CAS2005/C/841 CONI), at p. 24 – 25.

retrospective testing, thus allowing a second confirmation test to be conducted – or that the 'B' sample should only be opened in the presence of a bailiff or notary and divided in two separate urine samples – i.e. 'B1' and 'B2' – remains to be seen. What is necessary however, are clear and fair rules that would permit such testing and would detail exactly the procedures to be followed, offering the athletes the same protection of their rights as the current procedural rules and regulations do. Until that occurs, the spectre of meaningful retrospective testing that could yield lawful sanctions against athletes remains nothing more than an empty threat.

#### Summary of Conclusions

- 1.12 As a first matter, it is clear that the UCI is the organization with jurisdiction to investigate and take action with respect to this matter. This is established both by the current anti-doping rules of the UCI<sup>11</sup> and the UCI rules in effect in 1998 and 1999<sup>12</sup>. All issues of 'results management,' meaning the investigation and possible disciplinary action relating to drug testing during the 1998 and 1999 Tours de France, is and have always been the responsibility of the UCI. The investigator is unaware of any person or organization taking a contrary position during the course of his investigation, while WADA has consistently and repeatedly acknowledged the responsibility of the UCI to conduct this investigation.
- According to the rules of the UCI<sup>13</sup>, the Management Committee of the UCI and, by 1.13 extension, its Executive Committee, has the authority to make decisions concerning the proper conduct of the affairs of the organization and to take action in furtherance of the mission and purposes of the UCI, including to seek outside assistance in the conduct of drug testing and results management. The decision by the UCI to retain an independent investigator to eliminate any possible claim of conflict of interest or bias in the investigation was proper and prudent and was the responsible course of conduct in response to the call for an independent investigation by IOC President Jacques Rogge, as well as the ASOIF President Dennis Oswald and the President of the IOC Athletes Commission, Sergey Bubka. The independent investigator was properly commissioned and afforded the independence necessary to investigate this matter fully and without interference from the UCI. This report and the implementation of its recommendations and conclusions are within the authority of the UCI and the investigator. All parties involved eventually accepted the authority of the investigator and the propriety of the independent investigation. These conclusions are based on the information received to-date and are subject to supplementation and perhaps even modification upon the proper receipt from the LNDD, the French Ministry, WADA, and perhaps others of additional documents and cooperation concerning these matters.

<sup>11</sup> Union Cycliste Internationale (UCI), Anti-Doping Rules, art. 182, Aigle, Switzerland, 2004.

<sup>12</sup> UCI, Anti-Doping Examination Regulations, art. 4, Aigle, Switzerland, 1999.

<sup>13</sup> UCI, Constitution, art. 46, Aigle, Switzerland, 2005.

1.14 Despite the recognition of the proper jurisdiction of the independent investigator by all individuals and organizations that were contacted, the French Ministry, the LNDD and WADA, all refused to provide the investigator with the documents and full cooperation necessary to reach definite conclusions on certain issues that remain unresolved. The refusal by the LNDD, the French Ministry and WADA to provide documents and information that are necessary for the proper conduct of a complete investigation is extremely troubling and is inconsistent with the principles of the Olympic Movement. The fact that WADA President Dick Pound and the LNDD's Professor De Ceaurriz were willing to discuss the research project and its results in great detail with the media, while they at the same time were unwilling to cooperate with a proper investigation by the organization with jurisdiction over this matter, raises substantial questions regarding their reasons for doing so and makes one wonder as to what complete cooperation would disclose. The obligation of the LNDD, in its capacity as a WADA-accredited laboratory conducting doping control testing for the UCI, to cooperate fully with this investigation, does not only follow from the fact that this investigation examines what the LNDD was doing with UCI urine samples in its possession and subsequent publication of the analyses results. It also follows from the requirements as contained in the ISO/IEC international standard. The LNDD contends that the decision to create research reports, containing 'additional information' - i.e. the code numbers present on the original glass bottles used when conducting doping controls at the 1999 Tour de France, necessary for determining the identity of those riders having provided one or more of these urine samples during the 1999 Tour de France, and the analysis results for each of these urine samples - was the result of improper pressure WADA and the French Ministry exerted on the LNDD. WADA President Dick Pound has admitted that he directed the LNDD to prepare these research reports containing the 'additional information' WADA had been requesting. These disclosures, combined with WADA's request that the UCI conduct this investigation to determine whether or not the findings of the LNDD might constitute proof of a potential anti-doping rule violation, as well as the questions that remain about WADA's involvement in the research, all impose a clear obligation on WADA to cooperate fully and timely with this investigation, especially when keeping in mind the importance of the role WADA is supposed to fulfil in the international fight against doping in sport. WADA however, has refused to do so. To the extent that this report is incomplete or does not reach definite conclusions on certain issues, the responsibility lies with the French Ministry, the LNDD, and WADA. If the representations in the WADA Code and other rules, regulations and laws about athletes' rights are to have any credibility and if the WADA Code is meant to be a document that is as enforceable against its signatories as it is against athletes, it is essential that an organization with sufficient authority - whether that is the IOC, CAS, the WADA Foundation Board, the UCI, or a court of law - order the French Ministry, the LNDD, and WADA to produce all documents that relate in any way to this matter, and cooperate fully with the independent investigator in answering all remaining unanswered questions.

- 1.15 The results reported by the LNDD that found their way into the *L'Equipe* article are not what they have been represented to be. They did not involve proper testing of urine samples, as explained in detail in this report. While the testing conducted may have been useful for research purposes - which remains to be determined - the failure of the underlying research to comply with any applicable standard and the deficiencies in the report render it completely irresponsible for anyone involved in doping control testing to even suggest that the analyses results that were reported constitute evidence of anything. To suggest in any way that any of the analyses results could properly be associated with a particular rider or riders, is misleading and constitutes at least gross negligence, given the complete absence of an internal or external chain of custody, proper record keeping and security with respect to the urine samples from the 1998 and the 1999 Tours de France that were tested, and the absence of any protection against samples having been spiked with *r-EPO* or contamination by other samples. The investigator recommends the UCI to refrain from initiating any disciplinary actions whatsoever regarding those riders alleged to have been responsible for causing one or more alleged 'positive' findings, on the basis of the confidential reports of the LNDD 'Recherche EPO Tour de France 1998' and 'Recherche EPO Tour de France 1999', and to inform all of the riders involved that no action will be taken based on the research testing by the LNDD.
- 1.16 While the information and documentation presented to date is insufficient to judge the scientific nature and validity of the research conducted by the LNDD, in particular with regard to the analyses of the urine samples from the 1998 and 1999 Tours de France, the investigator has found no evidence that the decision to analyse those samples was intended as part of a deliberate effort to discredit Lance Armstrong, as has been suggested. However, the LNDD had no right to use those samples for research purposes without securing the permission of the rider(s) who provided the urine samples, and no reasonable explanation has been given as to why the UCI was not consulted before these urine samples were used for research purposes. Because of the refusal by the LNDD to provide any documentation about the research project, no definite conclusions can be reached about the intent of the LNDD in selecting those urine samples or the relationship of those urine samples to the original intentions concerning the research. The LNDD's decision to use the urine samples from the 1999 Tour de France in such a way that their analyses results could eventually be associated with original bottle codes, and subsequently with the riders associated with those bottle codes, raises questions that cannot be answered until the LNDD provides all documents related to the analyses of the aforementioned urine samples and the original reports that were created with regard to the overall research project.
- 1.17 According to the investigator however, the way in which the LNDD reported the findings of the research, combined with improper and false statements to the media attributed to the LNDD and WADA, has caused others given the reputation of the LNDD as being on the cutting edge of *r-EPO* research to suggest that Lance Armstrong used the prohibited substance *r-EPO* during the 1999 Tour de France.

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Had the LNDD conducted its testing in accordance with the applicable rules and regulations and reported its findings accordingly, any discussion about the alleged use of a prohibited substance by Lance Armstrong would not have taken place. Having concluded thus, the investigator however, would like to stress that ultimately it has been WADA's improper request to the LNDD - i.e. to include 'additional information' in its report - which has triggered the chain of events leading to the publication of said allegations in *L'Equipe* and subsequently this report. Contrary to what has been suggested in the media, the investigator has taken the position that the fact that the UCI may have provided Mr. Ressiot, the journalist of L'Equipe, with at least one (1) or more copies of the original doping control forms of Lance Armstrong from the 1999 Tour de France and/or related analysis reports, has not been material for the identification of Lance Armstrong as being one of the riders presumably responsible for having submitted one or more alleged 'positive' urine samples during the aforementioned Tour de France. According to Mr. Ressiot, the manner in which the LNDD had structured the results table of its report - i.e. listing the sequence of each of the batches, as well as the exact number of urine samples per batch, in the same (chronological) order as the stages of the 1999 Tour de France they were collected at - was already sufficient to allow him to determine the exact stage these urine samples referred to and subsequently the identity of the riders who were tested at that stage.

1.18 WADA and the French Ministry refused to disclose their oral and written communications with the media. The communications by Professor De Ceaurriz, Director of the LNDD and WADA President, Dick Pound, that were reported by the media were improper. According to the LNDD and supported by various statements by Dick Pound, the LNDD resisted WADA's efforts to coerce the LNDD to produce a report with the 'additional information,' the numbers that could be used to connect results with riders, and to overcome the LNDD's resistance, WADA provided certain assurances to the LNDD. WADA promised that it would treat the research data as confidential and that they would not be the basis for any sanction against any athlete. Despite the LNDD's acknowledgement of its obligation to maintain the confidentiality of the research results and WADA's representations that it would treat the results as confidential, as soon as the *L'Equipe* article was published, and perhaps even before the publication, WADA President Dick Pound, and LNDD Director, Prof. De Ceaurriz, communicated openly with the media about the analyses results, while WADA even did so in a manner that appears to have been designed to use the data to discredit Lance Armstrong publicly, and, to a lesser extent, to discredit the UCI and other 1999 Tour de France riders. Whatever the LNDD and WADA may have intended when agreeing that the analyses results would not be used 'for any sanction purpose', the investigator believes there is strength to the argument that being the subject of repeated media attacks supported by a leading WADA-accredited doping control laboratory and the President of the organization responsible for international doping control, does qualify as a 'sanction'. It is difficult to understand how WADA and/or the LNDD could believe their discussions with the media regarding the LNDD's research reports would be consistent with their agreement to treat those reports confidentially, or the LNDD's demands that these reports were to be treated as such. It is simply not proper for WADA, being the organization responsible for international doping control in sport, to fuel and subsequently give credibility to media attacks on an athlete, based on reports by a doping control laboratory under its supervision, while it knew or should have known that these reports have no scientific – i.e. forensic – value to support the allegations which were made.

- 1.19 Article 8 of the WADA Code provides that any person 'who is asserted to have committed an anti-doping rule violation' is entitled to a fair hearing. Nevertheless, the conduct and statements of WADA and its President, the LNDD and its Director, have effectively asserted that Lance Armstrong committed an anti-doping rule violation when they all knew or should have known that there was no evidentiary basis for such an assertion and that the current rules and regulations would not afford Lance Armstrong the opportunity to respond to these assertions by means of a fair hearing. IOC President Jacques Rogge acknowledged the unfairness and made public statements in the fall of 2005 criticizing the manner in which this situation had been conducted, and stated unequivocally that Lance Armstrong should not be placed in a position where he would have to prove these allegations to be false. However, as IOC President Rogge recognized, that is precisely the position the conduct and statements of the LNDD and WADA have placed Lance Armstrong in. If international doping control testing is to have any credibility, there must be a possibility to sanction the offenders when WADA-accredited doping control laboratories and 'Anti-Doping Organizations' (hereinafter: 'ADO') violate the applicable rules, regulations and laws as discussed in this report. While WADA's rules and regulations do provide for this in case of WADA-accredited laboratories, they do not for ADOs.
- 1.20 This case involves research testing not conducted in compliance with the applicable doping control testing standards. The investigator supports the concept of 'retrospective testing' for doping control purposes, especially when new detection methods can identify Prohibited Substances that were previously undetectable. However, rules concerning 'retrospective testing' must be adopted properly, WADAaccredited laboratories and the testing authorities must handle and store urine samples properly, to permit meaningful 'retrospective testing'. Research has to be conducted in order to be able to determine the accuracy of 'retrospective testing', especially when analysing urine samples that may be several years old. The WADA *Code* provision that there is an eight-year statute of limitations for anti-doping rule violations, does not by itself, authorize 'retrospective testing'. Before retrospective testing can be conducted, it is essential that clear rules and procedures authorizing 'retrospective testing', as well as the manner in which it is to be conducted -with sufficient guarantees regarding the accuracy of retrospective analysis results- are properly drafted, circulated, considered, and approved. To suggest that WADAaccredited laboratories are already entitled to and in fact engaging in 'retrospective testing' and that subsequent disciplinary proceedings could be initiated on the basis of those results, without any applicable rules and regulations or technical standards that govern 'retrospective testing', is simply irresponsible.

- 1.21 The analyses of the urine samples from the 1999 Tour de France were conducted by the LNDD for research purposes and did not satisfy any standard for doping control testing. The results summarized in the LNDD reports however, are questionable in a number of other ways and for a number of other reasons as well. The investigator has studied those summaries and finds them deficient and not credible in a number of ways. The research reports are merely summaries, while the underlying iso-elctropherograms and other essential documents necessary to evaluate the findings presented in both reports have not been produced. The process that generated those results and the subsequent reports was so deficient that it would be improper in this report to discuss these reports in more detail as it would give the reported results more credibility than they could possibly merit.
- 1.22 Based upon the evidence available, the investigator has found that WADA did force the LNDD to generate summarized results regarding the analyses of the urine samples from the 1998 and 1999 Tours de France, containing the original 1999 Tour de France bottle code numbers from which the riders having provided these urine samples can be identified. These bottle code numbers were neither relevant for the interpretation of the analyses results, nor for the overall LNDD research project. Not until April 2006, did WADA admit for the first time that it had requested the LNDD to include the aforementioned original 1999 Tour de France bottle code numbers. According to WADA, this was done in order to preserve for the UCI the possibility of a longitudinal study analysis of the abuse of *r*-EPO and to find out who among its riders was abusing *r-EPO* at the time. As explained in detail in this report, WADA's post facto rationalization for its request that the original 1999 Tour de France bottle code numbers be included in the summarized results is for a number of reasons not credible and entirely inconsistent with the evidence in this matter. WADA has not produced any evidence to support its claims. There was no reason for WADA to force the LNDD to produce these research reported with the aforementioned bottle code numbers if it had no intention – as it claimed – to look into any disciplinary action. Yet when the identity of one of the riders from the 1999 Tour de France said to have provided one or more alleged positive urine samples, the first thing WADA did was to ask the UCI whether it would investigate this matter or not to determine whether there had been an anti-doping rule violation or not. According to the investigator, the evidence available suggests that WADA was determined to have the LNDD create a report that could, when combined with a copy of 1999 Tour de France doping control forms, identify riders who participated in the 1999 Tour de France as having used *r-EPO*, apparently concentrating on Lance Armstrong only as it never asked the UCI for the identities of the other riders who might have been responsible for producing alleged positive urine samples during the 1999 Tour de France. The investigator needs full cooperation from WADA and needs to see all documents related to this matter from the French Ministry, the LNDD, and WADA, to determine who WADA and/or the French Ministry knew still had the 1999 doping control forms or numbers and what communications there have been between WADA and the L'Equipe reporter during the late spring and summer of 2005.

- 1.23 As discussed in detail in this report, the LNDD representatives contend that it is just a coincidence that LNDD analysis reports regarding 'positive' urine samples are routinely reported prematurely in *L'Equipe*. *L'Equipe* has reported the positive tests results of various athletes before those athlete or their respective IFs had even received notice. In all of these situations the rules and laws governing confidentiality and athletes' rights have been violated, but, as far as the investigator has been able to determine, there has been no indication to date that anyone is investigating this or taking steps to ensure that this does not happen again in the future or that those responsible face sanctions. This matter however, might be more than just a coincidence. Mr. Ressiot claims that he did not reveal the names of three (3) other riders alleged to have produced positive urine samples as well, because of very technical remarks on the lab results table regarding one of these three (3) urine samples. Yet the lab results table published by the LNDD as part of its research report regarding the analyses of the urine samples from the 1999 Tour de France, does not contain such remarks. Neither do the original doping control forms from the 1999 Tour de France, or the corresponding original analysis report from the LNDD. The investigator considers this a very serious matter, which needs to be investigated further, because it damages the credibility of international doping control testing. WADA, the French Ministry, and the LNDD should be compelled to cooperate with this investigation.
- 1.24 From the first day the *L'Equipe* story was published, it was readily apparent that rules about research reports and athlete confidentiality had to have been compromised. Nevertheless, only a few individuals with the status and credibility to make a difference were willing to speak publicly about this. WADA Vice President Brian Mikkelsen and the Director of the Canadian WADA-accredited doping control laboratory in Montreal, Dr. Christian Ayotte, were two of the few individuals within the international anti-doping community who were willing to voice their concerns openly and to put them on record. Other individuals to whom the investigator has spoken made it clear that they were aware of the problems, but were unwilling to speak out for fear of retribution from WADA. Similarly, the LNDD representatives made it clear that they were afraid to resist WADA's demands for including the 'additional information' in their research reports. After their interview, they were not prepared to speak anymore with the investigator, notwithstanding their promises to the contrary. Neither would they allow him access to the documentation they had referred to during the interview or provide him with copies of these, unless ordered to do so by a French court. Even when the ASOIF and the IOC Athletes Commission expressed their joint concerns regarding the violation of athlete's confidentiality in this matter, WADA apparently was able to block any hearing or consideration of those concerns. Even though the WADA Executive Committee decided that a suitable response to the ASOIF and IOC Athletes' Commission letter should be carefully prepared, the response from WADA President Dick Pound was anything but suitable or carefully prepared. The investigator believes that without the commissioning of an independent investigation by the UCI these concerns might never have been addressed. This may explain why WADA President Dick Pound responded to the ASOIF/IOC Athletes Commission

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letter in the manner he did, i.e. as a deliberate attemp to stop the ASOIF and the IOC Athletes Commission in their tracks. The investigator feels that this situation needs to be changed. The investigator recommends that WADA changes -if necessary- its governance structure and policies to ensure that concerns like those expressed by Mikkelsen, Ayotte, the ASOIF, and the IOC Athletes Commission are timely identified, considered, resolved, and remedied and that a mechanism will be devised as soon as possible to deal with any grievances any WADA stakeholder might have who is adversely affected by alleged misconduct either by WADA, a WADA-accredited laboratory, a WADA official or any other individual or organization involved in international doping control testing and results management system. Whether this should be achieved by instituting a 'Code of Ethical Behavior' applying to all WADA staff and personnel or having an 'Ethics Committee' not unlike the IOC Ethics Committee, is for others to decide. However, just as athletes are accountable for their behavior, so should WADA.

1.25 The investigator has determined that the LNDD, and WADA, to an undefined extent in cooperation with the French Ministry, have behaved in ways that are completely inconsistent with the rules and regulations of international anti-doping control testing and in certain cases even in violation of applicable legislation. Several of the issues addressed in this report however, require further investigation. As soon as an organization with authority has compelled the production of all relevant documents and cooperation with this investigation, the investigator can continue the investigation and go even farther in finding answers to the remaining questions, in particular concerning the leaking of the confidential information to the Mr. Ressiot, the L'Equipe reporter. In addition, a tribunal with authority needs to be convened, to provide a fair hearing to the individuals and organizations involved in the misconduct discussed in this report. If that tribunal finds, after affording all involved a fair hearing, that as the investigator has found in this preliminary report, that misconduct occurred, that tribunal should determine the appropriate sanctions to remedy the violations and to deter similar conduct in the future, whether by the specific individuals involved in this matter or by others in the future.

### 2 General Introduction

#### A newspaper article

- 2.1 On August 23, 2005, the French newspaper L'Equipe published the article 'Armstrong's lie', accusing the American cyclist and seven-time winner of the Tour de France, Lance Armstrong, of having used the Prohibited Substance 'recombinant EPO' during the 1999 Tour de France<sup>14</sup>. The naturally occurring hormone *EPO* (hereinafter: 'EPO') -also referred to as 'endogenous EPO' - is a 'glycosylated protein', produced primarily in the kidney of all human beings and stimulates the production of new red blood cells<sup>15</sup>. *r-EPO* however, is a synthetic *EPO* derived from other species -primarily produced in the ovary cells of Chinese hamsters<sup>16</sup> - that can be taken to cause the body to react in the same way as if the body itself (the kidney) had created additional EPO. According to the article, at least six urine samples of Armstrong from the 1999 Tour de France allegedly tested positive for *r-EPO* when analysed by the LNDD. The newspaper reported that analysis of these six-year old urine samples had been a part of LNDD's ongoing research efforts to further improve the existing detection method for r-EPO. In addition, six other urine samples, apparently from six other riders, were alleged to have tested positive for *r-EPO* as well.
- 2.2 Responding to the allegations in the aforementioned article, Armstrong vehemently denied ever having used *Prohibited Substances* and questioned whether the samples thus analysed did in fact contain his urine, as well as the manner in which the LNDD apparently had conducted the analyses of these urine samples. According to the Associated Press, Tour de France director Jean-Marie Leblanc, said in an interview with *L'Equipe* that it was a 'proven scientific fact' that Lance Armstrong had a prohibited substance in his body during the 1999 Tour de France:

'For the first time, and these are no longer rumours or insinuations, these are proven scientific facts; someone has shown me that in 1999 Armstrong had a banned substance called EPO in his body.'<sup>17</sup>

According to USA Today, WADA President Dick Pound responded by saying:

'If he had one, you could say it was an aberration,' Pound said. 'When you get up to six, there's got to be some explanation'.'

[...]

<sup>14</sup> Ex. 1, Damien Ressiot, "Le mensonge d'Armstrong", L'Equipe, August 23, 2005.

<sup>15</sup> This process is called "erythropoiesis". In both its natural and synthetic forms, EPO stimulates the production of red blood corpuscles, thereby increasing oxygen transport and aerobic power. Athletes are believed to use EPO to artificially enhance the number of red blood cells carrying oxygen to the muscles to boost the delivery of oxygen to the tissues thereby enhancing an athlete's performance in endurance sports.

<sup>16</sup> Ex. 2, Françoise Lasne et al., "Detection of Isoelectric Profiles of Erythropoietin in Urine: Differentiation of Natural and Administered Recombinant Hormones", Analytical Biochemistry 311, 2002, at 199 – 201.

<sup>17</sup> Ex. 3, Angela Doland, "Tour Chief: Armstrong Doping "Proven Fact", Associated Press, August 24, 2005.

'There's been an awful lot of rumour and accusations about him for a number of years, always of the he-said, she-said variety. This appears - I haven't seen the documents myself - to have some documentary connection. That's a lot more serious. It got to be taken more seriously.''<sup>18</sup>

Within days, a public debate was taking place regarding the accuracy of the article's reporting, the nature, reliability and -above all- the purpose of the analyses conducted by the LNDD, as well as the manner in which the UCI was to proceed with respect to these alleged 'positive' urine samples and the riders who allegedly had provided them. In an interview with VeloNews on August 23, 2005, Dr. Ayotte, director of the WADA-accredited doping control laboratory in Montreal, Canada, said that they had been extremely surprised at her laboratory: *'that urine samples could have been tested in 2004 and have revealed the presence of EPO'*.<sup>19</sup>. According to Ayotte:

'EPO – in its natural state or the synthesized version – is not stable in urine, even if stored at minus 20 degrees.<sup>'20</sup>

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'EPO is a protein hormone and it is not stable in urine, even when kept frozen', she said. 'This has long had implications for any plan we've had to keep samples and specimens for long periods of time with the hope that we might, some day, retest those samples for a new susbtance.'<sup>21</sup>

2.3 The article in *L'Equipe* raised other important (ethical) questions as well. Why did the report of the LNDD regarding the analyses conducted, list the original bottle code numbers? How was it possible that in 2005 a journalist was in possession of the confidential reports of the LNDD, as well as copies of the original doping control forms used six years earlier during the 1999 Tour de France for conducting the doping controls of Lance Armstrong only and apparently not of those of the six other riders?

In her interview with VeloNews on August 23, 2005, Dr. Ayotte, said that the Armstrong story in *L'Equipe* also raised critical ethical questions by the release of data without the possibility of follow-up tests.

'I am very worried about the circumstances about the way such information might have been leaked,' Ayotte said. 'We are fully allowed – and it is our duty – to investigate samples to make sure that if there is an adverse finding, it is properly reported. In this case however, the director of the laboratory acknowledges that it cannot be deemed a doping offense because 1) the athlete has retired and 2) he is placed in a situation where there is no way to have the samples re-tested or verified.'

<sup>18</sup> Ex. 4, Sal Ruibal, 'Armstrong says he's the victim of a 'setup'', USA Today, August 25, 2005.

<sup>19</sup> Ex. 5, Charles Pelkey, 'Top lab official wonders if delayed testing is possible. We are not that lucky here, says Canada's Christiane Ayotte', VeloNews, August 23, 2005.

<sup>20</sup> Id. 21 Id.

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'It seems to me', Ayotte continued, 'that this whole thing is a breach of the WADA Code. We are supposed to work confidentially until such time that we can confirm a result. By no means does this mean that we sweep a result under the carpet, but it has to meet a certain set of requirements.'

'[...]. I'm worried, because I have a great deal of respect for my colleagues in Paris. I am concerned that they did not cover their backs before being dragged into a very public issue of this kind.'<sup>22</sup>

#### **Official responses**

2.4 On August 25, 2005, two days after the publication of the *L'Equipe* article, WADA on its own initiative, sent a letter to the UCI informing the UCI that it had received information from the LNDD related to its studies of stored samples from previous Tours de France and suggesting that it would be beneficial if the UCI were to conduct an enquiry to determine what action can be taken:

These studies were conducted with the intention of improving the detection method for EPO. This is natural and typical ongoing research, which WADA encourages.

I can assure you from perusal of the documentation received that it is confidential, and has no information which by itself would identify any individual.' <sup>23</sup>

#### [...]

'As these matters precede WADA, and of course the WADA Code, jurisdiction rests with you [the UCI] as a responsible anti-doping organization. Can we ask, please, what steps you intend to take? We are at your disposal for any assistance you may seek, and are happy to work with you accordingly.'24

In its subsequent press release, dated August 29, 2005, the UCI announced that it was pursuing 'its global assessment of the situation' and that it would:

'whilst regretting, once more, the breach of confidentiality principle which lead to the divulgence of this information outside of the procedures foreseen within the regulations of the international sports instances'

communicate its conclusions regarding the matter within the next ten days<sup>25</sup>. Responding to the aforementioned press release, WADA sent a letter to the UCI on August 30, 2005, inquiring what UCI has meant with the expression that 'it is pursuing its global assessment of the situation' as no reference has been made to any investigation or inquiry<sup>26</sup>.

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Ex. 6, Letter from David Howman, Director – General, WADA, to Hein Verbruggen, President, UCI, (August 25, 2005).

Id.
 Ex. 7, UCI Press Release, 'Analysis of 1999 Tour Samples: Soon the UCI Conclusions', UCI, (August 29, 2005).

<sup>26</sup> Ex. 8, Letter from David Howman, Director - General, WADA, to Hein Verbruggen, President, UCI, (August 30, 2005)

'As earlier stated, we are very prepared to assist you with any investigation or inquiry. However, if such an inquiry is to be seen as transparent and impartial, we must express our concern that you have already published regrets that there has been a breach of confidentiality. We are not certain that this can be said without a full inquiry, nor are we certain on the basis of the information we currently hold whether such a breach has occurred. There needs to be a preliminary inquiry to indicate, for example, who held any confidential information, how was it held, who was responsible for maintaining it and in what way. Only then can there be inquiries made of those responsible?<sup>27</sup>

2.5 In the first of two letters to WADA, both dated August 30, 2005, Hein Verbruggen, then President of the UCI responded as follows:

'As you can expect from us, we will not take any action based upon a press article and most definitely not upon articles from Mr. Ressiot of which we know his attitude towards cycling and the UCI (De Galdeano and WADA IO report).

In this respect, I was again disappointed in your President who deemed appropriate to make comments and statements concerning UCI based upon this article.<sup>728</sup>

In his second letter, Verbruggen wrote:

You ask us to investigate the matter on the basis of a newspaper article.

As far as I understand, the analyses that are referred to were made at the request of WADA for research purposes. The laboratory confirmed in a press statement that the research results were given to you anonymously and could not be used for disciplinary purposes.

David, in a WADA-initiated research program conducted in a WADA-accredited laboratory, the most essential standards of confidentiality have been disregarded.

Confidential information of this study became available to the press.

And now you ask me to investigate...???<sup>29</sup>

2.6 In an interview with the German internet newspaper 'Netzeitung' on September 5, 2005, WADA President, Richard Pound, made it clear why WADA did expect the UCI to conduct an investigation. When asked what WADA was thinking of the accusations levelled against Lance Armstrong, Pound answered that he believed it very likely, after having seen all relevant documents in the matter that one can speak of doping<sup>30</sup>. As far as the 'credibility' of the French doping control laboratory

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ld. Ex. 9, Letter from Hein Verbruggen, President, UCI, to David Howman,, Director – General, WADA, (August 30, 2005).

Ex. 10, Letter from Hein Verbruggen, President, OCI, to David Howman, Howman, Director – General, WADA, (August 30, 2005).

Ex. 11, Hans-Joachim Seppelt, *'Pound sieht Dopingaktivität bei Armstrong'*, Netzeitung, September 5, 2005.

Q. 'Wie steht die WADA zu den Anschuldigungen gegen Lance Armstrong?'

R. 'Nachdem wir alle die Unterlagen in dieser Angelegenheid gesehen haben, sehe ich eine sehr hohe Warcheinlichkeit, dass es eine Dopingaktivitat gegeben habe.'

was concerned, Pound replied that, in his opinion, the laboratory is a good one.

'It is one of the World's leading laboratories concerning research of EPO. Consequently, I have no reason to believe that the analysis of the urine samples has not been conducted in accordance with the rules.<sup>'31</sup>

Mr. Brian Mikkelsen, Danish Minister of Culture and Vice President of WADA, however, did not agree with Pound's assessment of the matter at hand and said the *L'Equipe* story lacked hard evidence and as such should have been handled with caution<sup>32</sup>. According to publication "Pound slammed by WADA's vice-president for Armstrong accusation" on the internet website "Bikingbiz" on September 6, 2005, the Danish government website, Denmark.dk, had announced that Mikkelsen was to contact WADA President Dick Pound and expand on his opinion that rushing to accuse Lance Armstrong over disputed drug tests on five-year old urine was a bad move.

Mikkelsen was reported to have said<sup>33</sup>:

"Such a statement should only be made if there is a legal basis for it. That's why I think Dick Pound's statement was unwise."

While indicating initially that it did not intend to take action on the basis of the *L'Equipe* newspaper article only, the UCI nevertheless informed WADA in its letters, dated September 5, 2005 and September 8, 2005, respectively, that:

"we know that results management will have to be conducted in order to know whether it can be asserted if any anti-doping violations were committed."<sup>34</sup>

The UCI indicated to WADA which issues and additional questions needed to be clarified and which information needed to be provided by WADA, in order to:

'make us confident that we have a valid basis for a case'

and

'in order that we may investigate this matter'35.

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Q. 'Wie glaubwurdig ist das farnzosische Dopingkontrollabor, in dem die Urinproben nachtraglich getested wurden?'

R. 'Nach meiner auffassung ist es ein sehr gutes Labor. Es gehort zu den weltweit fuhrenden Labors bei der Erforshung von EPO. Ich habe also jeinen Grund zu der Annahme, dass die Analyse der Proben nicht ordnungsgemaß war.'

Ex. 12, "Pound slammed by WADA's vice-president for Armstrong accusation", www. Bikingbiz. co.uk, September 6, 2005. Id.

Ex. 13, Letter from Hein Verbruggen, President, UCI, to David Howman, Director – General, WADA, (September 5, 2005).

<sup>35</sup> Ex. 14, Letter from Hein Verbruggen, President, UCI, to David Howman, Director – General, WADA, (September 8, 2005).

While providing answers regarding most of the issues and questions raised by the UCI, WADA made clear in its letter to the UCI dated September 9, 2005, what it expected from the UCI in return:

'now this matter is one of public record, UCI will fully inquire to ensure that it is appropriately addressed publicly in the interest of transparency. The matter requires full public attention, not simply a search to determine how it became public. I am certain you agree and that you will ensure your review achieves this, including identification of the riders.<sup>'36</sup>

However, before any reply had been received from the UCI regarding WADA's letter of September 9, 2005, Dick Pound, sent another letter to the UCI on September 14, 2005, expressing his disapproval of the direction the UCI investigation appeared to be taking.<sup>37</sup>

'WADA has been completely supportive of assisting the UCI in its investigation of the matter, but only on the basis that the UCI would be conducting a thorough and complete investigation of all aspects of it, not simply selected elements.

WADA is not prepared to participate any further in this direction unless we receive your full assurances that the UCI investigation of the matter will deal with the truth or falsity of the facts alleged in the story, as well as the means by which L'Equipe happened to come into possession of the facts. I do not want WADA to be marked by participation in an investigation that may be seriously flawed and which may have no intention of dealing with all of the issues.

The questions you have directed at WADA thus have been generally accusatory in nature and have been surrounded by several statements and assertions with which WADA is unwilling to be associated. Every question points in one direction only, namely how the various elements of the L'Equipe story were obtained by the reporter. Not a single one focuses on the issue whether or not the allegations made in the story may be true and whether or not there was significant use of EPO during the 1998 and 1999 Tours de France, one of the showcase events of the UCI. I should have thought that the UCI would want to know whether the allegations are true or whether they are false. That seems to me to be in the interest of the responsible international federation as well as the public perception of the sport of cycling.

I appreciate that the revelations in L'Equipe (and more recently, other media as well), if true, may be embarrassing to the UCI and its efforts to control doping in cycling. But that, surely, is less important than knowing what was happening in the sport at various times and in various of its events. All of your investigative efforts, based on what we have seen, appear to be directed at finding someone to blame for the disclosure of information that you seem to regard as confidential and the statements attributed to you in the media (assuming that you have been correctly quoted) are to the same effect.<sup>'38</sup>

Ex. 15, Letter from David Howman Director – General, WADA, to Hein Verbruggen, President, UCI, (September 9, 2005). Ex. 16, Letter from Richard Pound, President, WADA, to Hein Verbruggen, President, UCI, (September 14, 2005).

<sup>36</sup> 37 38

Id.

In closing however, WADA's President nevertheless appeared still confident that both the UCI and WADA shared the same desire, i.e. that sport, worldwide, can be doping-free.

'This can only happen if we are relentlessly committed to complete transparency and that we follow the trails of those who may be doping as far as is necessary to expose their actions. In some cases, it may no longer be possible to impose any sanctions, but that is a secondary consideration to the discovery and exposure of doping.<sup>'39</sup>

2.7 According to 'Cycling News' <sup>40</sup>, Dick Pound, told reporters in a telephone press conference on September 16, 2005, that it had been UCI President Hein Verbruggen himself who had leaked the doping control protocols of the 1999 Tour de France to the French newspaper *L'Equipe*.

"It certainly wasn't WADA', Pound replied when asked who provided the official forms to L'Equipe. 'And it certainly wasn't the French Laboratory. Neither of us had the information. It is quite clear. Mr. Verbruggen told us that he showed all six of Armstrong's doping control forms to the journalist of L'Equipe and that he gave them one copy at least of the forms. As I understand it, one of the forms goes to the UCI, one to the athlete, and another one to the National Federation, one went to the French Ministry [of Sport]. The French Ministry destroyed its copies, I think, two years later. I have no idea whether the French federation have them or, if so, where, but the UCI has kept them. I don't know whether they have kept their own requirement to destroy the forms two years later but they obviously haven't.'

Interestingly, the forms reproduced on the L'Equipe headlines of August 23 show the mention 'Feuillet 1' (literally: Sheet 1). Cycling News understands that the first sheet of the protocols always goes to the UCI. So it really was Verbruggen himself who gave the documents to the L'Equipe journalist? 'That's what I understood from the letter that he [Verbruggen] sent to us', Pound replied, adding he didn't know whether Verbruggen knew of the purpose the information would serve. 'They certainly knew who [the journalist] was. But I certainly don't know how it was that the UCI would have made available those forms with the code numbers on them. If they were worried about confidentiality and so forth, you would have thought that would be a fairly routine and precautionary step.'<sup>41</sup>

- 2.8 Judging from its initial reply on September 16, 2005, the UCI must at that time still have been unaware of the contents of the aforementioned letter of Dick Pound, dated September 14, 2005<sup>42</sup>, as well as the subsequent statements he made during his telephone press conference on September 16, 2005, as it failed to respond to any of the statements contained therein concerning its investigation. Instead, the UCI informed WADA in the aforementioned initial reply of September 16, 2005, only that it
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 <sup>40</sup> Ex. 17, Hedwig Kröner & Jeff Jones, 'Pound: Verbruggen was the leak', Cycling News, September 16, 2005.
 41 Id.

<sup>42</sup> According to the UCI, this letter arrived at its offices on September 20, 2005 only.

was still waiting for the information it had urgently requested from WADA in its letter of September 8, 2005, as it was

'keen to reach a swift conclusion.'43

Having finally taken notice of the statements made by Dick Pound, the UCI sent a second letter to WADA the very same day, informing it that it found the statements made by its President regarding the matter at hand

'no longer acceptable'

and that it

'feels obliged to come out with an official reaction.'44

In reaction to the statements of WADA, the UCI issued a press release on September 19, 2005, denying having supplied the newspaper *L'Equipe* with the doping control forms necessary to link Armstrong with the 1999 Tour de France urine samples that *L'Equipe* allegedly indicates that Armstrong used *r-EPO* in winning the 1999 Tour de France.

<sup>'</sup>Mr Verbruggen has never been involved personally, contrary to what Mr. Pound has said in another statement.<sup>'45</sup>

and

'However, it is also apparent that the reporters were given at least five and perhaps fifteen of Lance Armstrong's doping control forms from the 1999 Tour de France, and it is certain that those forms did not come from the UCI.<sup>26</sup>

The UCI admitted that it had actually provided one of the doping control forms, however,

'WADA has been informed by the UCI that the reporter only received one doping control form from the UCI, and the false pretences used by the L'Equipe reporter to gain access to that form were explained in the UCI letter that [Dick Pound] references.<sup>47</sup>

WADA subsequently informed the UCI in its letter, dated September 22, 2005, that it would not respond to further requests from the UCI, until it would have received the assurances requested regarding the investigation<sup>48</sup>, notwithstanding the fact that the UCI had already stated in its letter of September 21, 2005 to WADA that:

46 Id.

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Ex. 18, Letter from Hein Verbruggen, President, UCI to David Howman, Director – General, WADA, (September 16, 2005).
 Ex. 19, Second letter from Hein Verbruggen, President, UCI to David Howman, Director – General, WADA, (September 16, 2005).

Ex. 19, Second letter from Hein Verbruggen, President, UCI to David Howman, Director – General, WADA, (September 16, 2005). Ex. 20, John Stevenson & Les Clarke, 'UCI denies leaking Armstrong documents', Cycling News, September 20, 2005.

<sup>47</sup> Id. 48 Ex

Ex. 21, Letter from David Howman Director – General, WADA, to Hein Verbruggen, President, UCI, (September 22, 2005).

'The investigation we are conducting is both thorough and complete<sup>'49</sup>,

which was reconfirmed again in its letter to WADA, dated September 29, 2005:

Please be assured that the UCI will investigate all aspects of the case and we thank you for your full support'.

In that same letter, the UCI asked WADA explicitly to confirm that it was not WADA, or someone within WADA, who had asked for the 'additional information' -i.e. the code numbers present on the original glass bottles used for conducting doping controls during the 1998 and 1999 Tours de France, which can be used to link an analysis result to a particular rider- to be included in the LNDD research reports<sup>50</sup>. WADA however, did not reply.

#### ASOIF and the IOC Athletes Commission

2.9 As a result of the ongoing public debate regarding the analyses of the urine samples from the 1999 Tour de France by the LNDD, in particular the statements made in public by representatives of the LNDD, the 'General Association of Summer Olympic Federations' (hereinafter: 'ASOIF'), together with the 'IOC Athletes Commission' (hereinafter: 'Athletes Commission'), sent a joint letter to WADA on September 20, 2005,

to protest in the strongest possible terms the irregularities committed in the so-called doping revelations against the cyclist Lance Armstrong<sup>'51</sup>.

While the IFs [International Federations] and the athletes would first like to reaffirm their determination to contribute by all means to the fight against doping, as well as their wish to collaborate at all levels of adjudication operating in this domain.

The consequences of a positive test for an athlete are so severe that the procedures that lead to such a result must adhere to extremely strict rules and the results must be based on irrefutable evidence.

We were therefore shocked to note that those admonishing Armstrong for a violation of the anti-doping regulations have not themselves respected, in their procedures, the fundamental rules that govern them. So, if anyone wishes to give lessons on fair and clean practices, he himself must first be beyond reproach.

In this case, it appears that numerous violations of the World Anti-Doping Code have been committed and that the most basic guarantees, for which every athlete has a right, have been held up to ridicule.'52

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<sup>49</sup> Ex. 22, Letter from Hein Verbruggen, President, UCI to David Howman, Director - General, WADA, (September 21, 2005).

Ex. 23, Letter from Hein Verbruggen, President, UCI to David Howman, Director - General, WADA, (September 29, 2005). 50

Ex. 24, Letter from Dennis Oswald, President, ASOIF, and Sergey Bubka, President, IOC Athletes Commission, to Richard 51 Pound, President, WADA, (September 20, 2005). ld.

After having identified a number of these violations and having asked WADA certain questions regarding the underlying facts, the following statements have been made in closing the letter:

'The IFs and the athletes do not intend to make any other comments about this matter, which includes other troubling elements, nor do we wish to pass judgement on the innocence or guilt of Lance Armstrong. We only ask that all those involved in the fight against doping are called upon to respect the rules.

As this was clearly not the case here, we demand that WADA conducts a thorough investigation in order to establish the violations committed and to identify and sanction those responsible. We also demand that, pending this investigation, WADA suspends the accreditation of the Châtenay-Malabry laboratory.<sup>53</sup>

2.10 In his reply, dated September 23, 2005, Dick Pound, responded as follows:

'In response might I, at the outset, suggest that you have used very strong accusatory language alleging many breaches of rules and procedures without identifying those rules. Indeed your letter makes reference only to one article of the International Standard for Laboratories, which is an article specifically referring to the conduct of laboratories in conducting analyses of samples received as a result of a doping control process and analysed for that purpose. The article itself is not applicable here, as you will realize these were not analyses conducted for doping control. As you well know, the situation presently being investigated by the UCI has not yet been completed, and there is certainly no determination of any factual position upon which such strong comments, as made by you, could be based.<sup>54</sup>

After having listed chronologically the situation in relation to the information WADA had, Pound continued by stating:

'You will see quite clearly from this brief synopsis that to allege and accuse in the way you have, in your letter of September 20, is not only unfair but also incorrect.

[...]

The hyperbolic nature of your attacks indicated a serious lack of understanding of the situation, which is all the more surprising, coming as it does from the ASOIF and the IOC Athletes Commission, and I am anxious that you desist from this form of publication in the future, if we are to usefully work with you in the fight against doping in sport. I need hardly remind you that this is not the first time that ASOIF has behaved in this matter regarding WADA. It causes me to wonder whether, in the pursuit of some different

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Ex. 25, Letter from Richard Pound, President, WADA, to Dennis Oswald, President, ASOIF, and Sergey Bubka, President, IOC Athletes Commission, (September 23, 2005).

objective, you may have lost sight of the essential purpose of the existence of WADA and the role of all stakeholders in it.

[...]

You demand that WADA suspend the accreditation of the Châtenay-Malabry laboratory, pending an investigation. With your evident thorough knowledge of the applicable rules, you might care to direct my attention to the particular rule that would enable WADA to do so.

[...]

*I will comment further on the specific allegations and arguments in your letter once you have expanded on the facts you have alleged and the rules that you claim to have been breached.*<sup>55</sup>

2.11 In their joint reply, dated October 6, 2005, both ASOIF President Oswald and Athletes Commission President Bubka, express their surprise at both the approach and tone of the response from WADA President Pound, dated September 23, 2005.

'You react with great indignation to our letter as if WADA or its Chairman were under attack. This is not the case. We only asked you and WADA to fulfil your role as the authority responsible for supervising and coordinating the anti-doping fight world-wide.

You repeatedly reproach us for not being sufficiently factual in our letter, saying we lacked detailed references to rule violations, however in doing so, you seemed to have missed the purpose of our letter. The simple fact is, athletes were identified from confidential internal laboratory reports appearing in the media and we considered this situation not only unacceptable but also illegal. As is our right and obligation, we asked you how this could happen. The fact that athletes' names appeared following research means someone breached the rules of confidentiality and, in fact, rules were broken.

These were the basic facts, to our knowledge, and this was also why we asked WADA to clarify several points, which seemed to us, and to many of our constituents, very troubling and, as stakeholders, we have the right to be fully informed.

If WADA, as the organisation exclusively responsible for the supervision and accreditation of anti-doping laboratories around the world, does not find this situation the least bit disconcerting or problematic, we frankly cannot see how WADA can claim to objectively represent all the stakeholders' interests in such a case.

We repeat what we said in our previous letter. We unequivocally support and defend the fight against doping. WADA was created to ensure that all athletes and sports

were treated equally and fairly in this fight, but it was also created as a responsible, independent body mandated to avoid that anti-doping is done with two weights and two measures. While we recognize and appreciate your zeal in wanting to determine the ' truth' in the interest of clean sport, we must ask, which truth at what price?

Are you, as a lawyer and administrator, willing to sacrifice ethical, legal and regulatory standards so as to obtain a result, which leaves serious doubts as to the truth? <sup>56</sup>

In closing, both Presidents conclude that the best way to address the questions they raised is to call for

'an independent investigation of these circumstances, completely outside WADA's control and under the auspices of a CAS mediator<sup>'57</sup>.

'For the sake of all athletes whose rights were violated in this case, we will only accept such an investigation on the condition that no disciplinary proceedings can be pursued as a result of the findings.'<sup>58</sup>

#### WADA Executive Committee Meeting September 20, 2005

- 2.12 Naturally, the matter concerning Lance Armstrong and the analyses conducted by the French WADA-accredited doping control laboratory, had already been tabled as part of the agenda of the WADA Executive Committee, when it met in Montreal, Canada, on September 20, 2005. Nevertheless, WADA Executive Committee member, Mr. Larfaoui, President of the International Swimming Federation asked the WADA management on behalf of the ASOIF for the necessary explanations regarding the Armstrong case, while submitting the joint ASOIF/IOC Athletes Commission's letter to WADA President Dick Pound, dated September 20, 2005, for consideration by the WADA Executive Committee.
- 2.13 After an account of the relevant facts by both WADA Director General, David Howman and WADA President Dick Pound, supported by additional remarks made by Mr. Lamour, the French Minister for Youth and Sport, WADA Executive Committee member and Deputy Director of the 'United Nations Drug Control Program' (hereinafter: 'UNDCP'), Mr. Burns, expressed his concern about the manner in which WADA had become involved in this matter, as well as the role it had played to date. According to Burns, WADA should not be involved in 'spin'.

'The professionalism or attributes of a particular laboratory had been discussed, but this was irrelevant. What was relevant was due process and process of reasoable expectations by athletes and governments. It was the antithesis of what was done at WADA to not follow the rules and to not wait for the process to be followed and to speak

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Ex. 26, Letter from Dennis Oswald, President, ASOIF, and Sergey Bubka, President, IOC Athletes Commission, to Richard Pound, President, WADA, (October 6, 2005).

<sup>57</sup> 58

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out or speculate precipitously, espeially in public, based on speculation or tabloid sensationalism or intuition or, as some would say, wishful thinking. WADA was about getting it righ, and he thought that it was bad for WADA, sport and government when WADA lost the trust of athletes.<sup>59</sup>

He also wondered if this had been a research activity, why was WADA speaking about potentially positive or negative doping tests. When did research morph into doping, and what were the rules and what could athletes expect? The facts might be allegations. While Burns admitted that it was important to know the truth as WADA President Dick Pound had said, as long as the truth were known with the process and procedures and rules in place, because frankly, that was what sport and fairness was all about. To come back later and not follow the procedures and, before the dust had even settled, make pronouncements and judgements was very troubling<sup>60</sup>.

Prof. Ljungqvist, WADA Executive Committee member and Chairman of the WADA Health, Medical and Research Committee, asked if it could ever be a doping case in the absence of a 'B' sample? According to the WADA rules, his interpretation was no, because there was no 'B' sample. When he asked if he was wrong, WADA President Dick Pound replied that he could be wrong, without explaining why this could be so<sup>61</sup>.

#### Interview with Ressiot

- 2.14 On September 7, 2005, Cycling News interviewed Mr. Damien Ressiot, author of the article 'Armstrong's lie', published in *L'Equipe* on August 23, 2005<sup>62</sup>.
  - *Q.* What can you tell us about the time that elapsed between December 2004 (when the laboratory started the retrospective testing) and August 2005, when you published the documents which linked six of the 12 positive samples to Lance Armstrong? Some say the newspaper, L'Equipe, which is owned by the same organisation as the Tour de France organiser ASO, did not want to publish the information too soon?'
  - A. 'The testing on EPO at the laboratory did indeed take a certain amount of time. Every test took them two and a half days and there were nearly 150 samples to test from the 1999 and the 1998 Tours. Nevertheless, and even before I got hold of the results which were communicated to the two instances concerned (WADA and the French Ministry of Sport) on August 22, it took a very long time to obtain the doping test protocols [official forms to be filled in by the UCI Anti-doping inspector in charge of the post-stage tests at the time these took place ed.] This explains the time gap.

When there was the Gonzalez de Galdeano affair in 2002, I wasn't afraid to reveal the fact that he tested positive for salbutamol right in the middle of the Tour, which provoked an enormous scandal between the UCI and WADA, as well as the fury of

59 WADA, 'Minutes of the WADA Executive Committee Meeting', September 20, 2005, Montreal, Canada, p. 28.

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<sup>62</sup> Ex. 27, Hedwig Kröner, 'The author of it all', Cycling News, September 7, 2005.

Jean-Marie Leblanc (ASO Tour de France director). So to protect the Tour against an Armstrong affair wasn't a priority at all. The only priority I had was that of the truth, and in order to obtain the information, I couldn't avoid the delay. '63

- Q. Why did you identify only Lance Armstrong and not the other six 1999 positive samples as well?'
- A. When I found out that the laboratory of Châtenay-Malabry was conducting research on 1999, my initial and purely theoretical hypothesis was that this could be an interesting lead to verify the truth about Lance Armstrong's statements about his performances. I did focus on him as a person, on the challenge that he threw at the journalists (Do you think I'm doped? Prove it!) and I admit that it's a little cruel to stigmatise him only. But he's the best rider of the seven last Tours, and after all, he's used to the fact that everything revolves around him. He declared himself patron of the peloton and addressed WADA Director Dick Pound sharply by writing him an open letter, which got published in a lot of newspapers. He therefore has the shoulders to bear something like this.

But anyway, I don't have the means to publish the identities of the other six samples -If I had them in my hands, they'd be in the newspaper, that's for sure. It's not my habit to protect anybody. '64

- Q. How can you know that four of the positive samples in 1999 were taken after the prologue?'
- A. 'When you read the results table of the laboratory, you see that the first series of samples that arrived in Châtenay-Malabry (the four flasks) bear one number that differs from the next number of presumably the first stage, where Lance's sample also revealed traces of EPO. Therefore we can conclude this.'65
- *Q.* 'But the names of the four riders tested at the prologue 1999 are no secret?'
- A. Yes, that is true. If you take the book L.A. Confidential, on page 202, the names of the riders that were tested after the proloque are listed. [Cycling news knows of at least one other source which would also reveal those rider's names] But I don't want to take the responsibility of publishing them because on the lab results table, there are very technical remarks added to one of the proloque samples, which also tested positive but where some sort of reservations were made by the lab director. So we decided not to publish those names, as we'd need the original 1999 protocols to identify which sample belonged to whom. But the concerns of the lab director weren't directed at Armstrong's sample.'66

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#### The decision to have an independent investigation conducted

2.15 In order to clarify the facts and circumstances concerning the analysis, conducted by the LNDD, of urine samples from the 1998 and 1999 Tours de France in general and the reporting of subsequent alleged Adverse Analytical Findings in particular, and responding to calls for an independent investigation, the UCI announced on October 6, 2005 that it had officially appointed the Dutch lawyer Mr. Emile Vrijman, to undertake an independent, as well as comprehensive inquiry regarding this matter, after having requested him to do so on September 30, 200567. That same day, Vrijman sent a letter to WADA, the French Ministry de la Jeunesse, des Sports et de la Vie Associative (hereinafter: 'the Ministry') and the LNDD, informing these organisations formally of his appointment by the UCI to undertake the aforementioned inquiry and asking them for their assistance, as well as their cooperation, in conducting it<sup>68</sup>. Vrijman also requested from the UCI all documents and other information in the possession of the UCI that was related in any way to this matter. A similar request was made to Lance Armstrong<sup>69</sup>. Both the UCI and Lance Armstrong<sup>70</sup> provided the information and documentation in their possession. However, whereas the Ministry<sup>71</sup> and the LNDD<sup>72</sup> acknowledged Vrijman's appointment and voluntarily forwarded copies of their correspondence with the UCI in the matter at hand, WADA did not. In its letter of October 13, 2005, WADA acknowledged Vrijman's appointment by the UCI as a matter of fact only, as Vrijman's letter of October 6, 2005 had not been accompanied by an official mandate indicating both jurisdiction and terms of reference in relation to the inquiry to be conducted.

'We expect that you will be forwarding all relevant documentation and, therefore, before responding to any of the other contents of your letter, we await such legal issues to be fully and appropriately explained.<sup>73</sup>

The reason for WADA's response however was clear, as WADA had already decided -notwithstanding the assurances of the UCI that it would investigate all aspects of the case<sup>74</sup>- to conduct its own investigation into the matter at hand. In its letter, dated October 5, 2005, WADA informed the UCI that it had decided:

'to conduct its own investigation by contacting all persons and organizations involved in the matter and asking questions (enclosed) that are designed to shed as much light as possible on the matter. This will include the French laboratory, the UCI, the French Sports Ministry, the rider and others that may have relevant information.' <sup>75</sup>

<sup>67</sup> Ex. 28, UCI Press Release, 'Analysis of samples from the 1999 Tour de France: Independent investigator appointed by the UCI', UCI, (October 6, 2005).

<sup>68</sup> Ex. 29, Letter from Emile Vrijman, independent investigator, to Richard Pound, President, WADA, (October 6, 2005); Ex. 30, Letter from Emile Vrijman, independent investigator, to French Ministry, (October 6, 2005) and Ex. 31, Letter from Emile Vrijman, independent investigator, to Prof. De Ceuarriz, Director, LNDD, (October 6, 2005).

<sup>69</sup> Ex. 32, Letter from Emile Vrijman, independent investigator, to Lance Armstrong, cyclist (October 7, 2005).

<sup>70</sup> Ex. 33, Letter from Mark Levinstein, legal counsel to Lance Armstrong, to Emile Vrijman, independent investigator, (October 11, 2005).

<sup>71</sup> Ex. 34, Letter from the French Ministry to Emile Vrijman, independent investigator, (October 10, 2005).

<sup>72</sup> Ex. 35, Letter from Prof. De Ceuarriz, Director, LNDD, to Emile Vrijman, independent investigator, (October 19, 2005).

Ex. 36, Letter from David Howman, Director – General, WADA, to Emile Vrijman, independent investigator, (October 13, 2005).
 Id.

<sup>75</sup> Ex. 37, Letter from David Howman, Director – General, WADA, to Pat McQuaid, President, UCI, (October 5, 2005).

According to WADA, there had been requests from its stakeholders, as well as others for an investigation into the facts alleged, which the UCI to date apparently had been unwilling to undertake.

'WADA had originally thought that the UCI, as the international federation responsible for cycling, would undertake such an investigation, but it appears to date that the only concern of the UCI is how the information emerged that enabled L'Equipe to match (apparently) the name of one rider with the sample numbers of the samples analysed by the laboratory in France.'<sup>76</sup>

2.16 Mr. Pat McQuaid, UCI President, responded quickly. In his letter, dated October 6, 2005, he not only completely rejected WADA's suggestion that the UCI apparently had been unwilling until then to undertake an investigation regarding all of the alleged facts in the matter at hand, but also made it clear why the UCI would not accept any investigation in this matter by WADA<sup>77</sup>.

'I reject completely your assertion that the UCI is only concerned with the how the information emerged in L'Equipe. The UCI is concerned as I told you in my letter of 29th September in investigating all aspects of this case.

# [...]

In relation to a possible WADA investigation, I must say that I cannot accept this. We feel WADA has played a doubtful role in this whole affair to date and, as such, I would question any possibility of independence in such an investigation. Indeed I find it surprising that your letter of October 5th completely ignores my letter of September 29<sup>th</sup>.

# [...]

Whereas WADA claimed to be outside of this case because it did not exist in 1999, it now obviously wants to initiate an investigation as an attempt to avoid itself being a subject of investigation and to have to answer questions on its own involvement. The UCI has never received an answer to its questions in its letter of September 5<sup>th</sup>. You did not answer our letter of September 29<sup>th</sup> which means you cannot confirm that it was not WADA that asked for the sample codes or other means of identification to be included in the laboratory report.<sup>78</sup>

# The 'Letter of Authority'

2.17 Partly in response to WADA's letter to Vrijman, dated October 13, 2005, and partly to clarify further what the exact nature and scope of the inquiry should be, the UCI issued on November 9, 2005 its 'Letter of Authority'<sup>79</sup>. According to this letter, the inquiry aims to:

<sup>76</sup> Id.

<sup>77</sup> Ex. 38, Letter from Pat McQuaid, President, UCI, to David Howman, Director – General, WADA, (October 6, 2005).

<sup>78</sup> ld. 79 Ex 39 Let

<sup>9</sup> Ex. 39, Letter of Authority from Pat McQuaid, President, UCI, to Emile Vrijman, independent investigator, (November 9, 2005).

- 1. determine what the reason(s) has/have been for the LNDD to analyse, in 2004 or 2005, the urine samples collected at the 1998 and 1999 Tours de France, which were being kept within its storage facilities and whether or not Third Parties might have been involved in the decision making process regarding such analyses;
- 2. determine the manner in which the analyses of the aforementioned urine samples have been conducted by the LNDD, in particular with regard to compliance with any applicable procedures for WADA accredited laboratories regarding research on and the analysis of urine samples conducted for doping control purposes in general and for the Prohibited Substance EPO in particular;
- 3. examine the manner in which the LNDD -after having completed the analyses of the aforementioned urine samples- subsequently reported its findings, to whom it did report those findings and why, in particular with regard to the inclusion of data allowing the owner of the sample to be identified;
- 4. examine allegations that a number of these urine samples should be regarded as constituting a so-called adverse analytical finding under applicable anti-doping rules of the UCI; and, if so
- 5. give an opinion on whether or not these alleged adverse analytical findings may be considered for an apparent anti-doping rule violation justifying the opening of disciplinary proceedings according to the applicable anti-doping rules, regulations and procedures of the UCI; and
- 6. examine how confidential research reports and doping control documents came in the possession of an unauthorized Third Party.'<sup>80</sup>

# Furthermore:

'Mr. Vrijman is fully authorized by the UCI to make any inquiry he deems necessary and appropriate to fulfil his mission.'

# [...]

'In conducting his investigation and preparing his report, Mr. Vrijman is to be free from control of the UCI, and any person working for, or associated with the UCI and/or its members.<sup>781</sup>

In closing its Letter of Authority, the UCI made the following request:

'that all persons associated with the UCI and its doping control program -including the LNDD, the World Anti-Doping Agency (WADA), the various WADA accredited doping control laboratories and all officers, directors and staff of those laboratories, national cycling federations, as well as coaches, administrators, officials, cyclists and other individuals associated with international cycling and/or cycling events- shall fully and completely cooperate with Mr. Vrijman and his investigation.<sup>32</sup>

2.18 Notwithstanding the fact that the UCI had informed WADA on November 24, 2005, accordingly -thereby providing WADA with the exact information it had requested earlier in its letter of October 13, 2005, to Vrijman<sup>83</sup>- WADA neither responded to 'any of the contents' raised in Vrijman's letter to WADA, dated October 6, 2005, nor provided any documents either to the UCI or the independent investigator concerning any of these matters, other than a copy of each of the reports of the research conducted by the LNDD regarding the analyses of the urine samples of the 1998 and the 1999 Tours de France respectively. Instead Dick Pound, confirmed in an interview with the Reuters Press Agency on December 22, 2005, that WADA was conducting its own investigation and announced that the investigation into the allegations against seven-times Tour de France winner Lance Armstrong would continue into the New Year<sup>84</sup>:

'It's not going to go away. We're dealing with all the spins out there right now but behind the scenes there are investigations quietly proceeding.'

[...]

'The UCI says it is conducting an investigation, although we can't seem to get information about it and we're doing our own.'

'I'd rather have the UCI do it, by all accounts they should. If they do a complete and thorough investigation more power to them.

But I'm not overly confident so far. Right now, the only thing they seem concerned about is how did this embarrassing information get into the public.

There are also another 15 or so positive tests on which they refuse to comment. '85

2.19 During the Winter Olympic Games in Turin, Italy, in February 2006, WADA President, Dick Pound, told Hein Verbruggen, UCI Vice – President since the end of September 2005, that he had in his possession copies of 15 doping control forms signed by Lance Armstrong during the 1999 Tour de France and that those copies originated

85 Id.

86 Ex. 41, UCI Press Release, 'Official Statement', UCI, February 27, 2006.

<sup>82</sup> Id.

<sup>83</sup> Id. I.e., the official mandate indicating both jurisdiction and terms of reference in relation to the inquiry to be conducted.

<sup>84</sup> Ex. 40, Steve Keating, 'Pound says Armstrong faces further investigations', Reuters, December 22, 2005.

from the UCI<sup>86</sup>. Pound however, only showed these copies briefly to Verbruggen. He did not hand them over to Verbruggen, nor did he provide any copies<sup>87</sup>. Pound did accept -contrary to what he had said before in September 2005- that it had not been Verbruggen who had provided copies of these to *L'Equipe*. Given the fact the UCI had, until then, denied that it had provided the journalist of *L'Equipe* with copies of all 15 doping control forms signed by Lance Armstrong during the 1999 Tour de France, it immediately carried out an internal investigation again.

'The internal investigation of the UCI has indeed resulted in the fact that the staff member concerned has now admitted that he must have given to Mr. Ressiot a copy of all 15 forms, instead of just one.

It is to be emphasized that this was done in the absolute conviction that Mr. Ressiot was indeed doing an inquiry for the purpose of writing an article proving that Mr. Armstrong never asked for an authorization to use any drugs after he successfully fought his cancer.

The UCI also underlines that the UCI management was not aware until now that more than one copy of a doping control form had been given to Mr. Ressiot and that the statements of the UCI after the publication in L'Equipe reflected the information that it had at that time.<sup>'88</sup>

- 2.20 During the same meeting Verbruggen, asked Pound, whether it was true that WADA had exerted a considerable amount of pressure on the LNDD in order to obtain the 'additional information' -i.e. most notably the code numbers present on the original glass bottles used for doping controls during the 1998 and the 1999 Tour de Franceit had been requesting for months. While admitting this unreservedly, Pound did ask Verbruggen how he got this information. Verbruggen replied that the information had come from Prof. De Ceaurriz, the head of the LNDD, while conferring with directors of some of the other WADA-accredited laboratories.
- 2.21 Following the aforementioned UCI press release, dated February 27, 2006, the investigator decided, having so far relied on the statements received from the UCI regarding its initial investigation with respect to the doping control forms signed by Lance Armstrong during the 1999 Tour de France, to conduct his own interviews of UCI staff members and management. Both UCI staff members who had been present at the meeting in July 2005 with Mr. Ressiot at the offices of the UCI in Aigle, Switzerland stated that Mr. Ressiot had told them that he had requested the UCI to be allowed to examine doping control forms signed by Lance Armstrong, after having returned to competition in 1999, had ever asked the UCI for permission to use, or used, any medication -either banned or not banned at that time- related to possible consequences of having had cancer. Because riders are obliged to declare the use of any medication on their doping control forms, Mr. Ressiot wanted to see for himself

<sup>87</sup> Interview with UCI Vice – President HeinVerbruggen, March 15, 2006.

<sup>88</sup> Supra, at 64.

whether Lance Armstrong had declared the use of any such medication or not. If possible, he wanted to receive a copy of one of these forms as well, in order to prove to his readers that he had in fact been able to examine these forms. Much to the surprise of both UCI staff members, Mr. Ressiot's interest in the doping control forms signed by Lance Armstrong turned out to be limited to the ones concerning the 1999 Tour de France only, even though copies of all doping control forms signed by Lance Armstrong after having returned to competition had been made available for consultation.

- 2.22 Notwithstanding the fact that the UCI had received permission from Lance Armstrong to allow Mr. Ressiot to consult his doping control forms, the UCI concluded that the information concerning the possible use of medication as listed on these forms, should be regarded as medical confidential information. Consequently, it had blacked out the particular section on all doping control forms signed by Lance Armstrong containing this information. In order to allow Mr. Ressiot to determine whether Lance Armstrong, after having returned to competition in 1999, had ever asked the UCI for permission to use, or used, any medication related to possible consequences of having had cancer, other information had to be made available. This consisted of the analyses reports containing the analysis results of the same urine samples as listed on these doping control forms.
- 2.23 According to one of the UCI staff members, Mr. Ressiot asked if he could receive one (1) copy of each of these forms, i.e. a doping control form from the 1999 Tour de France, signed by Lance Armstrong, as well as a copy of the corresponding analysis report and another laboratory form<sup>89</sup>. While both UCI staff members did agree that more then one (1) form was given to Mr. Ressiot, they neither recall the exact number of forms having been given, nor their nature, i.e. doping control forms only, or doping control forms with matching analyses reports.
- 2.24 The apparent willingness of WADA (to start) to cooperate with the investigation was further confirmed by Dick Pound, in an interview with BBC Sport in March 2006, indicating that WADA, contrary to previous statements, had not yet started its own investigation<sup>90</sup>.

'We will wait and see what the outcome of that investigation is.

The UCI says it is fully investigating the matter and, because it's the responsible international federation, our view at the World Anti-Doping Agency is to let them do it.

If it is not in fact a thorough investigation of everything that happened – including how the information got into the hands of L'Equipe – then we will decide accordingly what to do.<sup>'91</sup>

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<sup>89</sup> According to both UCI staff members, the analyses reports of the LNDD regarding the 1999 Tour de France, consisted of 2 pages; one page containing the analysis results and one page specifically reporting the analysis results regarding the T/E ratio and gluco-corticosteroids.

<sup>90</sup> Ex. 42, Matt Catchpole, 'WADA boss warns Armstrong inquiry', BBC Sport, March 3, 2006.

<sup>91</sup> 

## **WADA Questionnaires**

2.25 Consequently, the investigator decided to ask WADA again to provide further assistance to the investigation by answering the questions contained in two questionnaires, dated March 15, 2005<sup>92</sup> and March 20, 2006<sup>93</sup>, respectively. WADA's answers to the questions raised in both questionnaires were received on April 3, 2006<sup>94</sup>. In the accompanying letter WADA informed the independent investigator to have been

'somewhat surprised by some of the facts in your questions, which to our knowledge, are inaccurate'<sup>95</sup>.

WADA nevertheless did answer all questions posed, but did not produce any of the documents requested. Although WADA's answers will be discussed in more detail in Chapter IVB of this report, a summary can be found in the next paragraphs.

- 2.26 According to WADA's answers to the investigators' questions, WADA first learned on October 19, 2004, about the 'general nature' of research that the LNDD was conducting with regard to (the improvement of) the existing testing method for *r-EPO*. By the time it was informed about the analyses of the urine samples from the 1998 and the 1999 Tours de France, the project was already in progress. 'In the days that followed', WADA received more details about the project and the urine samples that were analyzed. WADA however, was neither 'involved in the design of the research protocol', nor in any manner in 'the initiation of this research'. WADA did, in other words, not know anything about the LNDD research project before it was started. Although WADA learned that frozen urine samples from the 1998 and the 1999 Tours de France were being, or had been tested, there had been no discussion whether these samples were frozen 'A' or 'B' samples. WADA also said that it had not supported the research project financially and that it consequently had not been financed by WADA grants.
- 2.27 WADA believed that the research project was consistent with the requirements of the WADA *ISL*, and

'within the objectives of the fight against doping'.

Because the issue of *EPO* stability, as well as the study of trends of use of *r-EPO* following the introduction of the test and the improvement of the *r-EPO* test, all were of interest, WADA asked the LNDD to be kept informed about the results of the project. WADA said it confirmed its willingness to receive the final report on July 27, 2005, while indicating clearly that the research results were outside the scope of the

Ex. 43, Letter from Emile Vrijman, independent investigator, to David Howman, Director – General, WADA, (March 15, 2006) and Ex. 44, Emile Vrijman, independent investigator, Preliminary Questionnaire WADA, (March 15, 2006).
 Ex. 45, Letter from Emile Vrijman, independent investigator, to David Howman, Director – General, WADA, (March 20, 2006) and Ex. 46, Emile Vrijman, independent investigator, Additional Questionnaire, WADA, (March 20, 2006).
 Ex. 47, WADA Answers to UCI Independent Investigation Questions of March 15 and March 20, 2006, (April 3, 2006).

 <sup>95</sup> Ex. 48, Letter from David Howman, Director – General, WADA, to Emile Vrijman, independent investigator, (April 3, 2006).

WADA Code and that it had no intention to look into any disciplinary action, especially as it had no way of linking any analysis result with the name of a rider. Although WADA did not explicitly state in its responses that it had asked the LNDD to include 'additional information' in its reports -i.e. the code numbers contained on the original glass bottles used when conducting doping control testing during the 1998 and the 1999 Tours de France, necessary for the identification of the riders having provided these samples- WADA did say that it

'made sure that such results would be of use to UCI'.

Because WADA could not imagine that UCI would not have wanted to preserve the possibility of a longitudinal study analysis of the abuse of *r*-*EPO* and

'would not have wanted to know who was abusing EPO at the time among its riders', it 'ensured that the UCI would have all elements to be in a position to act in accordance with its rules', 'UCI being the only entity having the information that could link a result to a particular athlete'<sup>96.</sup>

2.28 WADA did not discuss with the LNDD, nor had the LNDD ever told WADA, whether there might be any limitations with regard to the analysis procedure used by the LNDD when analysing the urine samples from the 1998 and the 1999 Tours de France, or about any ways in which its testing for *r-EPO* had been different from the usual analysis procedure for the detection of *r-EPO* when conducting testing for doping control purposes. WADA says that it was its understanding

'that all analyses were conducted in accordance with the usual EPO method',

that the LNDD had confirmed that the urine samples had been stored at –20 degrees, that no substance could have been added and that the information on storage was available. WADA also claimed that the LNDD told WADA that the internal chain of custody had been documented, that the frozen urine samples had been stored at -20 degrees, that there was no possibility of contamination or adding of anything to the urine samples, and that there were no other irregularities in the testing<sup>97</sup>. At the same time however, WADA claims that it had asked the LNDD during the course of the project, whether the detection method used by the laboratory for the detection of *r-EPO* in the urine samples from the 1998 and the 1999 Tours de France

'was significantly different from the method used since 2000'.

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Id. It is not clear when the LNDD allegedly provided his information to WADA. WADA only says it 'was provided ex post facto in answer to [WADA's] questions'.

According to WADA, the LNDD had responded that this was not the case, and

'that the usual Iso-electro-focalization would apply to the analyses of all samples under the project'.

2.29 WADA's answers do not acknowledge the existence of any relevant documents, and state that the information exchanged between the LNDD and WADA, other than the reports sent by the LNDD to WADA, were communicated orally. Apart from a meeting in Paris on February 25, 2005, between WADA Science Director Dr. Olivier Rabin and Prof. De Ceaurriz and Dr. Lasne from the LNDD, 'where no documentation was exchanged', communication took mainly place through phone conversations between the LNDD and WADA Science Director Dr. Olivier Rabin. When asked what documents or other relevant information WADA might have gathered in the course of its investigation and whether WADA would be willing to provide copies of these documents to the investigator in order to assist him with the investigation, the only response from WADA was that it had asked questions of the UCI and Lance Armstrong and had not yet received any answers to those questions. WADA did not produce any documents in response to the aforementioned request.

# 3 The start of the investigation

#### The investigative process

- 3.1 The inquiry started early in October 2005, with a quick screening of all available information and documentation on file with the UCI. After having completed the aforementioned screening, a schedule was made, which was intended to identify any gaps in the available information and documentation and to develop a plan for the subsequent investigation, including a timetable. The next step in the investigation, following the screening, consisted of a thorough examination and subsequent evaluation of the aforementioned information and documentation. This review took until the end of November 2005.
- 3.2 After having completed the aforementioned research and subsequent evaluation of relevant information and documentation available at the UCI and taking into account the specific aims formulated in the Letter of Authority<sup>98</sup>, Vrijman decided to continue the inquiry first by visiting the LNDD in Châtenay-Malabry, France. In order to be able to assess and review the information to be obtained from the LNDD with regard to the aforementioned aims, he decided to request Dr. Van der Veen to join the inquiry as expert. Together they visited the LNDD on December 9, 2005.

# Visiting the LNDD

#### **Preliminary questions**

3.3 In preparation for the upcoming visit to the LNDD, a letter was sent on November 24, 2005<sup>99</sup>, requesting the LNDD to provide further information regarding its research involving the analysis of urine samples of the 1998 and 1999 Tours de France, by answering a number of 'preliminary questions.'<sup>100</sup> The idea was to use the answers to these questions as a basis for further conduct of the inquiry at the LNDD. After having contacted the LNDD several times, both by phone, as well as by e-mail, the date for visiting the LNDD was set at December 9, 2005. The answers from the LNDD regarding the aforementioned preliminary questions were however received on December 8, 2005, one day prior to the visit and could therefore not be used as originally intended.<sup>101</sup>

100 Ex. 50, Emile Vrijman, independent investigator, Preliminary Questions to the LNDD, (November 11, 2005).

<sup>98</sup> In particular the aims sub 1 to 6, as laid down in the Letter of Authority; Supra, at 57.

<sup>99</sup> Ex 49, Letter from Emile Vrijman, independent investigator, to Prof. De Ceuarriz, Director, LNDD, (November 14, 2005).

<sup>101</sup> Ex. 51, E-mail from Prof. De Ceaurriz, Director, LNDD, to Emile Vrijman, independent investigator, (December 8, 2005).

#### The actual visit

- 3.4 The actual visit to the LNDD took place on December 9, 2005, starting at 10:00 hrs. and lasted approximately five hours. During that time, both Prof. De Ceaurriz, Director of the LNDD and Dr. Francoise Lasne, staff member of the LNDD and involved in conducting the scientific research, provided Vrijman and Van der Veen with a verbal explanation regarding the various issues concerned. Dr. Lasne explained first the involvement of the LNDD in the development of suitable detection methods for *r-EPO* in urine samples, the nature of its subsequent research in general and the analysis of urine samples of the 1998 and 1999 Tours de France in particular. Following this explanation, both Dr. Lasne and Prof. De Ceaurriz answered specific questions posed by Vrijman and Van der Veen regarding the analysis of the aforementioned urine samples. They explained the reasons for using the urine samples for this specific kind of research and addressed the manner in which the samples had actually been analysed, as well as their subsequent status. Finally, time was spent discussing the findings, as well as (the content of) the reports of the LNDD regarding the analysis of samples.
- 3.5 The discussion with Prof. De Ceaurriz and Dr. Lasne was frank and open, especially with regard to the manner in which the analyses actually had been conducted, as well as the reason(s) for including in its reports the 'additional information'. In this report 'additional information' is understood as the following information that is normally not included in a routine research report: i.e. the code numbers present on the original glass bottles used for doping controls during the 1998 and the 1999 Tour de France, but also the name of the sport, the name of the race, codes indicating the successive deliveries of samples to the LNDD. It was the statement of Prof. De Ceaurriz and Dr. Lasne that WADA had requested the additional information to be included in the research reports. However, apart from the reports summarising the analysis of the aforementioned urine samples, copies of other relevant documents, supporting the statements made by Prof. De Ceaurriz and Dr. Lasne, were neither shown, nor handed over by the LNDD. When specifically asked by the investigator whether any proof in writing did exist to support these statements, especially regarding the reason(s) for including the aforementioned 'additional information', both Prof. De Ceaurriz and Dr. Lasne expressly stated that such documents did exist and were available on file, if necessary. This was also true for the other statements they had made. Should any of these statements be challenged, the LNDD would be willing to allow the investigator either direct access to these documents, or to hand over copies, as proof. It was agreed that the investigator would draft a report regarding his visit to the LNDD, which would subsequently be discussed with Prof. De Ceaurriz and Dr. Lasne, prior to being filed. At that time, any additional questions the investigator might want to raise could be discussed as well. As the LNDD ceased to cooperate with the investigator, the report has never been discussed with the LNDD<sup>102</sup>.

<sup>102</sup> Ex 52, E-mail from Emile Vrijman, independent investigator, to Dr. Lasne, staff member, LNDD, (December 21, 2005).

#### The follow-up of the visit to the LNDD

3.6 On December 21, 2005, the investigator informed Dr. Lasne by e-mail that the explanation provided by the LNDD at the meeting on December 9, 2005, for including the 'additional information' in its reports -in particular in the report regarding the analysis of urine samples from the 1999 Tour de France- was contradicted by statements made by WADA regarding the same issue. Apart from a general statement to this effect, provided by WADA in its letter to the UCI, dated September 9, 2005, a more specific statement had been made by Dick Pound in a written submission to Lance Armstrong, containing Pound's reply to questions posed earlier by Lance Armstrong and his representatives<sup>103</sup>. In this statement Pound had said that it had been the LNDD's wish to share its test results, including the aforementioned 'additional information', with WADA. According to him, approximately one month (July 2005) or so before the data were actually sent, the French Government had informed WADA, that the LNDD wished to share that data with WADA:

'In July 2005 WADA was informed by the French Government that the Laboratory had [...] information available and wished to share the data with WADA under certain conditions, including that WADA would not use the data for any sanction purpose.'<sup>104</sup>

The LNDD representatives however, had made it very clear in their interview with the investigator, that the LNDD had not wanted to share the 'additional information' with WADA at all, as it was neither relevant for the research conducted, nor for the interpretation of the actual findings thus obtained. The LNDD had acted this way only after WADA had exerted considerable pressure on the Ministry over a period of six months prior to August 2005 and, in turn, on the LNDD to provide these data. In order to be able to determine whether or not the statements provided by the LNDD as to the reasons for including the aforementioned 'additional information' in its report regarding the analyses of urine samples from the 1999 Tour de France were indeed correct, the investigator had issued the aforementioned request to the LNDD by e-mail, dated December 21, 2005, as had previously been agreed upon, either to be allowed access to documents in the LNDD's possession supporting the explanation given by the LNDD or to be provided with copies of such documentation<sup>105</sup>. The statement by Pound that it was the LNDD, that wanted to share information with WADA in July 2005 is also contradicted by WADA's reply to the investigator's guestionnaires dated March 15 and 20, 2006, where WADA states that as from February 2005 it was ensuring that the UCI would have all elements to be in a position to act in accordance with its rules.

Ex. 53, E-mail and attached memo from Richard Pound, President, WADA, to Lance Armstrong, cyclist, (August 30, 2005).

103 104

104 Id. 105 Supra, at 78.

# 3.7 Dr. Lasne replied on behalf of the LNDD by e-mail, dated December 22, 2005:

'In answer to your request of the 12/21st/2005, I inform you that the LNDD will allow access to the documentation you ask for, as soon as a consent from the official authorities of the laboratory is obtained.'<sup>106</sup>

Having subsequently tried to contact the LNDD several times in vain, Vrijman was informed on January 9, 2006, by phone that a meeting had been scheduled with the 'official authorities of the laboratory' for January 11, 2006, in order to discuss his request for further information, dated December 21, 2005<sup>107</sup>. On January 12, 2006, Prof. De Ceaurriz informed the investigator by e-mail what had been the outcome of the meeting with the 'official authorities of the laboratory'.

'[...] the position of our official authority is that your request must follow the French legal procedure, especially that regarding the access to the administrative documentation. For this aspect of your investigation and for any further requests you may have, please contact the legal representative of the LNDD [...].<sup>108</sup>

3.8 On January 17, 2006, the investigator, joined as of January 1, 2006, by Paul Scholten, heading the law firm, which Vrijman had joined as of the same date, contacted the legal representative of the LNDD accordingly, repeating his request either to to be allowed access to the documents supporting the statements made by Prof. De Ceaurriz and Dr. Lasne regarding the reasons for including the aforementioned 'additional information' in the LNDD's studies or to be provided with copies of such documentation<sup>109</sup>. The legal representative of the LNDD, Me P.C. Ranouil, however, subsequently refused to grant this request<sup>110</sup>:

'Unfortunately, we are not able to provide you with the requested documents or grant you access to the LNDD for the following reasons.

First of all, there is no discovery procedure under French law, which means that the International Cycling Union (UCI) is not entitled to request materials from an opposing party unless a court orders discovery. We would therefore suggest that you take the appropriate French recourse to obtain the requested documents.

Please also note that the LNDD is a public national administrative entity that is supervised by the Minister for Sport and that specific rules are applicable to the disclosure of administrative documents.<sup>'111</sup>

Ex. 57, Letter from Emile Vrijman and Paul Scholten to the legal representative of the LNDD, (January 17, 2006).
 Ex. 58, Letter from the legal representative of the LNDD to Emile Vrijman and Paul Scholten, (January 27, 2006).

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<sup>106</sup> Ex. 54, E-mail from Dr. Lasne, staff member, LNDD, to Emile Vrijman, independent investigator, (December 22, 2005).

Ex. 55, E-mail from Emile Vrijman, independent investigator, to Prof. De Ceaurriz, Director, LNDD, (January 10, 2006).

<sup>108</sup> Ex. 56, E-mail from Prof. De Ceaurriz, Director, LNDD, to Emile Vrijman, independent investigator, (January 12, 2006).

<sup>111</sup> Id.

3.9 At the same time, the Ministry itself informed the investigator -responding to his request for further information, as well as for a meeting sometime in January, 2006<sup>112</sup>- that it did not consider such a meeting necessary, as requested information had already been made available to the investigator or could be obtained from other sources as well<sup>113</sup>. While the Ministry's response at this time at least qualifies as premature and misinformed -and therefore possibly open to change- it nevertheless obstructed and continues to obstruct the investigation, as the Ministry should be well aware that both the LNDD and WADA, the only other likely sources for any of the information sought, have refused to provide access (the LNDD even as directed by the Ministry(?)) to those documents and information the investigator also seeks from the Ministry. The investigator has therefore asked both the legal representative of the LNDD and the Ministry to reconsider their position with regard to their further cooperation with his investigation<sup>114</sup>. In his letter of February 6, 2006, the legal representative of LNDD however, maintained the position previously taken<sup>115</sup>.

'We understand that you would like to obtain additional information in order to produce a report emphasizing on your quality as independent expert. However, French civil procedure law does not recognize independent experts as there is no independent expert other than those who have been appointed by the Court.'<sup>116</sup>

Consequently, a reply from the Ministry seems to be unlikely. The LNDD, however, asked the investigator by fax message<sup>117</sup> of March 15, 2006 to have the opportunity to have a look at the first draft of the report in so far as the information was concerned it had given to the investigator during his visit to the LNDD on December 9, 2005. The investigator decided to refuse the request made by the LNDD, given the fact that any concern the LNDD might have regarding the text of the report could have been avoided if it had not refused to cooperate further with the investigation<sup>118</sup>.

116 Id.

<sup>112</sup> Ex. 59, Letter from Emile Vrijman and Paul Scholten to the Ministry, (January 24, 2006).

<sup>113</sup> Ex. 60, Letter from the Ministry to Emile Vrijman and Paul Scholten, (January 27, 2006).

<sup>114</sup> Ex. 61, Letter from Vrijman and Scholten to the legal representative of the LNDD, (January 30, 2006).

Ex. 62, Letter from Vrijman and Scholten to the Ministry, (February 2, 2006).

<sup>115</sup> Ex. 63, Letter from the legal representative of the LNDD to Vrijman and Scholten, (February 6, 2006).

<sup>117</sup> Ex. 64, Fax message from Prof. J. de Ceaurizz to Emile Vrijman (March 15, 2006).

<sup>118</sup> Ex. 65, Fax message from Emile Vrijman and Paul Scholten to Prof. J. de Ceaurriz (March 22, 2006).

# Addressing the issues concerned 4

### Introduction

- 4.1 In this chapter of the report, the results of the fact-finding to date will be presented first for each of the issues specified for further consideration in the order as listed in the Letter of Authority. This will subsequently be followed by a discussion and conclusions regarding each of the aforementioned issues. The following issues will be addressed:
  - 1. the reasons of the LNDD for conducting research, involving the analysis of the urine samples of the 1998 and the 1999 Tours de France<sup>119</sup>;
  - 2. the methods and procedures used by the LNDD to obtain the measurement data<sup>120</sup>;
  - 3. the manner in which and to whom the LNDD subsequently reported its findings<sup>121</sup>;
  - 4. confidentiality<sup>122</sup>; and
  - 5. the qualification of the findings under the applicable anti-doping rules, regulations and procedures of the UCI<sup>123</sup>.

#### 4A. Findings

# The reasons of the LNDD for conducting research, involving the analysis of urine samples from the 1998 and 1999 Tours de France

4.2 According to the staff of the LNDD, the objective for the research conducted had been the development of a new mathematical model for interpreting the analysis results of urine samples analysed for *r-EPO*, allowing the WADA-accredited doping control laboratories to deal more effectively with the use of "micro-dosages" of *r-EPO* by athletes during competitions<sup>124</sup>. In order however, to make the abovementioned mathematical model work, a considerable amount of relevant data from urine samples having tested both positive, as well as negative for *r*-*EPO* was needed.

<sup>119</sup> Issue 1, in: "Letter of Authority". Supra, at 78.

<sup>120</sup> Issue 2, in: "Letter of Authority". Supra, at 78.

Issue 3, in: "Letter of Authority". Supra, at 78. Issue 6, in: "Letter of Authority". Supra, at 78. 121

<sup>122</sup> 

Issues 4 and 5, in: "Letter of Authority". Supra, at 78. 123

<sup>124</sup> See also: Ex. 66, Letter from Jacques de Ceaurriz, Director, LNDD, to Hein Verbruggen, President, UCI, (September 15, 2005).

- 4.3 Urine samples from regular medical patients treated with r-EPO, as well as urine samples "spiked" with r-EPO had been collected and analysed, as well as urine samples from the staff of the LNDD, providing data of positive, as well as negative test results for *r-EPO*, respectively. The LNDD had also collected and analysed urine samples from volunteers who had been injected with varying pre-determined quantities of *r-EPO*. Notwithstanding these efforts to collect the necessary amount of testing data regarding *r-EPO* positives and negatives, the LNDD representatives stated that still more data were required to develop the database for the new mathematical model further. This was especially the case with regard to testing data for *r-EPO* positives. In order to solve this problem, the decision was made to analyse the urine samples from both the 1998 and the 1999 Tours de France still in storage at the laboratory to populate the database further. According to the LNDD, there was sufficient reason to believe that some of these urine samples would still contain detectable, if not appreciable, amounts of *r*-EPO and consequently could be used to provide additional data needed to populate the aforementioned database further. Without even having been asked, neither expressly, nor implicitly, the representatives of the LNDD emphatically denied that these analyses had been conducted in order to discredit Lance Armstrong, or the UCI.
- In his letter, dated September 15, 2005, Prof. De Ceaurriz informed the UCI that the 4.4 research project had not only been conducted in cooperation with WADA, but that WADA had even taken charge of that part of the research project, in particular the administrative part of *r*-EPO to volunteers -in accordance with a protocol- in doses subsequently varying from high to low<sup>125</sup>. The LNDD representatives however, claim that the decision to include the analyses of the (remaining) urine samples from the 1998 and 1999 Tours de France in the research program and to use the results thus obtained for the database for the new mathematical model had been their own. The LNDD representatives stated that they had never considered whether or not the laboratory was actually allowed to use these urine samples for research purposes and consequently had neither asked the riders or the UCI for any permission for their use, nor clarified their ownership. As far as financing was concerned, the LNDD representatives explicitly mentioned that while their overall research program regarding (the detection of) *r-EPO* had been financed by WADA, this had not been so for the costs of conducting the analyses of the urine samples of the 1998 and 1999 Tours de France. These had been financed by the Ministry.
- 4.5 In its letter, dated September 16, 2005, the Ministry informed the UCI that it had learned that the analyses of urine samples from the 1998 and 1999 Tours de France had been conducted within the framework of a larger scientific project and in

<sup>125</sup> 

Id. "Cette recherche a été menée en collaboration avec l'AMA qui a pris de charge une partie des travaux notamment ceux qui avaient trait a l'administration d'EPO recombinante a des volontaire selon un protocole qui intégrait l'administration de fortes doses d'EPO suivies de l'administration de faibles doses »».

cooperation with WADA, as recommended by art. 19.3 of the WADA Code<sup>126</sup>. According to the Ministry however, and contrary to what both LNDD research reports seem to suggest, the urine samples from the 1998 and the 1999 Tours de France have not been analyzed together, but rather (4) years apart<sup>127</sup>, referring to the publication of the LNDD in the scientific magazine "Nature" in June 2000 regarding the development of a detection method for *r-EPO* used to analyse the urine samples from the 1998 Tour de France<sup>128</sup>.

#### The reasons given by WADA for the analysis of the 1998 and 1999 Tour samples

4.6 Even though WADA had characterised the analyses of the urine samples from the 1998 and the 1999 Tours de France conducted by the LNDD in its letter to the UCI, dated August 25, 2005, as:

#### "natural and typical ongoing research, which WADA encourages"<sup>129</sup>,

it has nonetheless consistently denied any involvement in any manner whatsoever in the LNDD research project. In its letter to the UCI, dated September 9, 2005, WADA explicitly refutes the suggestion that it had been (actively) involved in (financing) the analyses of the urine samples from the 1998 and the 1999 Tours de France as conducted by the LNDD:

"This was not a WADA "research project", but testing conducted to assist in the further refinement of the EPO test and to expand its general knowledge of doping practices"<sup>130</sup>.

In its e-mail to Armstrong, dated August 30, 2005, WADA conveyed a similar message:

Q. "What role, if any, did WADA have in the research project?"

A. "This is not research conducted by the French laboratory pursuant to any specific WADA funded research project."

126 "Par ailleurs, je vous rappelle que les travaux du LNDD s'effectuent dans le cadre d'un réseau scientifique et en relation avec l'agence mondiale antidopage (AMA), comme le recommande l'article 19-3 du code mondial anti-dopage qui charge l'ÁMA d'une mission spécifique de coordination dans le domaine de la recherche"

129 Supra at 36.

130 Supra at 36.

See also: Art. 19.3, "Coordination", of the WADA Anti-Doping Code 2003, contains the following provision:

<sup>&</sup>quot;Coordination of anti-doping research through WADA is encouraged. Subject to intellectual property rights, copies of antidoping research results should be provided to WADA"

Ex. 67, Letter from Mr. Francois Lamour, Minister for Youth and Sport, to Hein Verbruggen, President, UCI, [September 16, 2005).

Those of the 1998 Tour de France some time in 1999 or early 2000 and those of the 1999 Tour de France some time in 2004, 127 at least before the alleged initial report had been submitted by the LNDD in January 2005. Ex. 68, Lasne F., and De Ceaurriz J., "Recombinant erythropoietin in urine; an artificial hormone taken to boost athletic

performance can now be detected", Nature, Vol. 405, June 8, 2000, p. 635. Ex. 68, Lasne F., and De Ceaurriz J., "Recombinant erythropoietin in urine; an artificial hormone taken to boost athletic 128 performance can now be detected", Nature, Vol. 405, June 8, 2000, p. 635.

4.7 WADA's consistent denial of involvement in any manner whatsoever in the LNDD research project might, at first glance, appear to contradict the statements made by both the Ministry and the LNDD regarding the involvement of WADA. It should be noted however, that the statements made by the Ministry, the LNDD and WADA regarding this issue do not differentiate between the overall research project of the LNDD -of which the analyses of the urine samples from the 1998 and the 1999 Tours de France allegedly were only a part- and the research specifically conducted with regard to the urine samples from the 1998 and the 1999 Tours de France. However, when the investigator in his questionnaires of March 2006 specifically referred to the statement having been made by the French Ministry in its letter dated September 16, 2005 -i.e. that these analyses had been conducted "in cooperation with WADA"-WADA replied –again- that it:

# "was not in any manner involved in the initiation of this research and did not support it financially."<sup>131</sup>

It was not a project financed by WADA grants. WADA had not been part of any discussion prior to the project being started and "was not involved in the design of the research protocol". WADA was, in other words, not involved in the research conducted by the LNDD regarding the urine samples from the 1998 and the 1999 Tours de France. As such its denials of any involvement in any manner whatsoever appear to be correct and in line with the statements of the LNDD and the Ministry, as far as the analyses of the urine samples from the 1998 and the 1999 Tours de France are concerned. WADA's explicit denial of any involvement in any manner whatsoever as far as the analyses of the urine samples from the 1998 and the 1999 Tours de France are concerned, constitutes at the same time an implicit admission of its involvement in the overall research project of the LNDD, as WADA has not denied any involvement in any manner whatsoever as far as the overall research project of the LNDD was concerned. It is not clear why WADA so far has refrained from mentioning its involvement in (financing a part of) the overall research project.

4.8 According to WADA, communication mainly took place through phone conversations between the LNDD Director, Prof. De Ceaurriz, and WADA Science Director, Dr. Rabin. As a matter of fact, WADA claims that by the time it was informed about the research project, "the project was already in progress".

"Initially, on October 19th, WADA was only informed about the general nature of the on going project and only got more details, in particular as to the samples that were analyzed, in the days that followed."<sup>132</sup>

<sup>131</sup> Supra at 94, p. 3.

<sup>132</sup> Supra at 94, p. 1.

- 4.9 While WADA knew the LNDD had in its possession retained urine samples from the 1998 and the 1999 Tours de France, it claims that it was not discussed whether they were "A" - or "B" samples<sup>133</sup>. WADA admitted however that it "was obviously aware that doping control took place in 1998 and 1999, that therefore could imagine that all the A samples had already been opened"<sup>134</sup>. Specifics of the samples were not discussed with the LNDD.
- 4.10 Having been informed by the LNDD regarding its research project, WADA, says it confirmed, "at that time", to the LNDD that it was interested in "the issue of *EPO* stability, as well as the study of trends of use of *EPO* following the introduction of the test and the improvement of the *EPO* test" and asked to be kept informed of the results of the research, suggesting these issues were its reasons for doing so<sup>135</sup>. During a subsequent meeting in Paris in February 2005, between WADA's Science Director and Prof. De Ceaurriz and Dr. Lasne of the LNDD, WADA was informed that the project was still ongoing and progress on the research project was being discussed, albeit no documentation was exchanged<sup>136</sup>. WADA however, did more than just confirm its interest in the research results. It made sure that these results would be of use to the UCI.

"WADA can not imagine that the UCI would not have wanted to preserve the possibility of a longitudinal study analysis of the abuse of EPO and would not have wanted to know who was abusing EPO at that time among its riders. WADA ensured that UCI would have all elements to be in a position to act in accordance with its rules."<sup>137</sup>

4.11 According to WADA the research report showed "that old samples could still reliably be analyzed for the presence of recombinant or endogenous *EPO*"<sup>138</sup>. The results from the project are being used in the current refining of the decision criterion for the *r-EPO* test. It should be noted that neither the LNDD, nor the Ministry, nor WADA to date have submitted any documentation regarding the scientific research of the LNDD regarding (the detection of) the prohibited substance *r-EPO* in general and/or the analyses of the urine samples from the 1998 and the 1999 Tours de France in particular, let alone regarding their respective involvement in the research project, supporting their different, at times contradictory, statements regarding these issues.

#### The analyses of the urine samples from the 1998 and the 1999 Tours de France

4.12 Apart from the aforementioned issues, several other matters are sufficiently important to require further consideration as well. When screening and reviewing the information and documentation obtained from the UCI, as well as from the LNDD itself and from the interviews conducted with staff members of the LNDD,

<sup>133</sup> Id.

<sup>134</sup>Supra at 94, p. 7.135Supra at 94, p. 1.

<sup>135</sup> Supra at 94, p. 1. 136 Supra at 94, p. 1 – 2.

<sup>137</sup> Supra at 94, p. 1 – 2. 137 Supra at 94, p. 2.

<sup>138</sup> Supra at 94, p. 4.

the investigator was confronted with different statements from the LNDD, the Ministry and WADA, regarding: (i) the total number of urine samples from both Tours de France actually analysed, as well as (ii) the total number of urine samples allegedly having tested "positive" and (iii) the exact date when these analyses were conducted<sup>139</sup>. It is therefore no coincidence that the first preliminary question attached to the letter of the independent investigator to the LNDD, dated November 14, 2005, concerned the number of urine samples from the 1998 and the 1999 Tours de France actually analysed by the LNDD<sup>140</sup>.

#### ad i: the total number of analysed urine samples 1998 Tour de France

Judging from the LNDD research report regarding the analyses of the urine samples from the 1998 Tour de France, a total of 102 urine samples has been listed as having been analysed by LNDD at the time it conducted its research<sup>141</sup>. This is also the exact same number of urine samples referred to by Dr. Lasne and Prof. De Ceaurriz in a publication in the scientific magazine "Nature" dated June 8, 2000, discussing the direct testing method developed by the LNDD for the detection of *r-EPO*:

"We have developed an analytical procedure for detecting recombinant EPO in urine and have applied it to specimen from cyclists participating in the infamous Tour de France 1998 competition, which was sullied by scandals about EPO doping."<sup>142</sup>

"We assayed 102 frozen urine samples from participants in the Tour de France 1998 cycling competition for EPO by using an enzyme-linked immunosorbent assay."<sup>143</sup>

The research report regarding the analyses of the urine samples from the 1998 Tour de France however, list 42 samples as "manquant" or missing, which means that only 60 samples were available for analysis by the LNDD. While these 42 urine samples were not available for testing, the summary table in the research report nevertheless does contain references to these urine samples by listing their respective batch codes and the corresponding original bottle code numbers from the 1998 Tour de France.

In his interview with the Dutch newspaper "*De Volkskrant*", dated October 23, 2005, Prof. De Ceaurriz stated that only ninety (90) urine samples from the 1998 Tour de France had been left, sixty (60) of which had been used by the LNDD for conducting its research<sup>144</sup>. This was the exact same number of urine samples mentioned by Prof. De Ceaurriz in his answer to the first preliminary question<sup>145</sup>. He did not explain however, why only sixty (60) and not all ninety (90) remaining urine samples from the 1998 Tour de France had been used for conducting research.

<sup>139</sup> Addressed sub (iii) in this paragraph.

<sup>140</sup> Supra, at 100.

<sup>141</sup> Counting the total number of cells listed as part of in the column "flacon" or "bottle", referring to the urine sample container. However, 42 of these have been listed as "manquant", or missing. See: Ex. 69, LNDD, "Recherche EPO Tour de France 1998, August 1, 2005, p. 1-4.

<sup>142</sup> Supra, at 128.

<sup>143</sup> Id.

<sup>144</sup> Ex. 70, Marije Randewijk, "Een klare zaak met duidelijke feiten", De Volkskrant, (October 23, 2005).

<sup>145</sup> Supra, at 101.

# The total number of analysed urine samples 1999 Tour de France

The LNDD research report regarding the analyses of the urine samples from the 1999 Tour de France indicates that a total of 91 urine samples from the 1999 Tour de France has been analysed by the LNDD<sup>146</sup>. In his interview with "*De Volkskrant*" however, Prof. De Ceaurriz puts the total number of analysed samples from the 1999 Tour de France at ninety (90)<sup>147</sup> and at eighty-seven (87) when answering one of the preliminary questions<sup>148</sup>.

In its letter to the UCI, dated September 9, 2005, WADA puts the total number of analysed urine samples from both the 1998 and the 1999 Tours de France at one hundred – ninety-one (191).

"v. There were 191 urine samples which were not required for the B analysis during the 1998-99 Tours and these, we are advised by the laboratory, were stored in optimum conditions."<sup>149</sup>

## ad. ii: The total number of alleged positives from the 1998 Tour de France

According to the LNDD research report, 29 urine samples out of a total of 102 allegedly tested "positive". The exact same number is mentioned in the publication in "Nature"<sup>150</sup>. However, in his interview with *"De Volkskrant"*<sup>151</sup>, Prof. De Ceaurriz put the total number of alleged "positives" at forty (40), while the Ministry, in its letter to the UCI, dated September 16, 2005, mentions a total of thirty-nine (39) alleged "positives", twenty-four (24) of which would still contain a sufficient volume of urine (20 ml) or "retentate" (20 µl) for possible re-testing<sup>152</sup>.

## The total number of alleged positives from the 1999 Tour de France

To date there have been contradictory statements regarding the reported total of alleged "positive" urine samples from the 1999 Tour de France, ranging between a total of twelve (12) and fifteen (15). According to the Ministry, twelve (12) of these alleged "positive" urine samples would still contain a sufficient volume of urine (20 ml) or "retentate" (20 µl) for possible re-testing<sup>153</sup>.

# ad iii: The date of the analyses of the urine samples from the 1998 and 1999 Tours de France

Even to date it remains uncertain when the urine samples from the 1998 and the 1999 Tours de France were actually analysed and whether or not they were analysed together,

147 Supra, at 144.

148 Supra, at 101.

<sup>146</sup> Based upon the total number of cells listed as part of in the column "flacon" or "bottle", referring to the urine sample container. See: Ex. 71, LNDD, "Recherche EPO Tour de France 1999, July 29, 2005, p. 1-4.

<sup>149</sup> Supra, at 36.

<sup>150</sup> Supra, at 128.

<sup>151</sup> Supra, at 144.

<sup>152</sup> Supra at 126. According to the Minster, the director of the LNDD had assured him these data to be correct: "Avant de répondre à votre lettre je me suis assuré auprès du Directeur de LNDD que, pour 1999, douze sur quinze des échantillons positifs a l'EPO sont reanalysable et, pour 1998, 24 sur 39 le sont (sur la base de 20µ l pour les retentats et 20 ml pour les urines) ».

<sup>153</sup> ld.

i.e. during the same phase of the research project. According to WADA in its letter to the UCI, dated September 9, 2005, the urine samples from both the 1998 and the 1999 Tours de France had been analysed together at the same time, apparently in 2004:

"Some time in 2004, WADA became aware, during the ongoing refinement of the process for a better EPO test (a test which had already been approved in, I believe, 2000) that the French laboratory had in its possession retained B-samples from the 1998 and 1999 Tours that could be used for further research. Indeed, WADA was informed that the laboratory was using these stored samples to refine their EPO test. Following receipt of this information, WADA asked to be informed. WADA is, of course, interested in expanding the knowledge of what doping substances were in use and during what periods, as, I am sure is UCI."154

Notwithstanding the fact that both research reports seem to suggest the same, the Ministry apparently believes otherwise. According to the Ministry, the urine samples from the 1998 Tour de France had already been analysed, either in 1999 or in the beginning of 2000, as the subsequent results had been published by the LNDD in the issue of the scientific magazine "Nature", albeit without having attracted any particular attention<sup>155</sup>. The subsequent analyses of the urine samples from the 1999 Tour de France had been part of the continued research efforts of the LNDD in this regard<sup>156</sup>.

Surprisingly, neither the LNDD, nor WADA, have made any reference to date to the aforementioned publication in "Nature", describing the analysis of 102 urine samples from the 1998 Tour de France as part of the development of a direct testing method for the prohibited substance *r*-EPO, let alone the consequences of the implied suggestion that the analyses of the urine samples from the 1998 Tour de France had already been conducted as early as 1999, or the beginning of 2000. WADA however, in its responses indicated it was aware of the 2000 publication by the LNDD in Nature magazine concerning tests on 1998 Tour de France urine samples. It is however, also possible that the LNDD tested the urine samples from the 1998 Tour de France a second time, this time in 2004. This would explain why (i) the various statements from the LNDD, the Ministry, as well as WADA, differ the most with regard to the numbers of urine samples actually having been tested ("positive") from the 1998 Tour de France and why (ii) forty-two (42) urine samples were "missing".

#### Methods and procedures used by the LNDD to obtain the measurement data

4.13 During the visit to the LNDD the representatives from the LNDD told Vrijman and Van der Veen, that they had used some kind of "accelerated measurement procedure" when conducting the analyses of the urine samples of the 1998 and 1999 Tours de France. This "accelerated measurement procedure" had been derived from the

<sup>154</sup> Supra, at 36.

<sup>155</sup> Id. "Les résultats de l'étude sur les échantillons de 1998 ont d'ailleurs fait l'objet d'une publication scientifique dans »Nature » en 2000(no 405 :635 Lasne F. et de Ceaurriz J.) sans susciter d'observations particulières". ld.

<sup>156</sup> 

regular analytical procedures for conducting doping controls. A detailed description however, was not provided. According to the LNDD, this "accelerated measurement procedure" allowed the laboratory to test the urine samples more rapidly, while, at the same time, producing data considered to be of sufficient quality for the limited purpose of the research the LNDD had been conducting, notwithstanding the fact that this procedure appears to differ considerably from the mandatory analysis procedure(s) for urine samples required by the *ISL*. However, the LNDD believed the use of the "accelerated measurement procedure" to be justified, as the testing data were only meant to populate a database for a new mathematical model, which was being developed for a new detection method for *r-EPO* and not for doping control purposes<sup>157</sup>. The "accelerated measurement procedure" however, has to date not been disclosed or validated.

- 4.14 Regarding the methods and procedures used for analysing the aforementioned urine samples from the 1998 and 1999 Tours de France, the representatives of the LNDD also stated that:
  - 1. the analyses results had been obtained, using a part of the mandatory screening measurement procedure only;
  - 2. only a single (measurement) standard had been used; no negative and positive control samples had been used;
  - 3. three different interpretation methods for *r-EPO* appear to have been used: i.e. a visual method, the so-called "direct urine test", applying the so-called "80% BAP Standard"<sup>158</sup> and the new "mathematical model";
  - 4. only "B" samples had been used, as "A" samples containing sufficient urine had not been available. Consequently, there is no urine sample available any longer which could function in a manner similar to the manner in which the so-called "B" sample is required to function during a regular doping control procedure;
  - 5. a number of the aforementioned "B" samples apparently had already been used "for other research purposes" prior to this research being investigated and consequently had been listed in the research reports as "missing"<sup>159</sup>. There was insufficient documentation available to be able to determine whether or not other urine samples had been opened for other purposes as well prior to the current research;

<sup>157</sup> 

This however represents another important issue for further consideration. While the use of an "accelerated measurement procedure" might in some instances be justified given the scientific objective of the analysis, this is however, an altogether different matter when these analyses results are intended to populate a database for a mathematical model intended to be used as part of a detection method for a prohibited substance or method.

In order to avoid false positive findings and to determine whether or not a finding could truly be qualified as constituting an adverse analytical finding, the "80% BAP standard" was being used. This standard requires a 100% EPO control sample to be used to establish a horizontal dividing line drawn at the bottom of the most acidic rung of the 100% EPO sample as "baseline". The so-called "EPO ladder" of the athlete's urine sample in question is then examined relative to this horizontal baseline. A machine then measures the volume of these rungs using densitrometry to determine what pertentage of the volume appears above the horizontal baseline in the basic area of the gel. This percentage figure is the "BAP" and represents one of several methods of interpreting the isoelctropherograms. Initially, a BAP of 80% or higher constituted an adverse analytical finding for r-EPO. This requirement created a threshold safety margin in order to avoid having false positive test results due to "overlap".

<sup>159</sup> Supra, at 141 and 146.

- 6. it is impossible to reproduce a chain of custody and it is clear that for many, if not all, of the urine samples the chain of custody was violated;
- 7. it could not prove, let alone guarantee that there had been a strict temperature control with regard to the urine samples from the 1999 Tour de France and whether they had continuously been stored at -20°C, after their arrival at the LNDD in 1999, given that some of these urine samples had been opened without any record being maintained of when they had been opened and for what purpose and given that these urine samples would likely have been thawed if some of their contents had previously been used for research purposes. No records of the storage temperature for these samples during the past six years were available, and
- 8. the stability test, a mandatory requirement since January 15, 2005, before an urine sample can be qualified as constituting an Adverse Analytical Finding, had not been conducted<sup>160</sup>.
- 4.15 These findings however, do not correspond with the information WADA claimed to have received from the LNDD regarding this issue. In its reply of April 3, 2006, concerning the investigator's questions posed in the questionnaires of March 15 and March 20, 2006, WADA says that it had asked the LNDD, "during the course of the project", whether the method used by the laboratory was significantly different from the method used since 2000.

"The lab responded that this was not the case, and that the usual Iso-electric-focalization would apply to the analyses of all the samples under the project."<sup>161</sup>

#### Furthermore:

"It is our understanding that all analyses were conducted in accordance with the usual EPO method. Furthermore, points (d) and (e) are in total contradiction with the information we received from the laboratory. The LNDD confirmed that the samples had been stored at –20 degrees; that no substance could have been added and that information on storage was available."<sup>162</sup>

4.16 However, while originally intended to assist the investigator in preparing for his visit to the LNDD, the reply from Prof. De Ceaurriz to the preliminary questions, dated December 8, 2005, can now be used to clarify this issue. When asked whether or not "laboratory documentation packages" were available regarding each of the separate alleged *adverse analytical findings* reported by the LNDD in its report regarding the analysis of the urine samples from the 1999 Tour de France<sup>163</sup>, Prof. De Ceaurriz replied as follows:

160 "Enzymatic activity" can impair the detection of r-EPO, but can be discerned through the use of a "stability test". See: Ex. 72, WADA, Technical Document TD2004EPO, January 15, 2005.

<sup>161</sup> Supra, at 94, p. 6. 162 Id.

<sup>163</sup> Supra at 100.

"The samples were analysed for EPO in the frame shift of a research program without applying the rules of WADA for anti-doping controls. So, no laboratory documentation packages are available."<sup>164</sup>

When asked if the fact that urine samples apparently were missing meant that they simply had not been found stored as might have been expected on the basis of the internal laboratory chain of custody for these samples, or that these samples had not been found present at the LNDD after a careful search of all available storage facilities for urine samples either within or available to the LNDD, Prof. De Ceaurriz answered:

"Research samples were managed differently from the chain of custody used for antidoping controls. The missing samples have been used for other research purposes."<sup>165</sup>

# The manner in which and to whom the LNDD subsequently reported its findings

- 4.17 According to the representatives of the LNDD, the initial reports regarding the analyses of the urine samples from the 1998 and the 1999 Tours de France were sent to both WADA and the Ministry some time in January 2005. After having received these reports, WADA subsequently requested the LNDD repeatedly to include in its final research reports all "additional information" regarding these analyses as well, in particular as far as (the report regarding) the analyses of the urine samples from the 1999 Tour de France were concerned. While the phrase "additional information" originally referred to all research data remaining which so far had not been included in the research reports, in practice it was used to indicate the code numbers present on the original glass bottles used for conducting the doping controls during the 1998 and the 1999 Tours de France. The LNDD however, claimed it refused to include the *"additional information"* WADA had requested. The LNDD believed that the *"additional* information" WADA had requested did not constitute information relevant for either explaining, or understanding the research it had conducted, or for interpreting its subsequent findings. The fact that the LNDD also believed that the results from the analyses of these urine samples could not be used -at least from a legal point of viewfor disciplinary purposes anyway, gave the LNDD an additional reason (to continue) to refuse WADA's request. WADA nevertheless continued repeating its request.
- 4.18 According to the LNDD, its refusal to provide WADA with the requested "additional information" resulted in a discussion between WADA and the Ministry, lasting approximately six (6) months before an agreement was reached. During all this time, the LNDD claimed to have felt a continuous pressure coming from WADA to include the requested "additional information" in its research reports, at least as far as the report regarding the analyses of the urine samples from the 1999 Tour de France was concerned. Under the terms of this agreement, the LNDD was to provide WADA with

the *"additional information"* it had specifically requested, under the explicit conditions that WADA would:

- maintain strict confidentiality regarding the additional information provided by the LNDD, in particular with regard to the code numbers present on the original glass bottles used for doping controls during the 1999 Tour de France; and
- 2. not use the information contained in the report regarding the analysis results of the urine samples from the 1999 Tour de France to initiate disciplinary proceedings against individual riders.

This might explain why WADA President, Dick Pound, stated in his memo to Lance Armstrong, dated August 30, 2005, that the result of the research conducted by the LNDD:

"is confidential and does not have any connection to any individual"<sup>166</sup>.

4.19 While reluctant to either discuss or comment on the possible reasons for WADA's request, the representatives of the LNDD nevertheless admitted to having had the strong impression that the additional information had been requested with the intention to determine accordingly the identity of one or more riders, allegedly responsible for having provided one or more of the alleged "positive" urine samples or alleged *Adverse Analytical Findings*. They also made it clear that the LNDD does not have an official policy for dealing with these kinds of requests. So far, the only criterion applied by the LNDD when being confronted with such a request appears to be the requirement that it originated from a "recognised public authority". What, according to the LNDD, actually constitutes a "recognised public authority" however, has remained unclear. Consequently, the LNDD was unable to explain whether the procedure it followed with regard to documenting and reporting in this matter was consistent with its policy and procedures for reviewing requests and if so, to what extent.

The LNDD claims it reported the results of its analysis of the samples of the 1998 and 1999 Tours de France to the Ministry and WADA only, using the following format for its reports<sup>167</sup>, comprising of:

a summary table listing the laboratory codes<sup>168</sup>, the sample bottle code numbers, present on the original glass bottles used for collecting urine samples during the 1998 and the 1999 Tours de France, the analysis results of the various detection methods apparently applied, possible remarks, as well as the urine samples' remaining volume of urine and/or "retentate"<sup>169</sup> after having been analysed;

<sup>166</sup> Supra, at 103

<sup>167</sup> Supra, at 141 and 144.

<sup>168</sup> The laboratory codes are sequential numbered codes attatched to batches of urine samples corresponding to order in which these batches arrived at the laboratory to be analyzed or the order in which these batches are alayzed.

<sup>169</sup> This means a "concentrated" urine sample. When conducting doping control analyses, it is sometimes necessary due to the condition of the urine sample itself (for instance when the urine sample is diluted) or the characteristics of certain prohibited substances- that the urine, contained in the so-called "collection vessel" needs to be concentrated first, before being used for doping control purposes.

- an overview of the analysis results having used the new mathematical model<sup>170</sup>;
   and
- a series of prints of the integration results of the equipment<sup>171</sup>.
- 4.20 WADA has a different version. In its reply dated April 3, 2006, to the investigator's questions posed in the questionnaires of March 15 and March 20, 2006, WADA says that it had no knowledge of a report from January 2005<sup>172</sup>.

"As indicated above no such report was ever received and therefore your statement is incorrect."<sup>173</sup>

According to WADA however, a meeting did take place in Paris on February 25, 2005 between WADA Science Director, Dr. Rabin, LNDD Director, Prof. De Ceaurriz and LNDD staff member Dr. Lasne.

"During the meeting, among other things unrelated to this research, progress on this research project was discussed. However, no documentation was exchanged, and WADA was informed that the project was still ongoing."<sup>174</sup>

When asked what WADA wanted to be kept informed about and what "additional information" it had requested from the LNDD, WADA replied that it had asked the LNDD to be kept informed of the progress and the final result of the research project. WADA did not specify explicitly what "additional information" it had requested from the LNDD, other than it having asked the LNDD:

"to ensure that such result would be of use to UCI (UCI being the only entity having the information that could link a result to a particular athlete) in view of a potential longitudinal study",<sup>175</sup>

and that it:

"can not imagine that the UCI would not have wanted to preserve the possibility of a longitudinal study analysis of the abuse of EPO and would not have wanted to know who was abusing EPO at that time among its riders. WADA ensured that UCI would have all elements to be in a position to act in accordance with its rules."<sup>176</sup>

<sup>170</sup> Supra at 141, p. 4 – 5.

Supra at 146, p. 4 – 5. 171 Supra at 141, p. 6 – 42.

Supra at 141, p. 6 – 42. Supra at 146, p. 6 – 42.

<sup>172</sup> Supra at 94, p. 3.

<sup>173</sup> Supra at 94, p. 4.

<sup>174</sup> Supra at 94, p. 1 - 2.

<sup>175</sup> Supra at 94, p. 4.

<sup>176</sup> Supra at 94, p. 2.

#### 4.21 According to WADA, the research report showed:

"that old samples could still reliably be analysed for the presence of recombinant or endogenous EPO. The report of August 2005 being self-evident, WADA did not need to request further information."<sup>177</sup>

WADA did not mention having received any information at all regarding the other components of the LNDD's overall research project, in particular with regard to the part concerning the analyses of the (spiked) urine samples of patients and volunteers that, according to LNDD, had been financed by WADA. The investigator has received no indication that there has been any reporting regarding the LNDD's overall research project, other than the two reports regarding the analyses of the urine samples from the 1998 and 1999 Tours de France.

When asked whether the LNDD had informed WADA about the manner in which the analyses of the urine samples from the 1998 and the 1999 Tours de France had been conducted<sup>178</sup>, WADA replied that it had not been involved in the design of the research protocol and therefore –"in answer to your question" - had not discussed with the LNDD the specific elements mentioned in the question.

"This was, in addition, not mentioned either at the time of the reception of the final report"<sup>179</sup>.

#### However,

"During the course of the project, WADA asked if the method used by the laboratory was significantly different from the method used since 2000. The lab responded that this was not the case, and that the usual Iso-electro-focalization would apply to the analyses of all samples under the project."<sup>180</sup>

#### Furthermore,

"It is our understanding that all analyses were conducted in accordance with the usual EPO method. Furthermore, points (d)<sup>181</sup> and (e)<sup>182</sup> are in total contradiction with the information we received from the laboratory. The LNDD conformed that the samples had been stored at –20 degrees; that no substance could have been added and that information on storage was available."<sup>183</sup>

<sup>177</sup> Supra at 94, p. 4.

Supra at 94, p. 5. In particular that the LNDD had used some kind of "accelerated measurement procedure", a non WADAaccepted non-validated screening procedure, which does not comply with the required mandatory rules and regulations for conducting doping control testing, as laid down in the "ISL", nor with the mandatory requirements regarding the testing of urine samples for the prohibited substance r-EPO, as specified in technical document "TD2004EPO"-Supra at 94, p. 6.

<sup>180</sup> Id.

<sup>181</sup> Id. "(d) that it could not provide the required mandatory internal chain of custody?"

<sup>182</sup> Id. "(e) that it could not guarantee that the urine samples from both Tours de France had been kept stored under

<sup>,200</sup> continuously at a temperature of – 200C during the period of time they were kept in storage at the laboratory

<sup>183</sup> Id.

According to WADA, there had been no discussion with the LNDD whether the retained urine samples it had in its possession, were "A" - or "B" samples.

"This point was never discussed as such. However, WADA was obviously aware that doping control took place in 1998 and 1999 and therefore could imagine that all A samples had already been opened."<sup>184</sup>

# Confidentiality

- 4.22 In his interview with "*De Volkskrant*", Prof. De Ceaurriz, stated that, when being confronted with the fact that the test results of such well-known athletes like Kelly White, Olga Jegorova and the tennis player Mariano Puerta whose urine samples had been tested by the LNDD were already reported in *L'Equipe* before these athletes themselves had been informed of their test results, the LNDD did not pass any information on to any newspaper<sup>185</sup>.
  - Q. "Including L'Equipe?"
  - A. "We wouldn't even be able to do so. The samples are being tested anonymously. It is really impossible for us to determine who they belong to."
  - *Q. "You do seem to have some sort of direct link with their office? It is after all situated only around the corner."*
  - A. "No, not at all. L'Equipe uses the means it believes necessary to. Sometimes to much, if you'd ask me. I find it often embarrassing that news about athletes having tested positive, is out on the street so fast. We are not looking for a "scoop". We just want to be able to do our work in peace and quiet."
  - *Q. "So this newspaper is simply good at what it does and the fact that your laboratory is involved every time is simply a coincidence?"*
  - A. "That is true. Until the Tour de France of 1998, L'Equipe had the reputation of deliberately ignoring doping cases. Now they employ four investigative journalists, specialised in doping, full time. And they also have a good network of correspondents. How else would it know that Puerta tested positive? That is not my mistake, that news came from Argentina."
  - Q. "So you were also surprised when you read the newspaper on August 23?"
  - A. "Like everybody, I was surprised and disillusioned as well. At the same time, I felt also reassured. The fact that six positive urine samples appear to have originated from Lance Armstrong, shows a certain consistency. I would have felt less reassured if only one urine sample would have belonged to him."<sup>186</sup>

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<sup>184</sup>Supra at 94, p. 7..185Supra, at 144.

<sup>186</sup> 

- 4.23 With regard to the nature of the additional information requested, both LNDD representatives were of the opinion that the *ISL* did not allow the LNDD to provide WADA with this kind of information, much less to publish it, as it could be used (to attempt) to discover the identity of one or more of the riders, having been responsible for providing one or more of the urine samples from the 1998 and the 1999 Tours de France. This would constitute a violation of the so-called "confidentiality provisions", as contained in the WADA Code, the *ISL* and the "UCI Anti-Doping Rules".
- 4.24 When asked whether they had any idea as to how Mr. Ressiot, the author of the article "Armstrong's lie", might have come into the possession of the research reports of the LNDD regarding the analyses of the urine samples from the 1999 Tour de France, both Prof. De Ceaurriz and Dr. Lasne of the LNDD replied that they had no idea. The LNDD had produced a limited number of copies of both research reports, which had been sent to the Ministry and to WADA only, under the condition that absolute confidentiality be maintained. They nevertheless appeared to be certain, that this information had not originated from the LNDD. As far as (the copies of) the original doping control forms of the 1999 Tour de France were concerned, these could not have originated from the LNDD. The only copies of doping control forms the LNDD ever received, were the so-called "laboratory copies", containing only (that part of) the information listed on the form considered relevant for the doping control test.
- 4.25 The LNDD representatives may claim that they have no idea as to how Ressiot might have come into the possession of the LNDD research report regarding the analyses of the urine samples from the 1999 Tour de France, the interview with CyclingNews on September 7, 2005, nevertheless shows how well informed Ressiot apparently was with regard to some of the most important aspects of the analyses of the urine samples from the 1999 Tour de France, whether technical or not. When asked in the interview what he could tell about the time that elapsed between December 2004 "(when the laboratory started the retrospective testing)" and August 2005, "when you published the documents which linked six of the 12 samples to Lance Armstrong", Ressiot replied as follows:

"The testing at the laboratory did indeed take a certain amount of time. Every test took them two and a half days and there were nearly 150 samples to test from the 1999 and 1998 Tours. Nevertheless, and even before I got hold of the results which were communicated to the two instances concerned (WADA and the French Ministry of Sport) on August 22, [...]."<sup>187</sup>

Ressiot, in other words, did not only know how much time the analysis of each of the 1998 and 1999 Tour de France urine samples the LNDD had actually taken, he also knew exactly the total number of urine samples thus analyzed. More importantly, he also knew who would be receiving the analyses results and why –i.e. the "two instances concerned"- showing a remarkable insight as far as organizational matters

<sup>187</sup> Supra at 62.

were concerned. When asked in the interview how he could know that four of the positive samples in 1999 were taken after the prologue, Ressiot replied that:

"when you read the results table of the laboratory, you see that the first series of samples that arrived at Châtenay – Malabry (the four flasks) bear one number that differs from the next number of presumably the first stage, where Lance's sample also revealed traces of EPO. Therefore we can conclude this."<sup>188</sup>

Ressiot then continued by saying that he had not wanted to take the responsibility of publishing the names of the other three riders alleged to have tested positive as well, because:

"on the lab results table, there are very technical remarks added to one of the prologue samples, which also tested positive but where some sort of reservations were made by the lab director."<sup>189</sup>

While Ressiot's knowledge regarding the lab results table itself, might have originated from having obtained and studied a copy of the original LNDD research report, this however does not explain how he could have noticed that on the lab results table "very technical remarks" had been added "to one of the prologue samples", let alone that these constituted "some sort of reservations made by the lab director". This because the laboratory results table of the LNDD research report regarding the 1999 Tour de France does not show any of these "very technical remarks", much less that these had been added to one of the prologue samples and constitued "some sort of reservations made by the lab director". If Ressiot did see these "very technical remarks", he could not have seen them on the laboratory results table as printed in the LNDD research report regarding the analyses of the urine samples from the 1999 Tour de France.

# The qualification of the findings under the applicable anti-doping rules, regulations and procedures of the UCI

4.26 When the investigator asked the representatives of the LNDD –while visiting the laboratory- whether or not they believed that the alleged "positive" urine samples listed in their research reports truly constituted *Adverse Analytical Findings*, they replied as follows:

## "technically, yes; legally no".

However, after having discussed with the investigator the mandatory analytical technical, as well the procedural requirements for analysing urine samples for doping control purposes as detailed in the *ISL* and "TD2004*EPO*", as well as in the *ISO/IEC 17025 international standard*, both representatives of the LNDD concluded on their own that their reply had been incorrect and that the right answer was an "unqualified no".

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4.27 When asked whether he was aware of any irregularities which might have taken place during the collection of his urine samples during the 1999 Tour de France, Lance Armstrong replied to have no recollection of any irregularities having taken place. He also replied that he did not have a "therapeutic use exemption" for the prohibited substance *r*-*EPO*<sup>190</sup>.

## 4B. Discussion of Findings

4.28 Having presented the results of the fact-finding conducted in this investigation to date for each of the aforementioned "issues for further consideration", an overview is now being provided addressing the applicable rules, regulations and legislation, subsequently followed by a comparison between what has actually been practise and the applicable (mandatory required) procedures that should have been applied. The applicable rules, regulations and legislation, as well as the subsequent comparison between practise and what is mandatory required will be discussed and made in the same order as the aforementioned "issues for further consideration" have been listed in the Letter of Authority.

The reasons of the LNDD for conducting research, involving the analysis of the urine samples of the 1998 and the 1999 Tours de France

# Applicable rules and regulations in general for conducting scientific research The 2003 World Anti-Doping Code

4.29 Article 19, paragraph "Research" of the WADA Code reads:

"Anti-doping research contributes to the development and implementation of efficient programs within Doping Control and to anti-doping information and education."<sup>191</sup>

Anti-doping research may include a variety of studies in an array of different scientific fields<sup>192</sup> and is to comply with internationally recognized ethical practices<sup>193</sup>. It is for this reason that article 6.3 "Research on Samples" of the *WADA Code* requires a WADA-accredited doping control laboratory to obtain written consent from the athlete first, before using his or her urine sample, originally collected for doping control purposes, for conducting research:

"No Sample may be used for any purpose other than the detection of substances (or classes of substances) or methods on the Prohibited List, or as otherwise identified by WADA pursuant to Article 4.5 (Monitoring Program), without the Athlete's written consent."<sup>194</sup>

<sup>190</sup> Letter Lance

<sup>191</sup> Supra at 3, p. 51.

<sup>192</sup> Supra at 3, art. 19.2 "Types of Research", p. 51.

<sup>193</sup> Supra at 3, art. 19.4, "Research practices", p. 51.

<sup>194</sup> Supra at 3, art. 6.3, "Research on samples", p. 20 - 21

In addition, adequate precautions are to be taken

"so that the results of anti-doping research are not misused and applied for doping"<sup>195</sup>.

# The WADA "ISL"

4.30 Given the importance being attributed in the *WADA Code* to anti-doping research, it is no surprise that according to article 2.1 of the "Laboratory Code of Ethics", as contained in Annex B of the *ISL*, WADA-accredited doping control laboratories are expected to develop a program of research and development to support the scientific foundation of Doping Control<sup>196</sup>, provided however,

"that the laboratory director is satisfied with the bona fide nature and the programs have received proper ethical (e.g. human subjects) approval"<sup>197</sup>.

As a matter of fact, conducting research and having a research program is even a mandatory requirement for laboratories aspiring to become WADA-accredited doping control laboratories. According to article 4.1.6 "Research", such a laboratory has to:

"demonstrate in its budget an allocation to research and development activities in the field of Doping Control of at least 7% of the annual budget for the initial 3-year period. The research activities can either be conducted by the laboratory or in cooperation with the other WADA-accredited Laboratories or other research organizations."<sup>198</sup>

Conducting research and having a research program is, however, just as much a mandatory requirement for laboratories wanting to maintain their WADAaccreditation. According to article 4.2.9 "Research", a WADA-accredited doping control laboratory:

"shall maintain an updated 3-year plan for research and development in the field of Doping Control, including an annual budget in this area.

The Laboratory should document the publication of the results in the research in relevant scientific papers in the peer-reviewed literature. These documents shall be made available to WADA upon request. The Laboratory may also demonstrate a research program by documenting successful or pending applications for research grants."<sup>199</sup>

<sup>195</sup> Supra at 3, art. 19.6, "Misuse of Results", p. 51.

<sup>196 &</sup>quot;This research may consist of the development of new methods or technologies, the pharmacological characterization of a new doping agent, the characterization of a masking agent or method, and other topics relevant to the field of Doping Control". See: WADA, International Standard for Laboratories, version 4.0, August 2004, Lausanne, Switzerland, Annex B "Laboratory Code of Ethics", art. 2.1, "Research in Support of Doping Control", p 54.

<sup>197</sup> Supra at 196, art. 2, "Research", p. 54.

<sup>198</sup> Supra at 196, art. 4.1.6, "Research", p. 13.

<sup>199</sup> Supra at 196, art. 4.2.9, "Research",p. 15.

Finally, a WADA-accredited doping control laboratory is also required to inform WADA annually of its research and development results in the field of Doping Control and the dissemination of the results<sup>200</sup>. When conducting research, WADA-accredited doping control laboratories are obliged to follow:

"the Helsinki Accords and any applicable national standards as they relate to the involvement of the human subjects in research."<sup>201</sup>

# The World Medical Association Declaration of Helsinki; Ethical Principles for Medical Research Involving Human Subjects

4.31 According to the "World Medical Association" (hereinafter: "WMA") the "Declaration of Helsinki" (hereinafter: the "Helsinki Declaration" or "Helsinki Accords") was developed as:

"a statement of ethical principles to provide guidance to physicians and other participants in medical research involving human subjects. Medical research involving human subjects includes research on identifiable human material or identifiable data."<sup>202</sup>

Research of urine and/or blood samples of athletes therefore qualifies as "medical research involving human subjects".

4.32 As such, the *Helsinki Declaration* contains a large number of basic principles providing an ethical standard for conducting medical research in general and involving human subjects in particular. It should be considered as constituting "best practice" when evaluating medical research. According to paragraph 8, Part A, "Introduction" of the *Helsinki Declaration*:

"Medical research is subject to ethical standards that promote respect for all human beings and protect their health and rights. Some research populations are vulnerable and need special protection. [...]. Special attention is also required for those who cannot give or refuse consent for themselves, for those who may be subject to giving consent under duress, [...]. "<sup>203</sup>

A "research investigator" should therefore be aware of:

"ethical, legal and regulatory requirements for research on human subjects in their own countries as well as applicable international requirements. No national ethical, legal or regulatory requirement should be allowed to reduce or eliminate any of the protections for human subjects set forth in this Declaration."<sup>204</sup>

<sup>200</sup> Supra at 196, art. 6.4.5, "Document implemented research activities", p. 40.

<sup>201</sup> Supra at 196, Annex B, "Laboratory Code of Ethics", art. 2.2, "Human subjects", p. 54.

<sup>202</sup> World Medical Association ("WMA"), World Medical Association Declaration of Helsinki Ethical Principles for Medical Research Involving Human Subjects, Helsinki, June 1964, Part A, "Introduction", par. 1, p. 1.

<sup>203</sup> Supra at 202, par. 8, p. 2.

<sup>204</sup> Supra at 202, par. 9, p. 2.

4.33 When conducting medical research involving human subjects, it is the duty of the researcher to protect the life, health, privacy and dignity of the human subject<sup>205</sup>. For this reason, both the design and performance of each experimental procedure, involving human subjects should be submitted for consideration and, where appropriate, approval of a special appointed "ethical review committee", independent from the "investigator" or "researcher". The researcher is obliged to provide many categories of information to this committee (for review) such as

"information regarding funding, sponsors, institutional affiliations, other potential conflicts of interest and incentives for subjects"206.

The subjects involved in the medical research should all be volunteers and informed participants<sup>207</sup>, whose right to safeguard their integrity must always be respected<sup>208</sup>. According to paragraph 21, Part B, of the *Helsinki Declaration*:

"Every precaution should be taken to respect the privacy of the subject, the confidentiality of the patient's information and to minimize the impact of the study on the subject's physical and mental integrity and on the personality of the subject."209

It is therefore no surprise that the requirement of "informed consent" represents one of the key conditions in the *Helsinki Declaration* for conducting medical research involving human subjects. This means that before research can actually be conducted, the human subjects involved must have been adequately informed of

"the aims, methods, sources of funding, any possible conflict of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail"210.

In addition, the subject should also be informed of:

"the right to abstain from participation in the study or to withdraw consent to participate at any time without reprisal. After ensuring that the subject has understood the information, the physician should then obtain the subject's freely-given informed consent, preferably in writing"<sup>211</sup>.

<sup>205</sup> Supra at 202, par. 10, Part B, "Basic Principles for all Medical Research", p. 2.

<sup>206</sup> Supra at 202, par. 13, p. 2.

<sup>207</sup> Further requirements as to the extent to which subjects need to be informed about the research being conducted, is contained in paragraph 22, while additional conditions for determining whether consent has been freely given, are specified in paragraph 23.Supra at 202, par. 20, p. 3.

<sup>208</sup> Supra at 202, par. 21, p. 3. ld.

<sup>209</sup> 

<sup>210</sup> Supra at 202, Part B, par. 22, p. 3. ld.

<sup>211</sup> 

# The Oviedo Convention for the protection of Human Rights and the dignity of the human being with regard to the application of biology and medicine

4.34 The Oviedo Convention for the protection of Human Rights and the dignity of the human being with regard to the application of biology and medicine (hereinafter: the "Oviedo Convention") of the Council of Europe<sup>212</sup> addresses issues with regard to the application of biology in medicine. According to article 15 in Chapter V, "Scientific Research", of the Oviedo Convention scientific research in the field of biology and medicine shall be carried out freely, subject to the provisions of this Convention

#### "and the other legal provisions ensuring the protection of the human being"<sup>213</sup>.

As is the case with the "*Helsinki Declaration*", the "Oviedo Convention" also contains a large number of provisions and ethical and legal considerations to be adopted by all Signatory States as part of their own national legislation regarding the application of biology in medicine<sup>214</sup>. Again, the requirement of "informed consent" constitutes a key condition in this regard for being allowed to conduct biomedical research.

#### **French legislation**

4.35 While at this time there exists no specific legislation in Europe addressing all issues related to the use of tissue, as well as bodily fluids, in research, several countries, such as the Netherlands, the United Kingdom and France, are all in the process of drafting and/or completing legislation regarding the use of tissue(s) and/or bodily fluids -i.e. "biological specimen"- in research<sup>215</sup>. In France, the Civil Code contains -as a matter of concern- some provisions, besides those contained in the Criminal Code and the Public Health Code, regarding the protection of human biological samples or parts of the human body, as well as regarding such issues as "informed consent", "privacy" and "respect for human dignity"<sup>216</sup>.

#### Comparing practice with procedures

4.36 The finding that the LNDD had been conducting research was, in light of the aforementioned rules and regulations for WADA-accredited laboratories, to be expected. It is clear that WADA-accredited laboratories are not just entitled to conduct research, but, as a matter of fact, are even obliged to do so, as it constitutes

<sup>212</sup> The Council of Europe consists of 43 countries, from both eastern, as well as western Europe, and was the result of the 1948 the Hague Congress, where a series of resolutions was adopted, calling, among other things, for the creation of an economic and political union to guarantee security, economic independence and social progress, the establishment of a consultative assembly elected by national parliaments, the drafting of a European charter for human rights, and the creation of a court to enforce the charter. The charter subsequently became a Convention [The European Convention for Human Rights] and currently constitutes one of the key - conditions for becoming a member State. Countries such as Switzerland, or the Holy Seat, neither being a member of the United Nations (UN), the European Union (EU) or the North Atlantic Treaty Organization (NATO), are however a member of the Council of Europe. This has made and to some extent still makes the Council of Europe an important forum in international politics.

<sup>213</sup> Council of Europe, Convention on Human Rights and Biomedicine, Oviedo, April 1997, Chapter V, "Scientific research", art. 15, p. x.

<sup>214</sup> As the Oviedo Convention constitutes an "open convention", it is open for signature by the member States, non-member States which have participated in its elaboration and by the European Economic Community and open for accession by other non – member States.

<sup>215</sup> Baeyens, A.J., et al, "The use of Human Biological Samples in Research: A Comparison of the Laws in The United States and Europe", Bio – Science Law Review, September 24, 2003.

<sup>216</sup> Articles 16, 16 – 1 to 16 – 9, Chapter II "Du respect du corps humain", Livre premier – Des personnes, Code Civil.

an integral part of their WADA-accreditation. Consequently, every WADA-accredited laboratory is expected to maintain an updated 3-year plan for research and development in the field of Doping Control, including an annual budget in this area<sup>217</sup>. However, a WADA-accredited laboratory is only allowed to participate in research programs, when its director has been satisfied with the "bona fide nature" of the research program itself, as well as the ethical approval received<sup>218</sup>. That the research conducted by the LNDD would concern (the detection of) the prohibited substance *r*-*EPO* was to be expected as well. It is a well-known fact that the first "urinary test" for the detection of *r*-*EPO* was developed by the LNDD<sup>219</sup>. Ever since, the LNDD has been at the forefront of research into new methods for (the detection of) *r*-*EPO*, as well as the further development of existing detection methods. The LNDD has claimed that the (overall) research project had not only been conducted in cooperation with WADA (this was also confirmed by the Ministry), but that WADA had even actively taken charge of a part of it, i.e. that part concerning the administration of *r*-*EPO* to volunteers.

# The reasons for conducting the analyses of the urine samples from the 1998 and 1999 Tours de France

### The LNDD

- 4.37 According to the staff of the LNDD, the urine samples from the 1998 and the 1999 Tours de France had been analysed in order to provide further data necessary to populate the database needed for the development of a new mathematical model for interpreting the analysis results of urine samples analysed for *r-EPO*, allowing the WADA-accredited doping control laboratories to deal more effectively with the use of "micro-dosages" of *r-EPO* by athletes during competitions. The investigator has no reasons at this time to doubt this explanation. Both the Ministry, as well as WADA, have confirmed this explanation in their respective statements regarding the research having been conducted in this matter by the LNDD. The LNDD however, has to date failed to submit any further information or documentation to the investigator in support of its statements, notwithstanding the promises the LNDD staff made in person to the investigator, to (a) either provide him with copies of all relevant documentation and correspondence regarding the research project, or, alternatively, (b) to allow him access to the aforementioned relevant documentation in person.
- 4.38 This has made it difficult for the investigator to determine both the scientific validity and nature of the research project of the LNDD for (improving the detection of) the prohibited substance *r-EPO* in general and the analyses of the urine samples from the 1998 and the 1999 Tours de France in particular. It is unclear whether the urine samples from the 1998 and 1999 Tours de France were suitable to further populate

219 Supra at 128.

<sup>217</sup> In addition, WADA-accredited laboratories should document the publication of results of the research in relevant scientific papers in the peer-reviewed literature. Supra at 196, art. 4.1.6, "Research", p. 13. Supra at 196, art. 4.2.9, "Research", p. 15. Supra at 196, art. 6.2.4, "Plan and implement research activities", p. 39. Supra at 196, art. 6.4.5, "Document implemented research activities", p. 40.

<sup>218</sup> Supra at 196, ANNEX B, "Laboratory Code of Ethics", art. 2, p. 54-56.

the database needed for developing a new mathematical model. Unlike the urine samples obtained from patients and volunteers, the urine samples from the 1998 and the 1999 Tours de France might have contained –at best- an unknown quantity of *r-EPO*. Furthermore, the LNDD research reports regarding the analyses of the urine samples from the 1998 and the 1999 Tours de France only contain the results of the analyses conducted. They do not explain in what manner the aforementioned urine samples were used for developing the mathematical model, or how the analyses of these urine samples fit into the overall LNDD research project. While the investigator does not have sufficient information to determine whether or not the mathematical model is scientifically sound enough to be used to refine the existing detection method for *r-EPO* when the necessary data have been obtained by means of an *"accelerated measurement procedure"* as described by the LNDD, he can at least express his concern.

#### WADA

4.39 Initially, WADA stated –just as the Ministry and the LNDD had done- that the urine samples from the 1998 and the 1999 Tours de France had been analysed in order to improve the existing detection method for *r-EPO*<sup>220</sup>. However, when the UCI -in its letter to WADA, dated September 5, 2005- questioned the necessity of the publication of the analyses results of the urine samples from the 1998 and the 1999 Tours de France for improving the exisiting detection method for *r-EPO*, WADA informed the UCI in its letter dated September 9, 2005, that the analyses of the urine samples from the 1998 and the 1999 Tours de France had also been conducted:

In addition to the refinement of the EPO test, interest in knowing the stability of EPO over long periods of storage, impact of implementation of a new anti-doping method on use/ abuse by athletes, monitor the possible switch from macro to micro doses of EPO."<sup>221</sup>

In its reply, dated April 3, 2006, to the investigator's questions posed in the questionnaires of March 15 and March 20, 2006, WADA claimed that it also wanted to make sure that the results of the analyses of the urine samples from the 1998 and the 1999 Tours de France would be of use to the UCI in order to:

"preserve the possibility of a longitudinal study analysis of the abuse of EPO [...] to know who was abusing EPO at the time among its riders."<sup>222</sup>

4.40 First and foremost, the investigator has been surprised by the fact that WADA did know that the urine samples from the 1998 and the 1999 Tours de France had been analyzed as part of an attempt to further refine the existing detection method for *r-EPO*, but apparently not in which manner, or to what extent. WADA never once mentioned the development of a new mathematical model for interpreting the analysis results of urine samples having been analyzed for *r-EPO*, or the necessity

<sup>220</sup> Supra at 23. Also: Supra at 103.

<sup>221</sup> Supra at 36.

<sup>222</sup> Supra at 94, p. 2.

of a database containing sufficient data regarding "positives", as well as "negatives", for *r-EPO*, let alone that the analyses results of the urine samples from the 1998 and the 1999 Tours de France would be used to further populate this database. Yet at the same time however, both the Ministry and the LNDD have claimed that WADA has been actively involved in the LNDD's overall research project and –even if partly- was aware, or should at least have been aware of all of these matters. The investigator does not understand why WADA has never referred to these matters.

- 4.41 At the same time, the investigator finds the explanations WADA has given to date in order to justify (its interest in) the analyses of the urine samples from the 1998 and -in particular- the 1999 Tours de France, for a number of reasons not credible and entirely inconsistent with the evidence in this matter. They were never ever mentioned as such by the LNDD, nor the Ministry. Furthermore, they do not make any sense from a scientific point of view for the following reasons:
  - neither one of the two LNDD research reports seems to provide the data, necessary for studying any of WADA's issues of interest<sup>223</sup>;
  - why not examine the stability as such, for example in relation with any enzymatic activity, the fact that samples have been thawed and opened previously and the possibility that normal endogenous *EPO* may shift into the *r*-*EPO* area?
  - why analyse urine samples from the 1998 and the 1999 Tours de France only, when the combined blood and urine *r-EPO* test was introduced in September 2000 and the direct urine test in April 2001, when the objective is to "study trends in *EPO*-use following the introduction of the *EPO* test"?
  - what kind of "longitudinal study analysis of the abuse of *EPO*" would require only the analyses of the urine samples from the 1998 and the 1999 Tours de France?
  - why would the analyses of urine samples from the 1998 and the 1999 Tours de France preserve the possibility of conducting a longitudinal study analysis better, than just keeping these urine samples stored?
  - why would it be of interest to the UCI to know "who among its riders" was abusing *r-EPO* at that time, when WADA has repeatedly stated that the research results were outside the scope of its own *WADA Code* and even admitted that it might not be possible to issue any sanctions for lack of evidence of an Adverse Analytical Finding, if only because there are no urine samples available for the required "B" sample analysis;
  - why would WADA want to make sure that the results of the research conducted by the LNDD would be of use to the UCI? If WADA really could not imagine that the UCI would not have wanted to "preserve the possibility of a longitudinal study analysis of the abuse of *EPO* and would not have wanted to know who was abusing *EPO* at the time among its riders" why did it refrain from informing the UCI timely and accordingly?

<sup>223</sup> Apart from refining or improving the existing detection method for r-EPO, the following issues were said to be of interest to WADA: i.e. EPO (and r-EPO) stability, trends of use of r-EPO following the introduction of the r-EPO test (to monitor the possible switch from macro to micro doses of r-EPO), to preserve the possibility of a longitudinal study analysis of the abuse of r-EPO (including the possibility of determining who of the riders who submitted these urine samples was abusing r-EPO at the time.

Neither the LNDD, nor WADA, took the trouble to inform the UCI of the LNDD research project for (improving the detection of) the prohibited substance *r-EPO* in general and the analyses of the urine samples from the 1998 and the 1999 Tours de France in particular. Even though WADA claimed in its reply dated April 3, 2006, regarding the investigator's questions posed in the questionnaires of March 15 and March 20, 2006, that it had "recommended that the LNDD inform the IF if all samples were from the same sport", it did not verify whether the LNDD had done so. The LNDD never asked the riders or the UCI for permission to use the urine samples from the 1998 and the 1999 Tours de France for research purposes and copies of both research reports were never sent to the UCI. Only after the publication in *L'Equipe* on August 23, 2005, did WADA inform the UCI of the research having been conducted by the LNDD and even then in general terms only;

- if WADA wanted to ensure that the results of the research conducted by the LNDD would be of use to the UCI and believed thie research to be "in line with the *ISL* requirements and within the objectives of the fight against doping", why did it fail to respond when the UCI asked WADA in its letters of September 29 and October 6, 2005, to confirm that it had not been WADA, or a WADA official that had asked the LNDD to include the additional information in its research reports? If WADA did believe that the additional information would be of interest to the UCI, there was no reason for it not to answer; and
- why did WADA write to the UCI in its letter, dated September 9, 2005, that "[...] the first step in conducting the assessment is to determine whether there is any basis of truth in the allegations and then to determine what, if anything, can be done"<sup>224</sup>, when it claims to have asked the laboratory to ensure that the analyses results would be of use to the UCI only "to preserve the possibility of a longitudinal study analysis of the abuse of *EPO*"<sup>225</sup>? Asking the UCI to conduct an assessment to determine whether there is any truth to certain allegations is something very different from asking the UCI to conduct a longitudinal study analysis of the abuse of *r-EPO*, especially when the analyses results could be forseen.
- 4.42 Given these questions, the investigator believes that the reasons given by WADA as to why it was interested in the analyses of the urine samples from the 1998 and in particular- the 1999 Tourde France are not intended to explain why the urine samples from the 1998 and the 1999 Tours de France had been analyzed by the LNDD, or why WADA would be interested in the outcome of these analyses. Instead, they appear to be intended to provide a justification for WADA having requested the LNDD to include the additional information in both research reports. Having concluded so and taking into account the fact that almost all of the reasons given, qualify as "highly unlikely", WADA might have had altogether different reasons for asking the LNDD to include the additional information in its research reports. The clearest indication

<sup>224</sup> Supra at 36.

<sup>225</sup> Supra at 94, p. 2.

for the existence of a "hidden agenda" is the fact that WADA on the one hand claims to have asked the LNDD "to ensure that such result [the final result of the project, ENV] would be of use to the UCI (UCI being the only entity having the information that could link a result to a particular athlete) in view of a potential longitudinal study", while on the other hand -when the analyses result finally have become public- the only request it has made to date of the UCI, has been to conduct an investigation "in accordance with its rules [UCI anti-doping rules, ENV]". WADA, in other words, said it wanted the LNDD to ensure that the results could be used by the UCI for scientific purposes, while in fact intending all along to use them for doping control and/or sanctioning purposes. This follows also from the list of questions WADA attached to its letters to the UCI<sup>226</sup> and Lance Armstrong<sup>227</sup>, dated October 5, 2005, as well as from the following statement in the letter from WADA to the independent investigator dated April 3, 2006:

"We cannot imagine that your independent inquiry would limit itself to questions surrounding the activity of the French laboratory, without looking into the other aspects of the questions, in particular the possibility of a doping infraction having been committed in 1998 and 1999, and the applicability of UCI rules."

Having already found that WADA said it wanted the LNDD to ensure that the results could be used by the UCI for scientific purposes, while in fact intending all along to use them for doping control and/or sanctioning purposes, it is just as clear that WADA did request the LNDD – "put the pressure on", according to the LNDD- to include the "additional information" in its research reports for the sole purpose of creating the opportunity -by means of the UCI- to link a "positive" analysis result to a particular rider and thereby establish a sufficiently valid basis for initiating disciplinary proceedings as anti-doping violations may -in principle- be established by all reliable means.

4.43 The investigator finds WADA's approach in this matter concerning the issue of retesting or retrospective testing versus testing for research purposes alarming. While there can be no doubt whatsoever that the LNDD analysed the urine samples from the 1998 and the 1999 Tours de France for research purposes intended to improve the current detection method for *r-EPO*, WADA apparently believes that the subsequent analyses result might still be used for doping control purposes. According to WADA President Dick Pound at the meeting of the WADA Executive Committee on September 20, 2005 in Montreal, Canada, this approach to the issue of retrospective testing is justified because this matter was about urine samples that:

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Ex. 73, Letter from David Howman Director – General, WADA, to Lance Armstrong, cyclist, (October 5, 2005). Ex. 74, WADA, "Questions for Lance Armstrong", Montreal, Canada, October 5, 2005.

"had been provided in a competition for purposes of anti-doping controls and it had been known at the time, or suspected at the time, that EPO was being used and that there was no viable test for it. As it happened, there had been some samples still available, there was a test now, and that test had been performed. These were samples provided within a regulatory context"<sup>228</sup>.

According to WADA President Dick Pound, this was not a case - as had been suggested in the publicity surrounding this matter - where urine samples had been provided for basic research<sup>229</sup>. There was a substantial difference between retesting a sample given in the course of an anti-doping programme for Prohibited Substances and the use of a sample for general research<sup>230</sup>. In other words, as long as urine samples have been provided as part of a regular doping control procedure, the subsequent analyses results can always be used for doping control purposes, even when the urine samples were retested for anti-doping research purposes. This point of view however, differs considerably from what is said on WADA's own doping control form with regard to using an athlete's urine sample for anti-doping research purposes. According to the WADA doping control form, an athlete is asked -"when all analyses have been completed, and my sample would otherwise be discarded"- to give his or her approval for using his or her urine sample for anti-doping research purposes under the explicit condition that the sample can no longer be identified as his or her sample<sup>231</sup>. The question is why would this matter be different, especially when WADA knew that a "B" sample analysis could not be conducted, so that, except for any other evidence such as an admission, it would unreasonable to assume that the research results -in combination with the additional information it requestedcould lead to proper disciplinary proceedings and, when public, would make Lance Armstrong a suspect.

# The analyses of the urine samples from the 1998 and the 1999 Tours de France part of the LNDD's overall research project?

4.44

Even though to date no information or documentation has been made available to the investigator regarding the LNDD's overall research program in the field of Doping Control, he nevertheless does not believe that the aforementioned analyses had originally been planned as part of the overall LNDD research program regarding (the detection of) *r-EPO*, as has been suggested. According to the LNDD, the decision to analyze these urine samples was only made after it had become clear that the planned research efforts to collect the required amount of testing data to populate the database for the new mathematical model had been insufficient. The decision was, in other words, made "ad hoc" and as such "unforeseen". While the investigator has no means available to establish whether this reason real or not, it might however explain why the LNDD failed to obtain the required "informed consent" before commencing with the analyses of the urine samples from the 1999 Tour de France.

<sup>228</sup> Supra at 59, p. 28.

<sup>229</sup> Id. 230 Id.

<sup>230</sup> Id. 231 Id.

#### Informed consent and ownership of the 1998 and 1999 Tours de France urine samples

4.45 Notwithstanding the mandatory requirement to obtain "informed consent" first, before commencing research involving human subjects, the LNDD failed to request and obtain permission from any of the riders having participated in either the 1998, or the 1999 Tours de France and responsible for having submitted one or more urine samples for doping control purposes, to use their urine sample(s) for research purposes, much less for the intended research purposes. As a matter of fact, the LNDD had not even tried to obtain "informed consent", violating one of the most important fundamental ethical principles of conducting scientific research.

## WADA's position regarding informed consent and ownership of the 1998 and 1999 Tours de France urine samples

4.46 In its letter to the UCI, dated September 9, 2005, WADA, however, takes the position that the provisions in the 2003 *WADA Code* -requiring the necessity for samples collected to have proper consent from the riders before they can be used for research- "obviously" could not have applied to the samples collected in 1998 and 1999 as the *WADA Code* came into effect for the UCI, just prior to the Olympic Games in Athens, in August 2004.

"If there is a suggestion that there be retroactive or retrospective seeking of consent by the laboratory in respect of such samples, then it is obvious that this would be impossible, as the laboratory had no way of knowing which individuals had provided samples and therefore would have no way of retrospectively ensuring that any required consent (if any) had been given."<sup>232</sup>

During the meeting of WADA's Executive Committee on September 20, 2005, in Montreal, Canada, WADA Director – General, Mr. David Howman, however told the Executive Committee also that:

"The samples in the laboratory had been the property of the laboratory or those who governed it."<sup>233</sup>

implying that the LNDD had never been obliged to obtain infomed consent prior to conducting the analyses of the urine samples from the 1998 and the 1999 Tours de France. Howman told the Executive Committee that WADA had done some studying of the rules in place in 1999, which had been the "Olympic Movement Anti-Doping Code"<sup>234</sup>. According to Howman, there was a brief statement in within the Olympic Movement Anti-Doping Code in relation to the accreditation, but no guidelines as to what should be done with samples. The UCI had had the discretion in 1998/1999 to ask that samples collected be given to the UCI to conduct research, but the UCI had not exercised that right in relation to these particular samples<sup>235</sup>.

- 232 Supra, at 36.
- 233 Supra at 59, p. 26.

<sup>234</sup> IOC, Olympic Movement Anti-Doping Code, Lausanne, Switzerland, January, 1999.

<sup>235</sup> Supra at 59, p. 26 – 27.

## Analysis position WADA regarding informed consent and ownership of the 1998 and the 1999 Tours de France urine samples

4.47 The position WADA seems to have taken with regard to the issue of informed consent and ownership of the urine samples from the 1998 and 1999 Tours de France, is
 - for obvious reasons- incorrect. The urine samples from the 1998 and 1999 Tours de

France are neither the property of the LNDD, nor of the French Ministry and *WADA Code* is applicable with regard to the analyses of the urine samples from the 1998 and the 1999 Tours de France.

#### Applicable rules and regulations

While it may be true that these urine samples have been collected in 1998 and 1999 under the then applicable rules and regulations as detailed above, according to WADA however, these urine samples were analyzed "some time in 2004", starting October 19, 2004<sup>236</sup>. According to the principle "tempus regit factum", any question regarding the LNDD's compliance with the applicable rules and regulations is to be decided on the basis of the rules and regulations in force at the time a particular action took place. As the urine samples from the 1998 and 1999 Tours de France were analyzed in 2004, the current anti-doping rules and regulations -such as the *WADA Code* and *ISL*- apply<sup>237</sup>. However, even had this not been the case, both the *Helsinki Declaration* and certainly the provisions of the French Civil Code and the French Code de la Santé Publique would still have applied, requiring the LNDD to obtain informed consent before conducting the analyses of the urine samples from the 1998 and 1999 Tours de France.

WADA's second objection, i.e. that even if the current anti-doping rules and regulations would be applicable it would have been impossible for the LNDD to obtain consent as it had no way of knowing which individuals had provided these urine samples, is not correct or relevant either. If this matter has proven one thing, it is the fact that it is still possible, seven years after the 1999 Tour de France has taken place, to ascertain the identity of riders having provided one or more urine samples during that event. Furthermore, the obligation to obtain informed consent is an absolute one, not depending on factual circumstances, i.e. whether or not it would be difficult to obtain. As a matter of fact, the difficulty to obtain informed consent should have made the LNDD actually even more aware of the necessity to protect the privacy of all of those who potentially might have provided one or more urine samples for doping control purposes during either one of the 1998 and 1999 Tours de France. It should, at the very least, have prompted the LNDD to contact the UCI in order to determine

<sup>236</sup> Supra at 94, p. 1.237 Supra at 10. par.

Supra at 10, par. 51, p. 14. In addition it should be noted also that the prohibition against the retrospective application of the law and the principle of lex mitior are not relevant as they apply only to substantive rules and not to procedural rules. In Espanyol v. Velez, (CAS 2004/A/635, unpublished), the CAS Panel affirmed that "as a general rule, transitional or inter-temporal issues are governed by the principle "tempus regit actum", holding that any deed should be regulated in accordance with the law in force at the time it occurred. As a consequence, procedural actions [...] should be done in compliance with the rules and time limits in force when they are performed." See: Supra at 10, par. 80, p. 25. In particular, as evidentiary rules pertain to procedure, in any anti-doping proceedings the evidentiary rules to be applied are those in force at the time of the proceedings and not those in force at the time of the possible doping offence. The CAS expressly stated S. V. FINA (CAS 2000/A/274, in Digest of CAS Awards, II, 406) that an anti-doping provision setting forth "an evidentiary or procedural rule [should] be applied in the case notwithstanding the fact that the doping control at issue ocurred before this provision came into force". See: Supra at 10, par. 81, p. 25.

whether the UCI, being the "relevant governing body", might be able to assist the LNDD in identifying those riders informed consent would have to be obtained from, or, alternatively, to obtain its approval for the research intended.

#### Ownership, relevant governing body

According to WADA Director - General, David Howman, the urine samples from the 1998 and 1999 Tours de France had been the property of the LNDD, or "those who governed it"238. Howman however, did not explain how the LNDD, or those who governed it, obtained a legally valid title, other than stating that the 1999 Olympic Movement Anti-Doping Code did not contain any guidelines as to what should be done with samples and that the UCI had the discretion in 1998 and in 1999 to ask that samples collected be given to the UCI to conduct research and that the UCI had not exercised its right in relation to the urine samples from the 1998 and 1999 Tour de France. It is clear that the studying WADA has done of the rules in place in 1999 has been insufficient for the following reasons.

At the time the urine samples from the 1998 and the 1999 Tours de France were collected, the applicable rules and regulations for the then IOC-accredited doping control laboratories could still be found in the 1999 "IOC Medical Code" (hereinafter: "IOC Medical Code")<sup>239</sup>, instead of in the IOC Olympic Movement Anti-Doping Code. According to art. 1.3.4 "Storage of analytical results" of APPENDIX D, "Laboratory Analysis Procedure", of the "IOC Medical Code", an IOC-accredited doping control laboratory was required to retain all records pertaining to a given urine specimen for a minimum of two (2) years only and -in case of a positive specimen- for a maximum period of five (5) years<sup>240</sup>. As far as the storage of urine samples was concerned, art. 1.4, "Long-term storage", of APPENDIX D, "Laboratory Analysis Procedure", of the "IOC Medical Code", required IOC-accredited doping control laboratories to retain the sealed "B" specimen corresponding to an analytical positive "A" sample and to place them in properly sealed long-term 4°C or less storage for a period of "at least 90 days"<sup>241</sup>. During this 90-day period of time, the "relevant governing" body" could request the IOC-accredited doping control laboratory to retain the sealed "B" specimen for an additional period of time. This was meant to ensure that the "B" specimen would be available for possible retesting during an administrative or disciplinary procedure. If the IOC-accredited doping control laboratory did not receive such a request from the "relevant governing body" during the aforementioned 90-day period, "the specimen might be discarded"<sup>242</sup>. The IOC Medical Code does not contain a provision regarding the (long-term) storage of "B" specimen corresponding to an analytical negative "A" sample.

240 Supra at 238, art.1.3.4, p.37.

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<sup>238</sup> Supra at 232.

<sup>239</sup> IOC. Medical Code. Lausanne. Switzerland. 1999.

<sup>241</sup> Supra at 238, p.37. ld.

It is correct that the "IOC Medical Code" does not contain explicit instructions as to when an IOC-accredited doping control laboratory is to "discard" "B" specimen corresponding to an analytical positive "A" sample after the aforementioned 90-day period has expired, or such period of time as requested by the "relevant governing body", much less what should be done with "B" specimen corresponding to an analytical negative "A" sample. This however, does not imply that an IOC-accredited doping control laboratory –after the aforementioned 90-day period would have expired, or such period of time as requested by the "relevant governing body"- would automatically be entitled to decide unilaterally whether it would maintain storage of these urine samples, much less that these urine samples would thus become its "property"<sup>243</sup>. However, the opposite is actually true. The "IOC Medical Code" might not contain explicit instructions as to when an IOC-accredited doping control laboratory is to "discard" "B" specimen, it does however establish the exact period of time during which an IOC-accredited doping control laboratory is required to retain possession of both records and urine samples related to doping controls already conducted. While a minimum period of time of two (2) years applies for storage of all records pertaining to any given urine specimen, the maximum period of time for storage in case of a positive specimen has been limited to five (5) years. In other words, once the aforementioned period of time of five (5) years would have expired, an IOC-accredited doping control laboratory would no longer be entitled to maintain possession of both records and urine samples for any given specimen, calling into guestion the legitimacy of the LNDD's possession of the urine samples. Only the "relevant governing body" has the authority to request the IOC-accredited doping control laboratory to retain the sealed "B" specimen corresponding to an analytical positive "A" sample for a longer period of time.

What is more important however, is the fact that the "IOC Medical Code" apparently considers the "relevant governing body" to be responsible for any decision regarding (the storage of) collected urine samples and not the IOC-accredited doping control laboratory. It is the "relevant governing body" to which the authority has been attributed to instruct the IOC-accredited doping control laboratory regarding the duration of storage of the "sealed "B" specimens corresponding to an analytical positive "A" sample", while the period of time the IOC-accredited doping control laboratory is allowed to retain possession of both records and urine samples has been explicitly limited to a maximum of five (5) years. As the urine samples from the 1998 and 1999 Tours de France were obtained during an event for which the UCI has been and still is the "relevant governing body", it would seem that any decision regarding maintaining storage of these urine samples should at least have required the approval of the UCI. The fact that the LNDD never even has contacted the UCI regarding the storage of these urine samples, or has asked for its permission to continue doing so, raises serious questions as to the legitimacy of the LNDD possession of the urine samples in the first place.

As a matter of fact, until this matter, the issue of "ownership" of urine samples has never been an issue for consideration.

According to WADA however, the UCI had had the discretion in 1998/1999 to ask that samples collected be given to the UCI to conduct research, but the UCI had not exercised that right in relation to these particular samples, implying that the ownership of the urine samples from the 1998 and 1999 Tours de France therefore rested with the LNDD. Article 130 of the 1999 "UCI Anti-Doping Examination Regulations" (hereinafter: "UCI 1999 Anti-Doping Regulations") however, stipulates the following:

"Other than in disputed cases, the UCI may, for the purpose of further research and analysis, preserve or request any laboratory report or sample which shall then become the property of the UCI."<sup>244</sup>

Article 130 of the UCI 1999 Anti-Doping Regulations should in the first place be interpreted against the backround of the existing anti-doping rules and regulations in 1999 of which the IOC Medical Code is the most important one, as it regulates the manner in which IOC-accredited doping control laboratories are expected to function. Because the IOC Medical Code only contained a provision covering the longterm storage of "sealed "B" specimens corresponding to an analytical positive "A" sample", providing the "relevant governing body" with the opportunity to request the IOC-accredited doping control laboratory that these sealed "B"specimen be retained for a longer period of time in case of retesting during disciplinary proceedings, article 130 of the UCI 1999 Anti-Doping Regulations was intended to provide the UCI, as "relevant governing body", with a similar opportunity as far as "sealed "B" specimens corresponding to an analytical negative "A" sample" were concerned. Article 130 of the UCI 1999 Anti-Doping Regulations confirms, in other words, that it is the "relevant governing body", i.e. the UCI, which is responsible for the collected urine samples and not the IOC-accredited doping control laboratory and that it is the "relevant governing body", i.e. the UCI, which has the authority to make any decision regarding (the storage of) these urine samples and not the IOC-accredited doping control laboratory.

Taking into account all of the aforementioned provisions valid in 1999, there can be no doubt whatsoever, that the LNDD should have contacted the UCI in order to determine whether the UCI, being the "relevant governing body", might approve of the research intended and -if so- would be able to assist in identifying those riders, informed consent would have to be obtained from. This approach however, was not followed this time, nor did the LNDD obtain the required informed consent. According to the representatives of the LNDD this was because they had actually never before considered who actually "owned" these urine samples, let alone whether or not the LNDD was allowed to use these samples for research purposes, or if permission from someone else would have to be obtained first. Because it had (been in) possession of these urine samples for such a long time, the LNDD felt it was entitled to decide what to do with them. When specifically asked, the representatives of the LNDD admitted not to be aware of any rule, regulation, or even legislation, requiring otherwise, notwithstanding the fact that the "Helsinki Declaration" requires research investigators to be aware of

"the ethical, legal and regulatory requirements for research on human subjects in their own countries, as well as the applicable international requirements"<sup>245</sup>.

Assuming the analyses of the urine samples from the 1998 and 1999 Tours de France did indeed constitute a part of the LNDD's overall research program regarding (the detection of) the Prohibited Substance *r*-EPO and as such should be regarded as "natural and typical ongoing research", one would at least have expected the LNDD to have been aware of the requirements for WADA-accredited doping control laboratories conducting research, as detailed in the "Laboratory Code of Ethics" in Annex B to the WADA "ISL", as well as in the "Helsinki Declaration" in general and the requirement of informed consent in particular. Whilst it might be true that the LNDD had been unaware of its obligation to obtain informed consent or to inform the UCI as "relevant governing body" and believed that having been in possession of these urine samples for the past seven (7) years entitled it to decide about their use unilaterally, this does not explain why the LNDD took the trouble in 2000 to contact the UCI to ask for its approval for using the urine samples from the 2000 Tour de France for research purposes.

### Methods and procedures used by the LNDD to obtain the measurement data

## Applicable Rules and Regulations for the analysis of doping control samples in general

## WADA's International Standard for Laboratories

4.48 According to WADA the main purpose of its "ISL" is:

> "to ensure laboratory production of valid test results and evidentiary data and to achieve uniform and harmonized results and reporting from all accredited Doping Control Laboratories."246

In order to accomplish this, the *ISL* includes:

"requirements for WADA accreditation of doping laboratories, operating standards for laboratory performance and description of the accreditation process."247

These requirements are only intended for laboratories -such as the LNDD- involved

<sup>2/5</sup> Supra at 202, par. 9, p. 2.

Supra at 196, Chapter 1.0: "Introduction, Scope and References" of PART ONE: "INTRODUCTION, CODE PROVISIONS AND 246 DEFINITIONS", p. 4 ld

<sup>247</sup> 

in doping control in sports, testing urine samples for the presence of *Prohibited Substances* and/or Methods:

This document sets out the requirements for Doping Control Laboratories that wish to demonstrate that they are technically competent, operate an effective quality management system, and are able to produce forensically valid results. Doping Testing involves the detection, identification, and in some cases demonstration of the presence greater than a threshold concentration of drugs and other substances deemed to be prohibited by the list of Prohibited Substances and Prohibited methods (The Prohibited List) in human biological fluids or tissues."<sup>248</sup>

However, in order to achieve these objectives, not only the laboratories responsible for conducting doping control themselves, but also the Public Authorities of their respective countries and other Parties to the *WADA Code* need to be aware that:

"The International Standard for Laboratories, including all Annexes and Technical Documents, is mandatory for all Signatories to the Code."<sup>249</sup>

It should be noted that not just the requirements contained in the WADA "*ISL*" itself are mandatory, but its "Annexes" and "Technical Documents" as well:

"Part Three of the Standard includes all Annexes. [...]. Annex C is a list of Technical Documents. Technical Documents are issued, modified, and deleted by WADA from time to time and provide direction to the Laboratories on specific technical issues. Once promulgated, Technical Documents become part of the Technical Standard for Laboratories. The incorporation of the provisions of the Technical Documents into the Laboratory's quality management system is mandatory for WADA accreditation."<sup>250</sup>

## The mandatory general requirements for the analysis of doping control samples

4.49 The mandatory general requirements for the analysis of doping control samples can be found in chapter 5 of the *ISL*, introducing specific general performance standards for a doping control laboratory. It should be noted however, that these general requirements only apply to the analysis of urine samples. Specific requirements for testing involving other acceptable "matrices" for testing, such as blood, plasma and serum, however, have not been included in the scope of the *ISL*. Testing is considered to constitute a process, structuring the doping control laboratory practice into three (3) main categories of processes, i.e. the analytical and technical process, the management process and the support process<sup>251</sup>. As this paragraph is only concerned with the methods and procedures used by the LNDD to obtain the measurement data, the focus will be only on the applicable rules and regulations concerning the analytical and technical process in general.

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<sup>250</sup> 251

Supra at 196, PART TWO: "LABORATORY ACCREDITATION REQUIREMENTS AND OPERATING STANDARDS", Chapter 5.0, "Application of ISO 17025 to the Analysis of Doping Control Samples", p. 16.

#### The analytical and technical process

- 4.50 The analytical and technical process in general can be subdivided into the following separate steps:
  - (a) Sample handling;
  - (b) Urine testing;
  - (c) Results management; and
  - (d) Documentation and reporting<sup>252</sup>.

However, as "results management", as well as "documentation and reporting" have already been identified as separate issues this investigation has been requested to address, they will not be examined as part of the doping control procedure. The requirements regarding "documentation and reporting" will be discussed in more detail in the following paragraphs, when the manner in which and to whom the LNDD subsequently reported its findings will be addressed. As far as the requirements for "results management" are concerned, these will be addressed in more detail, when the qualification of the findings under the applicable anti-doping rules, regulations and procedures of the UCI will be discussed.

#### ad (a) Sample handling

Sample handling deals with the receipt of samples for testing, the manner in which these samples are being processed during doping control testing and their subsequent storage. According to art. 5.2.2 of the *ISL*, a WADA- accredited doping control laboratory is required to have "Laboratory Internal Chain of Custody procedures" to maintain control of and be accountable for samples all the way through from receipt to their final disposition<sup>253</sup>. The possibility to link measurement results to a particular sample by means of an "internal chain of custody" is considered fundamental to any forensic use of laboratory results, including for doping control purposes<sup>254</sup>. Without an "internal chain of custody", a WADA-accredited doping control laboratory, such as the LNDD, would be unable to provide the necessary data to support the conclusions it reported.

Having an "internal chain of custody" also creates accountability regarding the manner in which doping control testing has actually being conducted in a certain case and by whom, thus establishing trust and confidence in the integrity of the doping control process and the analyses results subsequently reported. Not having an intact "internal chain of custody" means that the "integrity" of the urine sample can no longer be accounted for, i.e. whether the urine as originally provided by the athlete at the time of the actual sample collection, is the exact same urine being used for conducting the doping control analysis, and what has been done to the urine, and by whom, since the urine was received by the laboratory.

<sup>252</sup> Supra at 196, p. 16 – 24.

<sup>253</sup> Supra at 196, 17.254 Key to the ability to

Key to the ability to link analysis results to a specific sample by means of an "internal chain of custody" is the protection being provided by a well maintained and documented "internal chain of custody" regarding the integrity of the sample having been analyzed.

#### ad (b) Urine testing

The testing of urine samples consists of three (3) separate steps, i.e. "urine integrity testing", "urine screening testing" and "urine confirmation testing". Urine integrity testing deals with the actual determination by the laboratory whether an urine sample is suitable for testing<sup>255</sup>, while urine screening testing is meant to detect either the Prohibited Substance(s), their "metabolites", or "markers" of the use of a Prohibited Substance or Method present in an urine sample<sup>256</sup>. The objective of urine confirmation testing is to ensure the identification and/or guantification and to exclude any technical deficiency in the screening procedure<sup>257</sup>.

#### Urine testing

4.51 As the research conducted by the LNDD involving the samples from the 1998 and 1999 Tours de France consisted of the analysis of urine samples, the general requirements regarding urine testing as contained in chapter five of the ISL will be examined in more detail in order to be able to determine whether or not and -if so- to what extent, the methods and procedures used by the LNDD to obtain the measurement data have been in conformity with the applicable WADA requirements for urine testing. As already has been explained before, the process of testing urine samples consists of three (3) separate, distinct steps, i.e. "urine integrity testing", "urine screening testing" and "urine confirmation testing". These will now be examined in more detail.

### - urine integrity testing

The general requirements regarding "urine integrity testing" are few. Other than the obligation to have a written policy establishing the procedures and criteria for sample integrity tests, the laboratory is only required to test the urine sample for the pH and specific gravity and in general to determine and, if necessary, subsequently report, whether the urine is in an unusual condition or not<sup>258</sup>. This is important in the matter at hand, as the urine samples used have been kept stored for either five (5) or six (6) years, much longer than what usually is the case with urine samples analysed for doping control purposes, and especially now that it was only recently discovered that "enzymatic activity", or other agents in the urine, can cause a change in endogenous EPO molecules, as a result of which these endogenous EPO molecules suddenly appear to be exogenous, falsely suggesting that the Prohibited Substance *r-EPO* might have been used.

## - urine screening testing

As already has been stated before, "urine screening testing" is conducted by a WADA-accredited doping control laboratory in order to detect either the presence of (a) Prohibited Substance(s), their "Metabolites", or "Markers" of the use of a Prohibited Substance or Method in an urine sample:

<sup>255</sup> Supra at 196, p. 17-18.

Supra at 196, p. 19. Only for those substances listed in the Out-of-Competition or in - Competition Section of the prohibited 256 List as appropriate for which there is a WADA-accepted screening method. However, WADA may make specific exceptions to this section. ld.

<sup>257</sup> 

Supra at 196, art. 5.2.4.1, p. 19. 258

"for all substances listed in the Out-of-Competition or In-Competition Section of the Prohibited List as appropriate for which there is a WADA-accepted screening method. WADA may make specific exceptions to this section."<sup>259</sup>

"Urine screening testing" involves only the "A" samples collected for doping control. When conducting "urine screening testing", the laboratory does not use the complete volume of urine contained within the "A" sample bottles. Only a small part, an Aliquot, will be used.

According to art. 5.2.4.2.2, the screening procedure has to be performed with a WADA-accepted validated method that is appropriate for the substance or the method being tested.

"The criteria for accepting a screening result and allowing the testing of the Sample to proceed must be scientifically valid."<sup>260</sup>

All screening assays are therefore required to include negative and positive controls in addition to the samples being tested<sup>261</sup>.

#### - urine confirmation testing

"Urine confirmation testing" is being conducted for two reasons mainly: (a) to ensure the identification and/or quantification of the Prohibited Substance(s), their "Metabolites", or "Markers" of the use of a Prohibited Substance or Method detected to be present in the urine sample after screening and (b) to exclude any technical deficiency in the screening procedure. This means that a confirmation procedure is required to provide a greater "selectivity", or ability to discriminate, than a screening procedure, as its single objective is to accumulate additional information regarding the presumptive Analytical Finding<sup>262</sup>. "Urine confirmation testing" therefore involves both the "A" sample, as well as the "B" sample.

### - "A" sample confirmation

According to art. 5.2.4.3.1.1, the presumptive identification from a screening procedure of Prohibited Substance(s), their "Metabolites", or "Markers" of the use of a Prohibited Substance or Method a Presumptive Analytical Finding must be confirmed using a second Aliquot(s) taken from the original "A" sample. After the "A" sample confirmation has been completed, a WADA-accredited doping control laboratory is required to subsequently report its "A" sample test results within a certain number of days to the relevant "Testing Authority"<sup>263</sup>.

<sup>259</sup> Supra, at 117.

<sup>260</sup> Supra at 196, art. 5.2.4.2.2, p. 19.

<sup>261</sup> Supra at 196, art. 5.2.4.2.3, p. 19.

<sup>262</sup> A Presumptive Analytical Finding has been defined as "The status of a Sample test result for which there is a adverse screening test, but a confirmation test has not been performed". Supra, at 104, p. 11.

<sup>263</sup> Supra at 196, art. 5.2.6.5, p. 23.

## - "B" sample confirmation

In addition to the aforementioned "A" sample confirmation -meant to confirm the screening result of the "A" sample only- the "B" sample analysis is intended to subsequently confirm the "A" sample identification for the "Adverse Analytical Finding". In other words, in order to determine whether an "Adverse Analytical Finding" is valid, the result from the "B" sample confirmation needs to confirm that of the "A" sample identification<sup>264</sup>. If the "B" sample confirmation however, does not provide analytical findings that confirm the "A" sample result, the sample shall be considered "negative" and the "Testing Authority"<sup>265</sup> shall be notified of the new analytical finding<sup>266</sup>.

# Applicable Rules and Regulations for the analysis of doping control samples for r- EPO in particular

## Technical Document - TD2004EP0

4.52 While the aforementioned general requirements regarding the analysis of urine samples for doping control purposes are contained in the "ISL", specific requirements regarding the analysis of urine samples for *r-EPO*, are detailed in "WADA Technical Document – TD2004*EPO*" (hereinafter: "*TD EPO*")<sup>267</sup>. As technical documents – "once promulgated" - become part of the "ISL", "*TD EPO*" does so too, albeit only in so far as the detection of *r-EPO* is concerned.

"The criteria presented herein have been established to ensure harmonization in the performance of the EPO urine test and the subsequent reporting of results across the Laboratories.

All the Laboratories are required to apply these criteria in the routine performance of the urine EPO test."<sup>268</sup>

4.53 According to "TD EPO", any r-EPO urinary test must be performed strictly in accordance with the method described in "TD EPO"<sup>269</sup>. This testing method consists of four different steps, i.e. (a) sample preparation, (b) iso-electric focussing, (c) double blotting and (d) chemiluminescent detection<sup>270</sup>. A presumptive "Adverse Analytical Finding" in the screening procedure should be confirmed using a second aliquot taken from the original "A" sample<sup>271</sup>. Subsequent results however, also need to fulfil

<sup>264</sup> Supra at 196, art. 5.2.4.3.2.3, p. 21.

<sup>265</sup> A <sup>''</sup>Testing Authority" is defined as "The International Olympic Committee, World Anti-Doping Agency, International Federation, National Sport Organization, National Anti-Doping Organization, National Olympic Committee, Major Event Organization, or other authority defined by the Code responsible for Sample collection and transport either In-Competition or Out-of-Competition and/or of the management of the test results". See: Supra at 3, Paragraph 3.2, "Defined terms from the International Standard for Laboratories", of Chapter 2 "Code Provisions" of PART ONE: INTRODUCTION, CODE PROVISIONS AND DEFINITIONS, p. 11.

<sup>266</sup> Supra at 196, art. 5.2.4.3.2.7, p. 21.

<sup>267</sup> WADA, Technical Document – TD2004EPO "Harmonization of the method for identification of Epoetin alfa and beta (EPO) and Darbepoetin Alfa (NESP) by IEF-double blotting and chemiluminescent detection", version 1.0, October 15, 2004 (approved January 15, 2005), p. 1.

<sup>268</sup> Id. 269 Id.

<sup>269</sup> 270

<sup>270</sup> Id.271 Supra, at 269, p. 2.

the quality, identification and stability criteria described in "TD EPO", before a WADAaccredited doping control laboratory is allowed to report a "Presumptive Analytical Finding" for *r-EPO* in urine as an "Adverse Analytical Finding"<sup>272</sup>.

4.54 This last requirement -i.e. that subsequent analysis results need to fulfil the quality. identification and stability criteria described in "TD EPO", before a WADA-accredited doping control laboratory is allowed to report a "Presumptive Analytical Finding" for *r-EPO* in urine as an "Adverse Analytical Finding" - was promulgated only recently, when it was discovered that "enzymatic activity" or other agents in the urine can cause a change in endogenous *EPO* molecules, as a result of which the endogenous *EPO*, present within all human beings, appears to be exogenous, or, for the purposes of the EPO test, resembles the prohibited substance *r*-EPO. As explained recently by WADA in its "Clarification About the EPO Detection Method" (hereinafter: the "Clarification"):

"In rare circumstances, it appears that normally endogenous EPO may shift into the recombinant EPO area. WADA was fully informed of this phenomenon by a few accredited laboratories in the spring of 2005. Following review of this information, WADA contacted all accredited laboratories performing EPO analysis in July 2005 to inform them of the phenomenon to ensure that they integrate this information into their interpretation. Laboratories have also been advised that a second independent opinion is now mandatory before reporting any adverse result. At the same time, WADA initiated further research with anti-doping laboratories to better understand the origin of this phenomenon and to more easily predict its occurrence. WADA expects the result of this research project soon."273

After several urine samples that WADA-approved laboratories initially had declared to represent a "positive" or "Adverse Analytical Finding" for the prohibited substance *r-EPO*, were determined to have been "false positive" urine samples instead, WADA mandated that, when conducting testing for the prohibited substance *r*-EPO, all urine samples were required to be submitted to a specific stability test, in addition to the mandatory "A" – and "B" sample confirmation test, before these urine samples could be declared "positive" or to constitute an "Adverse Analytical Finding". It should be considered that there are no records about the behaviour of EPO or r-EPO in urine samples over very long periods of time (in this case, between July 1999 (certain samples perhaps July 1998) and the date of measurement). According to the LNDD, there is evidence that EPO and r-EPO are stable over several years in urine samples. provided that they are kept under suitable storage conditions. This evidence does not cover however, periods as long as relevant for this research while the fact that urine samples had been opened and used previously raises further questions about the storage conditions. It should also be considered that if enzymatic activity did cause endogenous EPO molecules to be changed so as to appear for the purposes of the test to be *r-EPO*, as explained in its "Clarification"<sup>274</sup>, it may not be possible, after six years, to detect evidence of that enzymatic activity still.

<sup>272</sup> Supra, at 269, p. 2 and p. 5.

<sup>273</sup> Ex 75: WADA, Clarification About the EPO Detection Method, November 2005. ld.

<sup>274</sup> 

# Rationale of mandatory rules and regulations for the analysis of doping control samples

4.55 The most important reason why WADA-accredited doping control laboratories are required to apply the mandatory requirements for conducting doping control testing, is, as has already been stated in the preceding paragraphs, to ensure scientifically valid test results and evidentiary data, as well as harmonized results and reporting from all WADA-accredited doping control laboratories. In other words, the test results and evidentiary data from WADA-accredited doping control laboratories are only then considered "scientifically valid", when it can be established that the WADA-accredited doping control laboratories did follow the mandatory requirements for conducting doping control testing as detailed in the *ISL*, including its Annexes and "Technical Documents".

## Comparing practice with procedures

4.56 It is clear, that the LNDD, when conducting the analyses of the urine samples from the 1998 and 1999 Tours de France, did not follow the mandatory required analytical technical procedures as detailed in chapter 5.0 of the *ISL*, i.e. (a) sample handling, (b) urine testing, (c) result management and (d) documentation and reporting, as it should have. As a matter of fact, the LNDD did not follow a single one of these. This is also true for the required mandatory stability test, specified in *TD EPO*. WADA may be of the opinion that this has not been the case, but the investigator does, relying on the information he personally received from both Prof. De Ceaurriz and Dr. Lasne, as well as the reply he received in writing from Prof. De Ceaurriz answering the preliminary questions. Examining some of the aforementioned analytical technical processes in more detail<sup>275</sup>, the following "departures" -or violations- of the mandatory requirements for WADA-accredited doping control laboratories conducting doping control testing in general and for the Prohibited Substance *r-EPO* in particular, have to date been established:

## ad (a) Sample handling

1. Failure to produce the mandatory "internal chain of custody" for each of the urine samples from the 1998 and 1999 Tours de France analysed<sup>276</sup>. The fact that a number of these urine samples has been listed in the research reports as "manquant" or "missing"<sup>277</sup>, while actually having already been opened and used by the LNDD "for other research purposes" prior to the research currently being investigated, illustrates the inability of the LNDD to account for any of these urine samples all the way through from receipt to their final disposition and thus -at least for doping control purposes- the inability to link the analysis results obtained to specific urine samples. It also means that the LNDD cannot guarantee the "integrity" of the sample, i.e. that the urine provided by the riders during the doping controls conducted at the 1999 Tour de France is the same urine, which has been analysed by the LNDD when it conducted its research. This is especially important,

<sup>275</sup> The procedure for documentation and reporting will be addressed as a separate issue.

<sup>276</sup> See also: Supra, at 42, p.2.

<sup>277</sup> Supra, at 66.

as urine samples "spiked" with *r-EPO* have been part of the research conducted by the LNDD as well, raising concern regarding the possibility of contamination of the 1999 Tour de France urine samples.

2. Inability to prove, let alone guarantee, that a strict temperature control with regard to the urine samples from the 1998 and 1999 Tours de France had been maintained continuously all the way through from receipt, sometime in 1998 or 1999, to their final disposition, let alone that this had been done at a temperature of -20°C, given that the contents of some of these urine samples had already been thawed once before, as some of these had been opened before for research purposes.

#### ad (b) Urine testing

 Failure to follow any of the mandatory requirements regarding the three urinetesting procedures, i.e. "urine integrity testing", "urine screening testing" and "urine confirmation testing".

### Urine integrity testing

1.1 Both Prof. De Ceaurriz and Dr. Lasne informed the investigator that sample integrity had been verified only to the extent that a visual check had taken place on enzymatic activity, which may impair the results of the measurements. The LNDD representatives said that serious deterioration of urine samples is readily detectable, but did not explain what parameters were used when actually verifying the integrity of the urine sample from both Tours de France or produce any proof of their findings regarding this matter.

### Urine screening testing

1.2 When analysing the urine samples from the 1998 and 1999 Tours de France, the LNDD did not use the WADA-accepted and validated method for screening urine samples for the Prohibited Substance *r-EPO*. It applied a single (measurement) standard only, when it should also have used negative and positive control samples. The use of negative and positive control samples when conducting urine-screening testing constitutes a mandatory requirement for all WADA-accredited doping control laboratories.

## Urine confirmation testing

1.3 The LNDD did not conduct any of the mandatory required urine confirmation testing procedures for WADA-accredited doping control laboratories, when analysing the urine samples from the 1998 and 1999 Tours de France. Neither an "A" sample confirmation, nor a "B" sample confirmation test was conducted.

## The TD EPO stability test

1.4 The LNDD did not conduct the stability test, a mandatory requirement when conducting urine sample testing for the Prohibited Substance *r-EPO*. The stability test needs to be conducted before an urine sample can be qualified as constituting an Adverse Analytical Finding.

#### Evaluating the departures

- 4.57 In light of the above, the investigator finds that the LNDD, when conducting the analyses of the urine samples from the 1998 and 1999 Tours de France, did not follow the mandatory requirements for WADA-accredited doping control laboratories for conducting doping control testing in general and for the Prohibited Substance *r-EPO* in particular. Instead, the LNDD applied some kind of "accelerated measurement procedure", resulting in a substantial number of departures from the standard doping control procedure as mandatory required in the *ISL*, as detailed above. The investigator believes that because the urine screening testing has been conducted without using the WADA accepted screening method for *r-EPO*, in particular without the required negative and positive controls, and no "urine conformation testing" has been conducted at all, let alone the mandatory "stability test", there is no option to improve upon the reliability of these findings by means of conducting urine confirmation testing and the mandatory "stability test" meeting the relevant requirements. It is the investigator's opinion that the lack of quality control in particular –illustrated best by the LNDD's failure to use control samples or to conduct a stability test- renders the findings far from reliable as required by the ISL.
- 4.58 This is further compounded by the fact that the *"accelerated measurement procedure"* used for conducting the analyses of the urine samples from the 1998 and 1999 Tours de France was not validated and to date has never been fully disclosed by the LNDD to the investigator. Furthermore, the LNDD also failed to disclose its standards for declaring a sample to be allegedly "positive" on the basis of the research testing conducted, while no assessment has been made as to whether those standards comply with the current WADA rules for declaring a *r-EPO* screen to be presumptively positive. Consequently, the "screening positives" reported by the LNDD in its research reports in fact can not be qualified as constituting a Presumptive Analytical Finding, much less an Adverse Analytical Finding.
- 4.59 Finally, the LNDD has admitted that it is unable to produce any "chain of custody", making it impossible to link, in a sufficiently reliable manner for doping control purposes, a result to a particular sample. Moreover the fact that the samples were opened previously and used for unknown research purposes means that the "integrity" of the urine samples from the 1998 and 1999 Tours de France can also not be guaranteed. This creates a serious problem, as the LNDD has stated that the analysis of urine samples from patients having received *r-EPO* for medical reasons, as well as urine samples "spiked" with *r-EPO*, were part of the same research project. Given the absence of an "internal laboratory chain of custody", the possibility that urine samples of the 1998 and 1999 Tours de France might have been contaminated can not be ruled out.
- 4.60 The LNDD has expressed to the investigator, as well as to the media, a strong belief that the measurement results obtained during this research are valid and trustworthy. This validity should however, be seen in view of the objectives of the

research and in light of all violations from the mandatory required procedures before any attempt can be made to use these research results in the context of doping control or for any other forensic purpose. The objectives of this research differ appreciably from those of routine doping control testing, and likewise differ from the mandatory quality standards employed for routine doping control testing. The laboratory has used -for what may have been legitimate reasons- an *"accelerated measurement procedure"* for obtaining the results in this research and has been satisfied with deficient "screening" measurements, rather than higher quality confirmation measurements. By acting this way, it has accepted that the quality of the results is altogether below the standard described in the *ISL* for doping control measurements. Consequently, all the LNDD can actually say is that it believes that its *"accelerated measurement procedure"* appears to have identified several urine samples as suspicious for containing *r-EPO*. It did not prove that.

#### The manner in which and to whom the LNDD subsequently reported its findings

## Applicable Rules and Regulations in general WADA's International Standard for Laboratories

4.61 According to the requirements regarding documentation and reporting as contained in the *ISL*, a WADA-accredited doping control laboratory must have documented procedures to ensure that it maintains a coordinated record relating to each sample analysed<sup>278</sup>. Apart from documenting the various steps of the technical analytical process actually conducted during the analysis of a particular urine sample, these records are also required to indicate which staff member of the laboratory has been involved with a particular step of the technical analytical process and whether or not a "significant variance" from the written procedure did occur<sup>279</sup>. In case of an Adverse Analytical Finding, these records must include the data necessary to support the conclusions reported<sup>280</sup>. In addition, a WADA-accredited doping control laboratory is also required to have a policy regarding the provision of opinions and interpretation of data<sup>281</sup>.

#### The ISO/IEC 17025 international standard

4.62 According to article 5.2.6.6 of the *ISL*, a report issued by a WADA-accredited doping control laboratory is required to fulfil the requirements regarding the reporting of results as contained in the *ISO/IEC 17025 international standard* as well<sup>282</sup>. While it might be argued that the requirements regarding reporting as contained in the *ISL* only apply to WADA-accredited doping control laboratories conducting testing for

<sup>278</sup> Supra at 196, art. 5.2.6.1, p. 22.

<sup>279</sup> Supra at 196, articles 5.2.6.2 and 5.2.6.3 respectively, p. 22 – 23.

<sup>280</sup> Id. In general the record should be such that in the absence of the analyst, another competent analyst could evaluate what tests had been performed and interpret the data.

<sup>281</sup> According to the footnote regarding article 5.2.6.9, an opinion or interpretation may include, but no be limited to: "recommendations on how to use the results, information related to the pharmacology, metabolism and pharmacokinetics of a substance, and whether an observed result is consistent with a set of reported conditions." Supra at 196, article 5.2.6.9, with footnote, p. 23.

doping control purposes, no such restriction exists when examining the requirements regarding reporting as laid down in the *ISO/IEC 17025 international standard*<sup>283</sup>. These requirements apply to any report issued by an ISO/IEC 17025 accredited laboratory, regardless whether the report constitutes an official test report or not. In other words, these requirements also apply to an unofficial publication of an ISO/IEC 17025 accredited laboratory regarding certain research activities it conducted on its own initiative, i.e. like the LNDD did in this matter.

According to ISO/IEC 17025 clause 5.10.2, each test report or calibration certificate shall include at least the following information, unless the laboratory has valid reasons for not doing so:

## "a) a title;

- *b)* the name and address of the laboratory, and the location where the tests and/or calibrations were carried out, if different from the address of the laboratory;
- c) unique identification of the test report or calibration certificate (such as the serial number), and on each page an identification in order to ensure that the page is recognized as a part of the test report or calibration certificate and as a clear identification of the end of the test report or the calibration certificate;
- d) the name and address of the client;
- e) identification of the method used;
- f) a description, the condition and unambiguous identification of the items(s) tested or calibrated;
- g) the date of receipt of the test or calibration item(s) (where this is critical to the validity of the application of the results) and the date(s) of performance of the test or calibration;
- h) reference to the sampling plan and procedures used by the laboratory or other bodies (where these are relevant to the validity or application of the result);
- i) the test or calibration results with, where appropriate, units of measurement;
- *j*) the name(s), function(s) and signature(s) or equivalent identification of person(s) authorizing the test report ot calibration certificate;
- *k*) where relevant, a statement to the effect that the results relate only to the items tested or calibrated."<sup>284</sup>

In addition to these items, a test report shall, where necessary for the interpretation of the test results, also include the following:

"a)deviations from, additions to, or exclusions from the test method and information on specific test conditions, such as environmental conditions;

*b)* where relevant, a statement of compliance/non-compliance with requirements and/or specifications;

<sup>282</sup> Supra at 196, art. 5.2.6.6, p. 23.

<sup>283</sup> International Standard, General requirements for the competence of testing and calibration laboratories, ISO/IEC 17025: 1999, clause 5.10, p. 19 – 22.

<sup>284</sup> Supra at 285, p. 20.

- c) where applicable, a statement of the estimated uncertainty of measurement; information on uncertainty is needed in test reports when it is relevant to the validity or application of the test results, when a client's instructions so require, or when the uncertainty affects compliance to a specification limit;
- d) where appropriate and needed, opinions and interpretations (see 5.10.5);
- e) additional information which may be required by specific methods, clients or groups of clients."285

## Specific rules and regulations Technical Document - TD2004EPO

4.63 In addition to the general requirements regarding reporting as laid down in both the ISL, as well in the ISO/IEC 17025 international standard, specific requirements regarding the reporting of test data concerning the Prohibited Substance *r-EPO* are contained within "TD EPO". According to these specific requirements, a description of the result based upon application of all the criteria described in this documents, is considered a part of the "minimum acceptable information" regarding the "screening and confirmation test data"286. Whether "TD EPO" requires a laboratory to provide an opinion regarding the screening and confirmation test data, remains unclear. Nevertheless, "TD EPO" defines the expression "opinion" as follows:

"Any comment(s) from the Laboratory deemed necessary in support of the analytical finding." 287

## The Helsinki Declaration

What has been argued before regarding the applicability of the ISO/IEC 17025 4.64 international standard, holds true as well with regard to the "Helsinki Declaration". While it might be argued that the requirements regarding reporting as contained in the "ISL" only apply to WADA-accredited doping control laboratories conducting testing for doping control purposes, there can be no doubt whatsoever regarding the applicability of the ethical principles contained in the "Helsinki Declaration" for WADAaccredited doping control laboratories conducting research. According to the article 2.2 in the "Laboratory Code of Ethics", as contained in Annex B to the "ISL", WADAaccredited doping control laboratories conducting research are obliged to follow:

"the Helsinki Accords and any applicable national standards as they relate to the involvement of the human subjects in research"288.

Paragraph 27 of Part B, "Basic Principles For All Medical Research", of the "Helsinki Declaration" deals with publication of the research results, making it clear that both authors and publishers of research involving human subjects have ethical obligations:

<sup>285</sup> Supra at 285, clause 5.10.3, "Test reports", p. 20.

<sup>286</sup> Supra at 269, p. 6.

<sup>287</sup> ld. 288

Supra at 196, p. 54.

"In publication of the results of research, the investigators are obliged to preserve the accuracy of the results. Negative as well as positive results should be published or otherwise publicly available. Sources of funding, institutional affiliations and any possible conflicts of interest should be declared in the publication. Reports of experimentation not in accordance with the principles laid down in this Declaration should not be accepted for publication"<sup>289</sup>.

The investigator is of the opinion that these principles apply as soon as a report on research is drafted and disclosed to third parties. Therefore these principles had to be taken into account when the LNDD reported to WADA and the Ministry.

#### The rationale of the applicable rules and regulations

4.65 According to article 5.2.6.1 of the *ISL*, the reason why a WADA-accredited doping control laboratory is required to keep such detailed records and to report accordingly, is to ensure that -in the absence of the analyst who conducted the analysis- another competent analyst would be able to evaluate what tests had been performed and to interpret the data thus obtained<sup>290</sup>. While this is certainly true, it constitutes only a small part of the much broader underlying principle of the "transparency" of the testing procedure, i.e. the ability of a WADA-accredited doping control laboratory to show that it operates a quality system, is technically competent and able to generate analytical technical valid results, generating at the same time confidence in the doping control system. This is especially important as a considerable amount of doping control testing is routinely being conducted without anyone other than the staff of the laboratory present.

In order to achieve such "transparency", both the *ISL*, as well as the *ISO/IEC 17025 international standard* contain provisions specifying not only what (kind of) data WADA-accredited doping control laboratories are required to present in their (doping control) test reports, but also the manner in which these data are to be presented and even, if necessary, to be interpreted or understood. It is for this reason that clause 5.10.3.1 of the *ISO/IEC 17025 international standard* requires that tests reports - "where necessary for the interpretation of the test results"- are to include "where appropriate and needed, opinions and interpretations"<sup>291</sup>.

The rationale behind paragraph 27 of the "*Helsinki Declaration*" is clear. The same ethical obligations, which exist for researchers when conducting research involving human subjects, also exist when reporting about the results of that research.

<sup>289</sup> Supra at 202, p. 4.

<sup>290</sup> Supra at 196, p. 22.

<sup>291</sup> Supra at 285, clause 5.10.3.1, p. 20.

### Comparing practice with procedures

- 4.66 According to the investigator there can be no doubt whatsoever, that the manner in which the LNDD apparently documented the analyses of the urine samples from the 1998 and 1999 Tours de France, violated also almost all of the requirements regarding documentation as contained in both the *ISL* and *TD EPO*. The admitted inability of the LNDD to produce a valid "internal laboratory chain of custody" illustrates this sufficiently, as does the absence in both research reports of any mentioning of a "significant variance" from the mandatory required procedure
- 4.67 While it might be argued that the mandatory requirements regarding documenting and reporting as contained in both the *ISL* and *TD EPO* do not apply in this case, as the analyses of these urine samples had not been conducted for doping control purposes, but for research instead, this is not the case with respect to the requirements contained in the *ISO/IEC 17025 international standard*. As the LNDD holds an accreditation for ISO/IEC 17025 (as well as a WADA-accreditation), it should have known that test reports (regardless of their nature or purpose) must meet the minimum requirements as specified in the *ISO/IEC 17025 international standard* regarding their format, as well as their content(s).
- 4.68 As a matter of fact, the investigator even believes that because these reports were research reports instead of routine doping control test reports, the LNDD should have been even more aware of its responsibility to provide the necessary information, needed to interpret these reports correctly. Knowing very well the contents of its research reports, their similar format when compared with a routine doping control analysis report and being fully aware of the possibility that the information contained therein might also be used for purposes other then the research it had originally been intended for, the LNDD should have taken the necessary precautions to avoid any misunderstanding regarding the findings contained in both research reports, as well as their interpretation. Had the LNDD really wanted to avoid this risk, both research reports would have had to contain at least, apart from the contents listed in the *ISL* and *TD EPO* and in addition to the matters referred to in clause 5.10 of *ISO/IEC 17025 international standard*, information regarding:
  - the objective(s) of the research conducted;
  - the methods and procedures of measurement actually applied;
  - any relation between the research conducted and regular doping control testing;
  - a justification of the research conducted; and
  - a discussion of the findings and conclusions".

Both research reports however, did not.

- 4.69 Even worse, judging from the contents of WADA's reply dated April 3, 2006, to the investigator's questions contained in the questionnaires of March 15 and March 20, 2006, it would appear that the LNDD, even after specifically having been asked to, still did not provide the necessary information needed to interpret its reports, as well as the findings contained therein, correctly. When apparently asked by WADA if it had used a method for the analyses of the urine samples from the 1998 and 1999 Tours de France "significantly different" from the method used since 2000, WADA claims that the LNDD had answered that this had not been the case, that all analyses had been conducted in accordance with the usual *EPO* method, that the aforementioned urine samples had been stored at –20 degrees, that no substance could have been added and that information on storage was available.
- 4.70 It is clear that these statements conflict with what the LNDD itself admitted to the investigator regarding these issues when he visited the LNDD on December 9, 2005. As explained in detail in this report, the LNDD's research was conducted in such a manner that the results thus obtained cannot be regarded as constituting evidence of a Presumptive Analytical Finding or an Adverse Analytical Finding, let alone an Anti-Doping Rule Violation. Nevertheless, the investigator and his team studied the LNDD's report thoroughly.

As a first matter, it should be understood that the only documents provided by anyone regarding the LNDD research project, are two reports; one dealing with the analyses of urine samples allegedly from the 1998 Tour de France and one dealing with the analyses of urine samples allegedly from the 1999 Tour de France. These reports however, are not themselves documents from which scientific conclusions can be drawn. Each report basically is nothing more than a table, with one line for each sample, indicating whether the laboratory, by three different methods, which are not fully disclosed, declared the sample to be positive or negative or inconclusive for the presence of *r-EPO*. The actual scientific result of the *r-EPO* detection test is an electropheragram, which is basically a photograph, and all the conclusions in the LNDD reports are assessments of the data shown in an electropheragram. However, none of the electropheragrams or other documents necessary to verify the LNDD's conclusions have been provided to the investigator by the LNDD. The LNDD has not produced any of the documents required by the ISL to support the claim of a "positive" urine test for *r*-*EPO*. Nevertheless, the investigator and his team studied the results reported by the LNDD in the 1998 and 1999 Tour de France reports. The numbers reported by the LNDD raise substantial questions about their accuracy. However, the investigator believes that the fundamental deficiencies in the manner in which the research testing was conducted and the complete absence of any forensic value of the reports means that it would be improper to even discuss the reports as if they had some bearing on the likelihood that a rider took *r-EPO*. The reports should never have been prepared in that form, should never have been disclosed, and should never have been used or referenced by anyone with an understanding of the proper methods and procedures for conducting drug testing results management.

4.71 Despite all the deficiencies that are obvious and readily admitted to by the LNDD representatives, WADA nevertheless claims that the LNDD had assured WADA that the analyses of the urine samples from the 1998 and 1999 Tours de France had been conducted in accordance with normal doping control procedures. The investigator does not understand why the LNDD would have given such assurances to WADA. Not only did the LNDD know that such assurances would be false, it could reasonably expect that this aspect would be examined in detail, especially when the analyses results -because of WADA's request for *"additional information"* would be used for disciplinary purposes against riders.

In addition, had these assurances been given, the investigator does not understand why they have not been mentioned in WADA's correspondence with the UCI, following the publication in *L'Equipe* on August 23, 2005. This is particular true for WADA's letter to the UCI, dated September 9, 2005, containing WADA's answers to a number of questions regarding the research conducted, posed by the UCI in its letter of September 5, 2005. As a matter of fact, WADA did not say anything regarding the manner in which the analyses of the urine samples from the 1998 and 1999 Tours de France had been conducted, until its reply of April 3, 2006.

It might be -although not very likely in view of the know-how of the parties involved, as well as the importance of the subject for both of them- that WADA misunderstood or misinterpreted the information the LNDD provided with regard to the manner in which it had conducted the analyses of the urine samples from the 1998 and 1999 Tours de France. According to WADA, the LNDD had denied that it had used a method "significantly different from the method used since 2000" and "that the usual Iso-electro-focalization would apply to the analyses of all samples under the project"<sup>292</sup>. Contrary to WADA however, the investigator does not believe that the aforementioned reply from the LNDD should be understood as the LNDD having told WADA that it had in fact applied "the usual iso-electro-focalization" to all samples under the project. Would this have been the intention of the LNDD, it would have said that it had applied the "usual iso-electro-focalization" to the analyses of all samples under the project. What the LNDD probably tried to tell WADA, was that, if "the usual iso-electro-focalization" was to be applied to the analyses of all samples under the project, the LNDD believed the analyses results would be the same. Not only did the representatives of the LNDD express themselves in a similar manner when the investigator was visiting the LNDD, it would also be in line with the manner in which the LNDD has been expressing its conviction that the measurement results obtained during its research should be regarded as valid and trustworthy even when the LNDD had not followed the mandatory doping control procedure.

The investigator does not understand why WADA would seem to suggest in its reply of April 3, 2006, that it did not make any detailed inquiry regarding the manner in which the LNDD had actually conducted the analyses of the urine samples from the 1998

<sup>292</sup> Supra at 94, p. 6.

and 1999 Tours de France. Neither at the time it was informed about the research being conducted, nor at the time it received the final reports, did WADA make any inquiry, not even when it was confronted with severe criticism from the ASOIF and the IOC Athletes Commission regarding the conduct of the LNDD. While the investigator can only speculate as to why this might be so, this picture certainly does not agree with the statement made by WADA President, Dick Pound, in an interview with the German Netzeitung that after - "having seen all relevant documents in the matter"he believed it very likely that there might have been doping in the matter of Lance Armstrong.

- 4.72 As has been the case with the mandatory requirements regarding reporting, as detailed in the ISO/IEC 17025 international standard, there can be no doubt whatsoever, that the manner in which the LNDD reported its findings regarding the analyses of the urine samples of the 1998 and 1999 Tours de France also violated the requirements for publishing results of research involving human subjects, as contained in paragraph 27 of the "Helsinki Declaration". As should have been the case with the mandatory requirements contained in the ISO/IEC 17025 international standard, the LNDD should have also been aware of the applicability of the "Helsinki Declaration", not only when conducting research, but also when publishing about it. Both research reports however, fail to provide any information as to the objectives of the research conducted, the manner in which the analyses of the urine samples of the 1998 and 1999 Tours de France were actually performed and the validity of the analysis method applied, thus making it impossible to determine whether the LNDD did or did not preserve the accuracy of the research results, as required by the "Helsinki Declaration". In addition, both research reports fail to declare the sources of funding for conducting the aforementioned analyses, the LNDD's institutional affiliations, and "any possible conflicts of interest"<sup>293</sup>.
- 4.73 By reporting in the manner as it has done in this case, the LNDD has made itself, as well as the research it conducted and its subsequent findings, vulnerable for misinterpretation. Understanding fully what the serious negative consequences might be for any of the riders having submitted an urine sample for doping control purposes during the 1998 and 1999 Tours de France of the inclusion in its research reports of the "additional information" requested by WADA, the LNDD should at least have had the insight to provide detailed information in both research reports regarding the differences between the analysis procedure it applied and the mandatory required analysis procedure for doping control testing for *r*-EPO. As a matter of fact, the LNDD was obligated to do so. In fact, many of the issues raised or suggested by the publication in *L'Equipe* would never have been raised at all, had the LNDD reported in a manner compatible with the mandatory requirements of the ISO/IEC 17025 international standard, or with those of peer-reviewed scientific journals. Not only did both reports fail to mention exactly what kind of measurement procedure had actually been used, but -more importantly- they did not even mention

the fact that this "accelerated measurement procedure" was only an approximation of a preliminary screening test and was not a WADA-accepted validated method appropriate for the substance or the method being tested, let alone to what extent this measurement procedure deviated from the required mandatory standard measurement procedure. Had it been clear from the beginning to what extent the measurement procedure used was not even an "A" sample confirmation test and actually deviated from the standard WADA-validated testing method, there would have been no doubt whatsoever whether or not the measurement results obtained by the LNDD met the required mandatory standards for doping control as contained in the *ISL* and *TD EPO*. A debate regarding the question whether any of these research findings might qualify as a finding, let alone an "Adverse Analytical Finding" and whether the UCI should have taken disciplinary action on the basis of any of these findings, would simply never even have taken place, as it would have been clear that these debates lacked any ground.

4.74 According to the representatives of the LNDD, both the manner and format of reporting, were -at least to some extent- the result as well of WADA's repeated requests to include *"additional information"* in both research reports, in particular in the report regarding the analysis of the urine samples from the 1999 Tour de France. WADA has confirmed that there had been:

"an appropriate exchange of correspondence, [after which] the laboratory forwarded the information to WADA on 22 August 2005."<sup>294</sup>

While it might be inferred from the statements made by the representatives of the LNDD during the interview on December 9, 2005, that the LNDD had not taken the decision to release the data requested by WADA lightly, that it believed that the request for "additional information" from WADA, had been requested for purposes other than those of the research and that it had only yielded to these requests after having received approval/instructions from the Ministry to do so, the LNDD -to this point- however, has not produced any documents to support these contentions. To date, notwithstanding the assurance of their existence, neither WADA's requests to include "additional information" in the research reports -i.e. the code numbers present on the original glass bottles used for doping controls during the 1998 and 1999 Tours de France- nor the LNDD's refusals to do so, or copies of the subsequent "exchange of correspondence" between WADA and the Ministry, have been produced. The LNDD was also unable to explain how the procedure it followed with regard to WADA's request for additional information to be included in both test reports, was consistent with its policy and procedures for reviewing such requests, as required by the ISO/IFC 17025 international standard<sup>295</sup>.

<sup>294</sup> Supra at 102.

<sup>295</sup> Supra at 285, clause 4.4, p. 5.

## Confidentiality

4.75 While being addressed in this report as a separate issue, "confidentiality" or "athlete confidentiality" actually constitutes an integral part of the mandatory requirements for documentation and reporting. It is for this reason that the requirements regarding "confidentiality" can also be found in chapter 5 of the *ISL*. Furthermore, confidentiality or "athlete confidentiality" is not only an issue of concern for the reporting body, i.e. the WADA-accredited doping control laboratory, but also for the recipient(s) of the laboratory's report, i.e. the "Anti-Doping Organization" (hereinafter: "ADO") concerned<sup>296</sup>. The issue of "confidentiality" or "athlete confidentiality" will be addressed from both perspectives, starting with requirements for the reporting body, i.e. the LNDD.

# Applicable Rules and Regulations in general for "reporting organizations" such as the LNDD

## The World Anti-Doping Code

4.76 Article 19.4 of the WADA Code requires that:

Anti-doping research shall comply with internationally recognized ethical principles."

#### The WADA International Standard for Laboratories

According to article 5.2.6.13 of the ISL:

"athlete confidentiality is a key concern for all Laboratories engaged in Doping Control cases. Confidentiality requires extra safeguards given the sensitive nature of these tests"<sup>297</sup>.

In order to ensure that confidentiality is being maintained, any requests for information from a WADA-accredited doping control laboratory must be made in writing<sup>298</sup>. Information regarding *Adverse Analytical Findings* shall not be provided by phone, while information may only be sent by facsimile

*"if the security of the receiving facsimile machine has been verified and procedures are in place to ensure that the facsimile has been transmitted to the correct facsimile number."*<sup>299</sup>

In addition, when reporting or discussing an Adverse Analytical Finding and the athlete can be identified or information regarding the athlete is included, only the use of encrypted email is authorized. In other words, all communication about allegedly

<sup>296</sup> WADA, Result Management Guidelines, World Anti-Doping Program, version 1.0, February 2004,.art. 1.1, "Laboratory Results and Possible Failure to Comply Reports", p.7. in case of an "Negative Analytical Finding", also the "relevant stakeholders" and -when having asserted there has been an Anti-Doping Rule Violation- the Athlete's National Anti-Doping Agency, International Federations and WADA as well.

<sup>297</sup> Supra at 196, art. 5.2.6.13, p. 24.

<sup>298</sup> Supra at 196, art. 5.2.6.13.1, p. 24.

<sup>299</sup> Supra at 196, art. 5.2.6.13.2, p.24.

positive results for which an athlete can be identified must be maintained in the strictest sense of confidentiality.

4.77 In addition to the requirements, laid down in the ISL, "confidentiality" is also addressed in the "Laboratory Code of Ethics" as contained in Annex B to the ISL, prohibiting statements to the media prior to the completion of any adjudication without specified permission:

#### "1.Confidentiality

The heads of Laboratories, their delegates and Laboratory staff shall not discuss or comment to the media on individual results prior to the completion of any adjudication without consent of the organization that supplied sample to the Laboratory and the organization that is asserting the Adverse Analytical Finding in adjudication."300

While the aforementioned requirements regarding "athlete confidentiality" appear to be directed primarily at "all Laboratories engaged in Doping Control cases", article 2 of the "Laboratory Code of Ethics" deals with WADA-accredited doping control laboratories conducting "research in support of doping control"<sup>301</sup>. According to article 2.2, WADA-accredited doping control laboratories -when conducting research involving human subjects- are required to:

"follow the Helsinki Accords and any applicable national standards as they relate to the involvement of human subjects in research."302

#### The ISO/IEC 17025 international standard

4.78 As has already been stated before, a report issued by a WADA-accredited doping control laboratory is required to fulfil the requirements regarding the reporting of results as contained in the ISO/IEC 17025 international standard as well. As has also been remarked before, these requirements apply to any report issued by an ISO/IEC 17025 accredited laboratory, regardless whether the report constitutes an official doping control test report or not. In other words, these requirements apply to any report or publication of an ISO/IEC 17025 accredited laboratory -official or unofficialregardless of the nature of the activities or work reported on. According to clause 5.4.7.2 regarding the control of data, an ISO/IEC 17025 accredited laboratory shall ensure that:

"procedures are established and implemented for protection of the data; such procedures shall include, but not be limited to, integrity and confidentiality of data entry or collection, data storage, data transmission and data processing;"303

<sup>300</sup> Supra at 196, Annex B, "Laboratory Code of Ethics", art. 1, p. 54.

<sup>301</sup> Supra at 196, Annex B, "Laboratory Code of Ethics", art. 2, p. 54.

<sup>302</sup> Supra at 196, Annex B, "Laboratory Code of Ethics", art. 2.2, p. 54. 303

Supra at 298, clause 5.4.7.2, p. 14.

### The WADA doping control form

4.79 The WADA doping control form stipulates the following as far as consent for research is concerned:

"In order to help combating doping in sport, by signing below I (the athlete that is being tested) agree that my sample may be used for anti-doping research purposes. When all analyses have been completed, and my sample would otherwise be discarded, it may then be used by any WADA-accredited laboratory for anti-doping research for any type, provided it can no longer be identified as my sample."304

In other words, WADA also adheres to the fundamental rule regarding research on human samples that a sample used for research purposes can no longer be identified as having been provided by a specific person. This however, did not stop WADA from insisting repeatedly that LNDD should provide the code numbers present on the original glass bottles used for conducting doping controls during the 1998 and 1999 Tours de France, as well as other confidential information.

### The Helsinki Declaration

4.80 Paragraph 21 of Part B, "Basic Principles For All Medical Research", of the "Helsinki Declaration". makes it clear that:

"the right of research subjects to safequard their integrity must always be respected"<sup>305</sup>.

"Every precaution should be taken to respect the privacy of the subject, the confidentiality of the patient's information and to minimize the impact of the study on the subject's physical and mental integrity and on the personality of the subject"306.

According to paragraph 27 of the aforementioned Helsinki Declaration, the requirements contained in paragraph 21 also apply to publications regarding the results of the research conducted<sup>307</sup>.

## Comparing practice with procedures as far as reporting organizations, such as the LNDD, are concerned

4.81 The investigator would have expected that the LNDD would have prevented, before analysing the urine samples from the 1998 and 1999 Tours de France for research purposes, all possibilities for linking the research result to any of these urine samples. This is the only way to give full effect to the requirement that is also found in WADA's doping control form, that the sample can no longer be identified. The request of WADA to the LNDD to provide the research result of each sample together with the original sample code is an obvious violation of its own rule that urine samples for research can no longer be identified.

<sup>304</sup> WADA, WADA doping control form, version 3, March 2005.

<sup>305</sup> Supra at 202, p. 3. ld.

<sup>306</sup> 

<sup>307</sup> Supra at 202, p. 4.

- 4.82 According to WADA, its request to the LNDD for "additional information" regarding the analyses of the 1999 Tour de France was made verbally, notwithstanding the mandatory requirement as laid down in article 5.2.6.13.1 of the ISL that any requests for information from a WADA-accredited doping control laboratory must be made to that laboratory in writing. When the Ministry, the LNDD and WADA produce the "exchange of correspondence" among WADA, the Ministry and the LNDD that preceded the LNDD preparing the reports and sending them to WADA, the facts concerning this issue should be more clear. Notwithstanding the fact that the LNDD explicitly admitted to have been aware of the fact that the "additional information" requested was (a) neither useful, nor necessary for understanding the research conducted or its findings, (b) of a confidential nature<sup>308</sup> and (c) providing it to WADA might constitute a violation of the "confidentiality provisions" as contained in the WADA Code and the ISL, it nevertheless did provide the requested "additional information" to WADA. Furthermore, it did so without any safequards protecting its confidential nature. The LNDD could at least have encrypted the "additional information" requested by WADA, making it impossible for others -in case of a leakto have access to this confidential information.
- 4.83 The investigator feels that if the LNDD had reported its research findings to WADA in a manner consistent with the "confidentiality provisions" contained in the WADA Code and the ISL, as well as in the ISO/IEC 17025 international standard, other parties would not have been able to use the information contained in these reports (to try) to determine the identity of the riders having provided one or more urine samples during the 1999 Tour de France and the article in *L'Equipe* could not have been written as it has been. The fact that it had been agreed with WADA -prior to releasing both research reports- that strict confidentiality was to be maintained with regard to the "additional information" provided, in particular with regard to the code numbers present on the original glass bottles used for doping controls during the 1999 Tour de France, does not absolve the LNDD from its obligations under the "confidentiality provisions", as contained in the WADA Code and the ISL, the ISO/IEC 17025 international standard and the "Helsinki Declaration", but rather suggests its awareness and subsequent intentional disregard of that obligation. This obligation is an absolute one, as it requires the LNDD to maintain "confidentiality" with regard to anybody and not with regard to just one party.
- 4.84 It might be argued again, that the requirements regarding "confidentiality" or "athlete confidentiality" as contained in the *WADA Code*, or the *ISL*, only apply to WADA-accredited doping control laboratories conducting doping control testing. This is however not correct. According to the Laboratory Code of Ethics, as contained in Annex B, of the *ISL*, these requirements apply also to WADA-accredited doping control laboratories conducting. It might also be argued that the requirements regarding

<sup>308</sup> 

Because of the fact that this information could be used (to attempt) to discover the identity of one or more of the riders, having been responsible for providing one or more of the urine samples of the 1999 Tour de France.

"confidentiality" or "athlete confidentiality" apply a fortiori to research reports from WADA-accredited doping control laboratories, when the data presented in such reports has been obtained by other means and procedures than those mandatory required, which do not offer the same guarantees as those means and procedures normally applied for the detection *Adverse Analytical Findings*. Furthermore, as has been pointed out before, the importance being attached to the principle of "athlete confidentiality" as far as research is concerned also follows from WADA's doping control form, which may be understood as a representation that WADA adheres to these principles and wants all its stakeholders to respect them as well.

The same is true with regard to the *ISO/IEC 17025 international standard* and the principles contained in the *"Helsinki Declaration"*. The requirements contained in the *ISO/IEC 17025 international standard* apply to any report issued by the LNDD regardless of its contents or nature, while the principles contained in the *"Helsinki Declaration"* apply to all (reports regarding) research involving human subjects. So far, the LNDD has not made any information or documentation available to the investigator regarding the establishment or implementation of procedures for the protection of the data, including, but not limited to,

# the integrity and confidentiality of data entry or collection, data storage, data transmission and data processing<sup>"309</sup>.

This makes it difficult to determine whether the LNDD did or did not violate the *ISO/IEC 17025 international standard* in this regard. No such problem however, exists when having to determine whether the LNDD violated the principles regarding "confidentiality" contained in the "*Helsinki Declaration*". The "*Helsinki Declaration*" takes the position that the right of research subject to safeguard everybody's integrity must always be protected. This right is not limited to the subject's privacy or the confidentiality of his or her patient's information, but also requires that the impact of the research itself on the subject's physical and mental integrity, as well as his or her personality is minimized. According to the investigator, there can be no doubt whatsoever, that providing the "additional information" required by WADA itself, as well as the manner in which it was provided, violated the principles regarding the protection of the research subject's integrity and privacy, as laid down in paragraph 21 of the "Helsinki Declaration".

4.85 The investigator has to date not been able to determine any reason why the LNDD would violate the ethical principles regarding research on human subjects as laid down in the "*Helsinki Declaration*" or even the French Civil Code, other than it apparently having been unaware of the applicability of these regulations and legislation in the matter at hand (while the LNDD must have been aware of the other

applicable regulations concerning athlete confidentiality). He would nevertheless at this time like to express his concern regarding the explicit content of the statements made by Prof. De Ceaurriz in his interview with "*De Volkskrant*" on the issue of "confidentiality" and the attitude implied.

- Q. "IOC President Jacques Rogge has asked WADA President Dick Pound to draft such rules [i.e. new doping control rules, ENV]. What do you think should be in these rules?"
- A. "These rules should exceed the boundaries of the sportive domain. They should allow analysis results from doping controls to be used in legal proceedings before the Courts as well. Important information should not be allowed to be buried because of medical ethics, which do not apply to athletes anyway. They are not patients. The pretense of protecting the athlete protects especially those who cheat. The new Code should protect athletes who do not cheat."<sup>310</sup>
- 4.86 Apart from having made public confidential information it should not have used, the LNDD also violated the "confidentiality provisions" contained in the ISL -in particular in its "Laboratory Code of Ethics" - as well as it violated the ethical principles for research on human subjects contained in the "Helsinki Declaration", by commenting in the media on various occasions and in considerable detail on the analysis results of the urine samples from the 1999 Tour de France in general and the alleged "positives" or Adverse Analytical Findings in particular. By doing so, the LNDD also violated the condition of "strict confidentiality" it had imposed itself on WADA for receipt of the research reports. In particular, the LNDD should not have confirmed by its statements in the media that some of the alleged "positive" samples were related to the seven-times Tour de France winner Lance Armstrong, especially in light of the complete absence of any chain of custody and the clear admonitions contained in the aforementioned rules and regulations regarding the mandatory nature of (maintaining) "athlete confidentiality". The amount of information reported in the media about the testing and the results is quite substantial, when taking into account the existing confidentiality requirements and appears to have been intended to support the idea that the testing the LNDD had conducted should be regarded as providing a sufficient basis for concluding that one (1) or more urine samples from Lance Armstrong had yielded an Adverse Analytical Finding, which the LNDD knew was simply not true.
- 4.87 For instance, Professor De Ceaurriz, told the magazine "Bicycling" that:

"as long as the samples have been well cared for, there is no problem. And I know the samples in question were. EPO is a very resilient molecule as long as the temperature is sufficiently cold to preserve it. The hardest part comes in the transport of samples from the competition to the lab, but I know that already in 1998 the Tour de France had set up a

<sup>310</sup> Supra at 144.

very reliable transportation system. In addition the 1998 and 1999 samples used this year were backed up by more recent examples, and the results were consistent, so I have no doubt that they were still valid. The Châtenay lab didn't test the samples years earlier, De Ceaurriz says, because there was no compelling reason; the lab was simply fine-tuning the EPO test and ran these samples as a check according to De Ceaurriz. They wanted samples that would almost surely have EPO in them, which is why they selected samples from a Tour before the test existed in 2001. He says they couldn't test prior to 1998 because the sample transport and storage system was not reliable for such long storage times."<sup>311</sup>

In fact, in the initial *L'Equipe* article and in subsequent articles discussing the *L'Equipe* story, the following statement is attributed to Professor De Ceaurriz<sup>312</sup>:

"There is no possible doubt about the validity of the result, even though the analysis was carried out five years after the samples were taken."

In his interview with the abovementioned newspaper "*De Volkskrant*", Professor De Ceaurriz makes the following statements regarding the analysis results of the urine samples from the 1999 Tour de France:

- *Q. "You have no doubts regarding the results of your research?"*
- *A.* "We classify all our test results as black, white or gray: positive, negative or doubtful. Positive is positive, so there is no reason for doubt."
- Q. "Not even a little bit?"
- A. "The test results are what they are. By coincidence they happen to belong to the winner of the 1999 Tour de France. They could also have belonged to someone else who did not win the Tour. Moreover we found EPO present in nine other urine samples as well. We are blamed that these did not make the papers, while we have absolutely nothing to do with that"<sup>313</sup>.

### Applicable rules and regulations in general for "recipient organizations", such as the UCI and WADA

4.88 While the aforementioned mandatory requirements are directed at the "reporting organization", i.e. the WADA-accredited doping control laboratories, the following rules and regulations concerning "confidentiality" or "athlete's confidentiality" address the obligations of the "recipient organizations" such as the "Anti-Doping Organization" concerned and -in case of an "Negative Analytical Finding"- the "relevant stakeholders" and, when having asserted there has been an Anti-Doping Rule Violation, the Athlete's National Anti-Doping Agency, International Federations and WADA.

<sup>311</sup> Ex. 47: Interview in Bicycling magazine.

<sup>312</sup> Supra at 14.

<sup>313</sup> Supra at 144.

#### The 2003 World Anti-Doping Code

4.89 According to article 14 of the WADA Code, the mandatory requirements regarding "confidentiality" or "athlete's confidentiality" for "recipient organizations" are based on the following principles:

"The Signatories agree to the principle of coordination of anti-doping results, public transparency and accountability and respect for the privacy interest of individuals alleged to have violated anti-doping rules [...]."

Consequently, "recipient organizations" shall not:

"disclose this information [i.e. regarding an Adverse Analytical Finding] beyond those persons within the organization with a need to know until the Anti-Doping Organization with results management responsibility has made public disclosure or has failed to make public disclosure as required in Article 14.2 below."<sup>314</sup>

#### As a matter of fact:

"The identity of Athletes whose Samples have resulted in Adverse Analytical Findings, or Athletes or other Persons who were alleged by an Anti-Doping Organization to have violated other anti-doping rules, may be publicly disclosed by the Anti-Doping Organization with results management responsibility no earlier than completion of the administrative review described in Articles 7.1 and 7.2."<sup>315</sup>

Public disclosure however is eventually expected:

"Not later than twenty days after it has been determined in a hearing in accordance with Article 8 that an anti-doping rule violation has occurred, or such hearing has been waived, or the assertion of an anti-doping rule violation has not been timely challenged, the Anti-Doping Organization responsible for results management must publicly report the disposition of the anti-doping matter."<sup>316</sup>

#### Specific rules and regulations The 2004 Anti-Doping Rules of the UCI

4.90 The 2004 Anti-Doping Rules of the UCI also contain specific rules regarding "confidentiality" or "athlete's confidentiality". These apply in those cases the UCI should be regarded as the "Anti-Doping Organization with results management responsibility". According to article 292, "Duty of confidentiality", as contained in the aforementioned UCI Anti-Doping Rules:

314 Supra at 3, art. 14.1, "Information Concerning Adverse Analytical Findings and Other Potential Anti - Doping rule Violations", p. 40.

<sup>315</sup> Supra at 3, art. 14.2, "Public disclosure", p. 41 - 42.

<sup>316</sup> Id.

"Persons carrying out a task in Doping Control are required to observe strict confidentiality regarding any information concerning individual cases which is not required to be reported under these Anti-Doping Rules.

Such breaches of confidentiality shall be penalized by a fine of between CHF 1.000,-- and CHF 10.000,-- as decided by the UCI Disciplinary Commission, which may also suspend the person in question from specified tasks for such time as it shall determine."<sup>317</sup>

According to articles 293 and 295 of the "2004 UCI Anti-Doping rules", either the UCI Anti-Doping Commission, or the National Federation of the rider concerned, shall be responsible for public disclosure, depending on the kind of decision establishing a violation of the "2004 UCI Anti-Doping rules"<sup>318</sup>. The definitive sanctions and the name of the person penalized shall be published in the UCI Official News Bulletin and/or in the official bulletin of the National Federation of the person penalized<sup>319</sup>.

# Comparing practice with procedures as far as the "recipient organizations" are concerned

The UCI

- 4.91 As is clear from the rules and regulations discussed above, a "recipient organization" such as the UCI in this matter -while being the responsible ADO- is expected and required to maintain "athlete's confidentiality" or "confidentiality" as well, even when conducting result management. Consequently, it might be argued that this means that the UCI should not have provided Mr. Ressiot, the journalist of *L'Equipe*, with copies of the aforementioned "doping control forms", as the information contained therein is of a confidential nature and providing it to third parties -especially to those not being a part of the regular doping control process- violates the applicable rules and regulations regarding "athlete's confidentiality", as contained in both the *WADA Code*, as well as in the UCI's own 2004 Anti-Doping Rules. It has been suggested in this matter, that the information contained on these forms assisted Mr. Ressiot in determining which of the urine samples of the 1999 Tour de France analyzed by the LNDD apparently had been provided by Lance Armstrong and that the violation of the athlete's confidentiality consequently should be attributed to the UCI.
- 4.92 The investigator however, does not agree with these suggestions. First and foremost it should be understood that the UCI did not function as an ADO conducting result management, when asked by Mr. Ressiot, whether he could have access to and

Supra at 11, art. 292, "Duty of confidentiality", Chapter XII "CONFIDENTIALITY AND PUBLIC DISCLOSURE", p. 42.
 Article 295 states the following:

<sup>&</sup>quot;Once a violation of these Anti-Doping Rules has been established in a decision referred to in article 243, it shall be publicly reported as follows:

<sup>-</sup> if the UCI decides to appeal to the CAS, the UCI will report the violation, the decision and its decision to appeal no later than the expiration of the time limit for the appeal;

<sup>-</sup> if the UCI decide snot to appeal to the CAS, the UCI will report the violation, the decision and its decision to appeal no later than ten (10) days after the expiration of the time limit for the appeal;

<sup>-</sup> if the License-Holder or WADA appeals to the CAS, the UCI will report the violation, the decision and the appeal within ten (10)days after the appeal was notified to the UCI." Supra, at 11, p.43.

<sup>319</sup> Supra at 11, art.296, "Publication", p. 43.

subsequently receive a copy of one (1) or more of the doping control forms of Lance Armstrong regarding the 1999 Tour de France. The UCI did not know and could not reasonably have known that "athlete's confidentiality" might be an issue for consideration when it was confronted with Mr. Ressiot's request. Consequently, neither the applicable rules and regulations regarding "athlete's confidentiality", as contained in the WADA Code, nor those contained in the UCI's own 2004 Anti-Doping Rules apply. As a matter of fact, the decision of the UCI to blank out the information on the copies of the doping control forms from Lance Armstrong regarding any medication used, actually provides proof of the opposite. As this kind of information is medically privileged, not only the requirement of "athlete's confidentiality", but also those regarding the confidential nature of this kind of privileged medical information, prohibited the UCI from providing this information to Mr. Ressiot. It was exactly because of these requirements, that the UCI did not provide Mr. Ressiot with the information he had originally requested. Acting in good faith however, the UCI tried to assist Mr. Ressiot with his request by providing him with one (1) or more copies of analysis reports corresponding with the copies of the doping control forms from Lance Armstrong, as this would allow Mr. Ressiot as well to verify matters regarding the suggested use of medication by Lance Armstrong, albeit in an indirect matter. Finally and most importantly, the investigator believes that the fact that the UCI may have provided Mr. Ressiot with at least one (1) or more copies of the original doping control forms of Lance Armstrong from the 1999 Tour de France and/or related analysis reports, while perhaps useful for the identification, has not been material for the identification of Lance Armstrong as being one of the riders presumably responsible for having submitted one or more alleged "positive" urine samples during the aforementioned Tour de France. The UCI, in other words, did not violate the requirement of "athlete's confidentiality" by providing one (1) or more copies of doping control forms and/or corresponding analysis reports to Mr. Ressiot. According to Mr. Ressiot, the manner in which the LNDD had structured the results table of its report -i.e. listing the sequence of each of the batches, as well as the exact number of urine samples per batch, in the same (chronological) order as the stages of the 1999 Tour de France they were collected at- was already sufficient to allow him to determine the exact stage these urine samples referred to and subsequently the identity of the riders who were tested at that stage. While it is true that possession of these forms might have confirmed matters for Mr. Ressiot, to permit him to claim that six (6) of Lance Armstrong's fifteen (15) urine samples were positive, the fact remains that he did not necessarily need copies of the doping control forms of Lance Armstrong from the 1999 Tour de France to be able to identify Lance Armstrong as having been one of the riders supposedly responsible for having submitted one (1) or more of the alleged "positive" urine samples.

#### WADA

4.93 Notwithstanding the clear rules regarding the obligation for "recipient organizations" to maintain "confidentiality", or the agreement reached with the French Ministry and/or the LNDD to maintain strict confidentiality with regard to the contents of both research reports from the LNDD, the media reported, as soon as the *L'Equipe* article

was published, a series of statements by WADA officials that, if accurately reported, appear to have been designed to give credibility to the *L'Equipe* story, to support the idea that the results reported by the LNDD were connected to Lance Armstrong and to support the allegations that the *L'Equipe* "condemnation" of Lance Armstrong and the other riders were credible.

- 4.94 The investigator does not yet know whether the statements attributed by the media to Professor De Ceaurriz and WADA officials were made by them as they were reported However in light of what is known so far concerning the failure of the LNDD to follow the mandatory analytical technical processes as laid down in the *ISL* and *"TD EPO"*, the invetigator strongly believes that both the LNDD and WADA should have refrained from issuing any comments at all regarding the matter at hand.
- 4.95 Finally and most importantly, it is the conclusion of the investigator that it has been WADA's request to the LNDD to include in its research report regarding the analyses of the urine samples from the 1998 and 1999 Tours de France the code numbers present on the original glass bottles used for doping controls during those Tours de France, which has caused the current situation. Without WADA's request and subsequent insistence that the research report regarding the analyses of the urine samples of the 1998 and 1999 Tours de France should also contain the code numbers present on the original glass bottles used for doping controls during those same Tours de France, it would have been impossible to determine the identity of the riders having provided one or more urine samples during the 1999 Tour de France and thus to write the article.

## The qualification of the findings under the applicable anti-doping rules, regulations and procedures of the UCI

4.96 As indicated in paragraph 4.29 of this report, it is the view of the investigator that the issue of the qualification of the findings has to be judged according to the rules in place at the time of the analysis of the samples and the reporting of the results respectively

### Applicable Rules and Regulations in general The 2003 World Anti-Doping Code

- 4.97 The qualification of the results of analyses conducted for doping control purposes should be regarded as the most important part of the result management process undertaken by Anti-Doping Organizations. Consequently, the *WADA Code* requires each Anti-Doping Organization conducting result management to establish a process for the "pre-hearing administration of potential anti-doping rule violations"<sup>320</sup>, respecting the following principles:
  - an initial review of an Adverse Analytical Finding;
  - the notification of the athlete after the initial review;

- a further review of an Adverse Analytical Finding, when so required by the Prohibited List;
- a review of other anti-doping rule violations; and
- a provisional suspension<sup>321</sup>.

#### The 2004 Result Management Guidelines

4.98 In 2004, WADA issued, as part of its "World Anti-Doping Program", so-called "Result Management Guidelines" (hereinafter: "RMG") to provide a model

"for the best practice developed regarding the management of test results".

"These Guidelines may be applied by any Anti-Doping organization with responsibility for conducting result management, from the time of notification of initial results to the assertion of an Anti-Doping Rule Violation and notification of the appropriate disciplinary body."322

According to the RMG, the manner in which an Anti-Doping Organization is required to conduct its result management process depends primarily on the nature of the potential anti-doping rule violation, i.e whether it concerns a possible Adverse Analytical Finding, or another Anti-Doping Rule Violation. As the independent investigation is dealing with a "Laboratory Results Report", alleging an Adverse Analytical Finding, only those steps of the suggested result management process dealing with an Adverse Analytical Finding will be examined in this report in more detail.

#### **Result Management involving an Adverse Analytical Finding**

4.99 As stipulated in Chapter 7 of the RMG, in cases where there has been an Adverse Analytical Finding and:

a) The test has not been declared void due to an irregularity in accordance with clause 3.2.6;

- b) The presence of the Prohibited Substance is not consistent with a therapeutic use exemption that has been granted in accordance with clause 3.3.1;
- c) The Athlete has not requested that the B Sample be analyzed, or the B Sample Analysis has been conducted and confirms the A Sample Adverse Analytical Finding in accordance with clause 3.5.8; and
- d) Any follow-up investigation conducted that has led to the conclusion of a possible Anti-Doping Rule Violation in accordance with clause 3.2.7,

then the ADO shall assert that there has been an Anti-Doping Rule Violation"<sup>324</sup>.

In other words, an Adverse Analytical Finding can only be qualified as an Anti-Doping Rule Violation, if the conditions sub a to d have been met. In order to determine

<sup>321</sup> ld.

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<sup>323</sup> WADA, Result Management Guidelines, version 1.0, Lausanne, Switzerland, February 2004, Chapter 7, "Assertion of an Anti-Doping Rule Violation", article 7.1, p. 16. ld.

<sup>324</sup> 

whether or not this is correct, an ADO is required to conduct the following investigations:

#### Ad a) An Initial Review

Upon receipt of an Adverse Analytical Finding, the responsible Anti-Doping Organization is required to review "all documentation relating to the Sample Collection Session (including the Doping Control Form, DCO Report and other Records) and the laboratory analysis" for "any irregularity"<sup>325</sup>. If irregularities are found in the documentation, the ADO is to determine whether these irregularities can "reasonably" be considered "to undermine the validity of the Adverse Analytical Finding"<sup>326</sup>. The RMG however, do not specify which irregularities should or should not "reasonably" be considered to undermine the validity of an Adverse Analytical Finding, nor is the expression "irregularity" used in this regard in the WADA Code. Instead the WADA Code uses the expression "departure", but provides no definition for this expression<sup>327</sup>. According to articles 3.2.1 and 3.2.2 in the WADA Code however, a departure or departures from either the ISL, or the International Standard for Testing (hereinafter: "IST"), which did cause an Adverse Analytical Finding or the factual basis for the other Anti-Doping Rule Violation, shall invalidate the test result. In other words, an irregularity can "reasonably" be considered "to undermine the validity of the Adverse Analytical Finding", when the departure from the either the ISL and/or the IST did cause the Adverse Analytical Finding or the factual basis for the other Anti-Doping Rule Violation. Should this be the case, the ADO "shall declare the test result void"<sup>328</sup> and "immediately inform the Athlete's International Federation and WADA"<sup>329</sup>.

#### Ad b) Follow-up Investigations

If the initial review has not revealed any "irregularities", the ADO is required to conduct subsequent "follow-up investigations", only if the alleged Adverse Analytical Finding shows the presence of a "Prohibited Substance (for example endogenous substances) where further investigations are required to determine an Anti-Doping Rule Violation"<sup>330</sup>. When having to conduct follow-up investigations, an ADO may require the assistance of the laboratory, as well as other scientific and/or medical expertise as necessary to conduct an investigation, while "not revealing the identity of the Athlete"<sup>331</sup>. If the ADO believes that the past doping test history of an Athlete is relevant to the investigation, the ADO is required to notify the Athlete of this in writing, providing "reasoning for such request"<sup>332</sup>. The Athlete must then forward details of his or her past doping test history to the ADO and authorize the ADO to request information from other ADO's, other laboratories or WADA,

<sup>325</sup> Supra at 324, article 3.1, "Initial review", p. 8.

<sup>326</sup> Supra at 324, art 3.1.2, p. 8.

<sup>327</sup> Supra at 324, art. 3, "Proof of Doping", p. 12 – 13. The UCI Anti-Doping Rules however use the expression "departure" both with regard to evidence, as well as results management. Supra at 11, artt. 18, 19 and 186.

<sup>328</sup> Supra at 324, art 3.1.3, p. 8.

<sup>329</sup> Supra at 324, art. 3.1.5, p. 8.

<sup>330</sup> Supra at 324, art. 3.2.1, "Follow – up Investigations", p. 8. Follow – up investigations are to be conducted in cases "where the laboratory has reported the presence of a of testosterone/epitestosterone ratio greater than 6 to 1".

<sup>331</sup> Supra at 324, art. 3.2.3, p. 8 – 9.

<sup>332</sup> Supra at 324, art. 3.2.4, p. 9.

to verify the Athlete's past doping test history<sup>333</sup>. Finally, when making the final consideration as to whether the follow - up investigation provides evidence of an Anti-Doping Rule Violation, the ADO is required to take into account: all laboratory analyses and the findings and recommendation of any medical advisory" or review committee. The ADO may consult the laboratory and any other experts to assist in the interpretation of the follow – up investigation results."334

#### Ad c) Verification Therapeutic Use Exemption

After having conducted the initial review, as well as the follow-up investigations if so required, the ADO needs to determine whether or not a "Therapeutic Use Exemption" (hereinafter: "TUE") has been granted to the Athlete in accordance with the "International Standards for Therapeutic Use Exemptions" (hereinafter: "ISTUE"), allowing the Athlete to use the prohibited substance found on medical grounds<sup>335</sup>. According to article 4.4 "Therapeutic Use" in the WADA Code, each International Federation is required to ensure that:

*"a process is in place whereby the Athletes with documented medical conditions* requiring the use of a Prohibited Substance or a Prohibited Method may require a therapeutic use exemption."336

If the athlete has been granted a TUE, no further action is required, other than following the procedure for "Negative Analytical Findings"<sup>337</sup>. Has no TUE been granted, or if the level of the prohibited substance in the sample is not consistent with the exemption, the ADO is required to continue the result management process as stipulated in case of an "A Sample Adverse Analytical Finding"<sup>338</sup>.

#### Ad d) **B** Sample Analysis

Once the ADO has determined that the Adverse Analytical Finding is not due to any irregularity and that no TUE applies, it is required to notify the Athlete in writing of the Adverse Analytical Finding and to inform him or her of his/her right to promptly request the analysis of the B-sample or, "failing such request, that the B-Sample may be deemed waived and the A Sample finding used as evidence of the Anti-Doping Rule Violation"<sup>339</sup>. If the analysis of the B-sample does not confirm the result of the A-sample analysis, the sample will be declared "negative" and the Athlete informed accordingly<sup>340</sup>. If the analysis of the B-sample however does confirm the result of the A-sample analysis, the ADO shall assert that there has been an Anti-Doping Rule Violation and notify in writing accordingly the Athlete, the Athlete's National Anti-Doping Agency, International Federations and WADA<sup>341</sup>, as well as the "appropriate disciplinary or Hearing body"<sup>342</sup>.

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<sup>333</sup> 

<sup>334</sup> Supra at 324, art 3.2.5, p. 9.

Supra at 324, art. 3.3.1, "Therapeutic Use (TUE)", p. 9. 335 Supra at 324, art. 4.4, "Therapeutic Use", p. 17 - 18.

<sup>336</sup> 337

Supra at 324, article 3.3.1, p. 9. 338

Supra at 324, art. 3.3.2 and art. 3.3.3, p. 9.

<sup>339</sup> Supra at 324, art. 3.4.1 sub f, "Notification After Initial Review", p. 10.

<sup>340</sup> Supra at 324, art. 3.5.7, p. 12.

#### Confidentiality during the result management process

4.100 It is clear that the very nature of the results management process requires that the identity of the Athlete involved is established. However, according to article 5.2 in Chapter V, "Identity of Athletes", of the RMG:

"The Athlete's and/or Support Personnel identity shall be kept confidential throughout the results management process. Only the Athlete or other Person who may have committed an Anti-Doping Rule Violation shall be notified. The Athlete's National Anti-Doping Organization and the International Federation and WADA shall be notified no later than the final determination."<sup>343</sup>

### Specific rules and regulations The 2004 Anti-Doping Rules of the UCI

4.101 The UCI has incorporated its adaptation of the results management process as detailed in the RMG in Chapter VII, "Result Management", of its "2004 Anti-Doping Rules". According to article 182 of the UCI 2004 Anti-Doping Rules the "UCI Anti-Doping Commission" (hereinafter: "Anti-Doping Commission") shall conduct results management under these anti-doping rules,

*"including results management from a test by a National Federation pursuant to articles 3 and 7"*<sup>344</sup>.

This means that the Anti-Doping Commission shall also conduct result management in case of "in-competition testing" at "International Events" as well as in case of "out- of-competition testing", regardless whether these tests have been initiated and directed by the UCI, the National Federation of the country where a particular "International Event" takes place, or any other organization or person authorised to do so by the UCI<sup>345</sup>. In cases involving a "Licence-Holder" who "usually does not participate in international events" however, results management shall be referred to the "Licence-Holder's" National Federation<sup>346</sup>.

4.102 The manner in which the Anti-Doping Commission is required to conduct its results management process is almost identical to the RMG procedure as discussed in the previous paragraphs, with some exceptions. Should, for instance, the Anti-Doping Commission consider that, having conducted an initial review, that no Anti-Doping Rule Violation, or any other breach of the UCI 2004 Anti-Doping Rules has taken place:

"then the case shall be taken no further. This decision shall not be definitive and the Anti-Doping Commission may reopen the case at its own initiation."<sup>347</sup>

<sup>341</sup> Supra at 324, art. 7.2, p. 16.

<sup>342</sup> Supra at 324, art. 7.3, p. 16.

<sup>343</sup> Supra at 324, art. 5.2., p. 14.
344 Supra at 11, art. 182,

<sup>345</sup> Supra at 11, artt. 3 and 7,.

<sup>346</sup> Supra at 11,Article 183,.

<sup>347</sup> Supra at 11,Article 184,.

The Anti-Doping Commission is however, required to inform WADA of its decision not to proceed with a case.

*"If WADA so requests, the Anti-Doping Commission shall reopen the case and request the National Federation to instigate disciplinary proceedings in accordance with article 224"*<sup>348</sup>.

#### Comparing practice with procedures

4.103 Keeping in mind the conditions which need to be met according to both the RMG, as well as the UCI Anti-Doping Rules, before an alleged Adverse Analytical Finding can be qualified as constituting an Anti-Doping Rule Violation and taking into account that the prohibited substance concerned is *r-EPO*, for which neither follow-up investigations are required nor a TUE has been granted to the rider, the actual results management process in this matter will be limited to determining (i) whether any irregularities might have occurred which "reasonably" could be considered to have undermined the validity of a presumptive Adverse Analytical Finding and (ii) whether a "B" Sample Analysis had been requested and, if so, confirmed the "A" Sample Adverse Analytical Finding or should be deemed to have been waived.

#### (i) Irregularities

According to article 186 of the UCI Anti-Doping Rules, the Anti-Doping Commission needs to determine whether there has been:

"any apparent departure from these Anti-Doping Rules, the Procedural Guidelines or the International Standards for Testing or laboratory analysis that undermines the validity of the Adverse Analytical Finding"

It has already been determined in this report that (a) the manner in which the urine samples form the 1999 Tour de France have been analyzed by the LNDD was only a preliminary screening test that contained a large number of departures from the *ISL* and *TD EPO*, as well as the *ISO/IEC 17025 International Standard* and that (b) the alleged *Adverse Analytical Findings* have been the result of the manner in which these urine samples were analyzed. The fact that no "A" Sample confirmation or stability test were ever even attempted and the fact that the screening method used for the analysis of the urine samples from the 1999 Tour de France was neither validated, let alone accepted by WADA, as the approved analysis method for the prohibited substance *r-EPO* -and as such representing a departure in its own right- means that the aforementioned alleged *Adverse Analytical Findings* should be declared void and consequently can not be qualified as constituting an Anti-Doping Rule Violation.

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#### (ii) B Sample Analysis

A "B" Sample analysis has not been conducted in this matter. Not because the rider concerned might be deemed to have waived his right to have one conducted -as a matter of fact, the rider concerned was never even notified of his right to have a "B" Sample analysis conducted- but simply because of the fact that there are no "B" Samples left available to be tested as such. As the original "A" Samples from the 1998 and 1999 Tours de France had already been used in 1998 and 1999 for conducting the regular doping control test requested, the only possibly unopened urine samples left from both Tours de France for conducting research were the original "B" Samples. As these urine samples have been opened and used by the LNDD for conducting its research, no unopened urine samples are left for conducting the mandatory required "B" Sample analysis. As there are no "B" Sample analysis results confirming the alleged results of the analyses already conducted by the LNDD, these urine samples have to be declared to be "negative".

It has been suggested that a "surrogate B sample analysis" could be conducted by using the urine left over from the analyses of the urine samples from the 1999 Tours de France, as not all of the urine from all of these urine samples has been used by the LNDD when conducting its research<sup>349</sup>. Any doubt as to the "origin" of the "leftover urine", i.e. the "identity" of the rider responsible for having provided the urine, could be avoided by submitting the "leftover urine" to a DNA-test first. It would, in other words, be impossible to attribute the analysis result of the "leftover urine" by mistake to the wrong rider. This suggestion however, completely fails to address the issue at stake here. Firstly, the "leftover urine" may not contain sufficient DNA for proper DNA testing. Secondly, there is no basis for requiring any of these riders to undergo DNA testing. Thirdly, the "B" sample analysis is not just meant to provide a verification of the result of the "A" sample analysis only, but to allow the athlete concerned to ascertain that the urine to be tested to verify the result of the "A" sample analysis, is the exact same urine as he or she originally provided at the time the urine sample had been collected and to preserve a record of everything that has happened to that urine sample from the moment it was given by athlete, including detailed information about everyone who had access to that sample and under what conditions the sample was stored, maintained, and secured. Once the "B" sample has been opened, and no chain of custody records have been maintained, such guarantee can no longer be given. It is for this very reason that the Athlete, or his or her representative, is always invited -in case of a "B" sample analysis- to be present at the opening of the "B" sample to prove that the "integrity" of the urine as contained in the sample collection bottle has

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For 74 of the 151 urine samples from the 1999 Tour de France used for conducting reserach, urine or "retentate", concentrated urine is left, which could be used, at least according to some, for conducting a surrogate B sample analysis. Supra at 146, p. 1 - 4.

remained intact. It also explains the importance being attached in the applicable rules and regulations with regard to maintaining the external, as well as internal laboratory chain of custody. As these urine samples have already been opened and even been used for conducting research, the "integrity" of these urine samples can no longer be guaranteed, thus rendering any confirmation testing on the basis of the "leftover urine" null and void. Conducting a DNA test could not change this.

In this case the first valid *r-EPO* analysis would still have to be conducted. Taking into account that the athlete has the right to request a "B" sample analysis and assuming that in this case the athletes concerned would certainly do so, two intact samples, the identity and integrity of which cannot be challenged, are needed. This is impossible in this case because there are no intact urine samples and the identity and integrity of the residual urine has been compromised and cannot be established at all.

## 5 Unanswered Questions, Conclusions and Recommendations

#### **Unanswered** questions

#### **Research reports**

5.1 The investigator does not know how the research reports of the LNDD came into the possession of Mr. Ressiot, the journalist of *L'Equipe*. These reports however, must have been provided either by the LNDD, the Ministry or WADA, as WADA and the Ministry had received copies of reports drafted and sent by the LNDD. The investigator regrets the lack of cooperation of these three bodies. It is clear that only a thorough investigation within each of them might find the answer to this important question, that affects the confidence that athletes, ADO's and the public are entitled to have in these bodies. The only thing the independent investigator can do is to list some facts and questions that he identified while conducting his investigation, which should be subject of further investigation.

#### When did L'Equipe receive the LNDD reports?

- 5.2 Ressiot writes in the article in L'Equipe of its August 23, 2005 edition: "L'Equipe has acquired the results of scientific analyses by LNDD". The final reports<sup>350</sup> were sent to WADA and the Ministry on August 22, 2005. A copy was sent by mail to WADA, to the attention of its Director General, David Howman. This mail was received by Mr. Howman at WADA's office in Montreal on August 25, 2005. Normally the Ministry would have received the report the day after it was sent, i.e. on August 23, the date of the publication in L'Equipe. The report might also have been forwarded to the Ministry by fax, e-mail or courier the same day. It is not excluded either that another copy of the reports was sent to other persons at WADA's office in Montreal or to WADA's Lausanne office, by mail, fax or e-mail.
- 5.3 Furthermore *L'Equipe* writes that the LNDD reports were sent to WADA and the Ministry "yesterday", i.e. 22 August 2005. *L'Equipe* writes also that it contacted Armstrong's lawyer "yesterday", i.e. the day that the LNDD reports were sent to WADA and the Ministry. *L'Equipe* received these reports (or the final version of these reports) before they were received by WADA and the Ministry (supposing the Ministry received them the day after they were sent only). The article "Trois cures pour six étapes" tries to reconstruct "three doping cures" in relation with the stages at which an allegedly positive sample was taken. Details on the course and ranking of each stage are given. The drafting of this article must have taken some time. The same applies to the other articles that have clearly been prepared in view of the revelation.

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The expression "final report" has been used by WADA in its answer of April 3, 2006 to question 8 of the investigator's questionnaire and has not been used by either the investigator, or any of the other parties involved. Supra at 94, p.3.

- 5.4 The investigator concludes from the article "Armstrong's Lie" that *L'Equipe* has been given the following information that does not originate from the LNDD report:
  - The analyses were done for research purposes;
  - The analyses were done in collaboration with WADA and the Ministry;
  - The research was done on the whole of 1998 and 1999 Tour samples;
  - Only B-samples have been analyzed.

This means that *L'Equipe* was given information before the final LNDD reports were sent out and was given more information than that contained in these reports.

5.5 In the same article it is written that:

"WADA, currently chaired by Richard W. Pound, would be currently studying possible legal recourses for not leaving these analysis results without consequences".

If this is correct, this suggests possible contacts between WADA and *L'Equipe* prior to August 23, 2005 and that *L'Equipe* and WADA may have discussed the contents of the reports and the possibility of further "consequences". Of course, this information could have come from the Ministry or the LNDD, based on their conversations with WADA. It confirms also that WADA had been asking for the "additional information" for disciplinary purposes. If there were contacts between *L'Equipe* and WADA, LNDD and/ or the Ministry prior to August 23, 2005, it would be important to know when these contacts started and what was their content. *L'Equipe* writes that it had been working on the case for a long time, more precisely 4 months which indicates that its inquiry would have started in April 2005.

#### What has been done during these four months?

- 5.6 It certainly took not four months to write the articles that were published on August 23, 2005. The analysis results were produced by the LNDD by the end of December 2004, or early in 2005. During the four months that *L'Equipe* is referring to (May-August 2005) the pressure by WADA, according to the LNDD, or requests, according to WADA, were continuing to obtain the sample codes and other *"additional information"*. It is likely that WADA must have known as from that time that there were "positives" indeed. WADA declared in April 2006 that its motivation was that it wanted the UCI to know to whom these "positives" belonged. It cannot be excluded, as was suspected by the LNDD, that WADA wanted to know that for its own purposes as well. In any case, WADA wanted to have the sample codes.
- 5.7 The articles in *Le Monde* of July 21 and 23, 1999 reveal that the press knew the contents of original doping forms of the 1999 Tour de France. If the press knew the contents, it is possible that the press was in possession of copies of the original forms at that time. Such copies may have been kept until now. The question arises then whether the samples codes assigned to the LNDD research results were not already in December 2004-January 2005 the only missing link to identify the riders?

Is it possible that WADA, the LNDD or the Ministry knew who was in possession of the forms or already knew how to find out the identity of the riders at that time?

- 5.8 WADA knew that it could ask the UCI to compare the data in the reports with the original forms in the possession of the UCI. WADA could have asked LNDD to send its reports with the sample codes to the UCI only, the competent body for results management. WADA didn't need to have the samples codes itself, especially as WADA has claimed that it had no jurisdiction in this case. Once it knew that the UCI had received the reports, WADA could ask the UCI to follow up and identify the riders concerned. WADA knew as well that UCI could and would identify the riders, but probably reckoned that UCI might not make this identification public, might conduct any results management process under its confidentiality rules and might not consider the reports as a sufficient basis for disciplinary action. However, why did WADA want the reports sent to WADA with code numbers if WADA did not have the forms and did not anticipate receiving them?
- 5.9 Also, the LNDD had stipulated vis-à-vis WADA that WADA should keep the reports confidential and that the data contained therein should not be used for disciplinary purposes. So it is not impossible that WADA took the position that it was not entitled to pass the reports to the UCI and was certainly not entitled to ask the UCI to start disciplinary proceedings, without breach of contract vis-à-vis the LNDD. The investigator finds an indication for this in the fact that immediately upon the publication in *L'Equipe*, WADA asked the UCI to undertake an inquiry and further action on the basis of the publication in *L'Equipe*, not on the basis of the LNDD reports, a copy of which was sent by WADA to the UCI only by letter dated September 14, 2005. Therefore, if it would have been the intention of somebody to make the identification of the riders public and also to force the UCI to conduct further investigations in public, two ingredients were needed: (i) the leaking of the report with the sample codes and (ii) the forms.

#### Ad. (i): the leaking of the report

5.10 The contents of the LNDD reports including the additional information never should have been made public if the rules would have been followed and never would have been made public without the leak. The leak of the LNDD reports made public that riders, and Lance Armstrong in particular, might have been using *r-EPO* in 1999 and, apart from putting Armstrong and cycling in an unpleasant position, put public pressure on the UCI to investigate the matter further. WADA did not fail to point this out to the UCI:

"Now this matter is one of public record, UCI will fully inquire to ensure that it is appropriately addressed publicly in the interest of transparency. The matter requires full public attention."

WADA seemed to forget that there should have been no more publicity than imposed or allowed by the *WADA Code*.

- 5.11 One cannot but find also that, where on the one hand WADA claims to have asked the LNDD for the 'additional information' in order to enable UCI to act "in accordance with its rules" and, on the other hand, the conditions imposed by the LNDD prevented WADA to use that information for that purpose, the leak was, from a purely objective point of view, at best a coincidence that changed the situation. If one accepts that it would have been no use to pass the LNDD reports without publicity to UCI because it was not to be expected that UCI would make a case on this basis, it was no use either to insist that the LNDD provide the "additional information". This could mean that "additional information" would only be useful if one had at its disposal a copy of the forms with the code numbers and the names.
- 5.12 For *L'Equipe* the leak can be considered as a matter of professional interest and prestige. For the journalist, Ressiot, it was also a personal challenge, as he claimed to have acted in reaction to Lance Armstrong's challenge to the press that if they suggested that he took doping, they should prove it. However, *L'Equipe* was the beneficiary of the leak. More serious is the question who from WADA, LNDD and the Ministry leaked the report. WADA and the Ministry are ADO's and LNDD is a WADAaccredited laboratory. Respect for confidentiality imposed by the rules, is of critical importance for the confidence of all stakeholders of the fight against doping.
- 5.13 It is known that *L'Equipe* has (had) access to confidential information regarding doping analysis in the LNDD as is shown by the fact that *L'Equipe* has announced more than once positive results, even before the International Federation concerned was informed. Respect for the freedom of the press should not prevent the LNDD or the Ministry or whatever authority to investigate this and see that the confidentiality rules are respected. On the other hand the LNDD has assured the investigator in this case that during six months it has opposed the request of WADA to have the additional information included in the reports. The LNDD and the Ministry have stipulated strict confidentiality. This however does not exclude a leak in the LNDD or the Ministry, in particular one that might have been caused by other individuals than those who stipulated confidentiality. The statements by Professor De Ceaurriz to the media also call into question his understanding of and his commitment to athlete confidentiality.
- 5.14 The copy of the report shown in *L'Equipe* is obviously not a print of the copy that arrived at WADA on August 25, 2005 but there might have been other and earlier copies than those that have been sent out on August 22, 2005. Also, *L'Equipe* might have, and there are indications for thinking so as it was working on the case for four months, the information contained in the final report before this final report was sent out. As indicated above, the articles that were published on August 23, 2005, must have been prepared before. Apparently *L'Equipe* knew that the research was going on or that it had been conducted, some time before August 23, 2005. UCI was not informed. In fact, it is reasonable to conclude that prior to Mr. Ressiot's visit to the UCI, he already was in possession of, or believed he would receive a report of, allegedly positive urine tests from the 1999 Tour de France, identified

with the original doping control numbers. Mr. Ressiot was only interested in Lance Armstrong's forms from the 1999 Tour de France and those forms would have been useless to him without the LNDD report.

5.15 Finally there is the conclusion of the investigator that WADA must have been targeting the riders, and in particular Lance Armstrong, as well as the UCI. It has been mentioned before that the LNDD had the strong impression that the "additional information" had been requested with the intention to determine the identity of one or more riders. There is the admission of WADA in its reply of April 3, 2006 that the "additional information" was requested to enable the UCI to apply its (anti-doping) rules, despite WADA's eventual agreement that the results would be confidential and would not be used "for any sanction purpose". There is the fact that WADA and Dick Pound had no interest in LNDD's published report in 2000 in Nature magazine of multiple positive results associated with the 1998 Tour de France (perhaps because those tests, like the research testing at issue in this case, did not satisfy the standards for pursuing a sanction against an athlete, and could not be used for those purposes under the same rules that govern this situation). The 1998 Tour de France was the last Tour de France in which Lance Armstrong did not compete, and in this case the only rider from either the 1998 or 1999 Tour de France who has drawn Dick Pound's attention or comments has been Lance Armstrong. There is the fact that WADA's aborted investigation in October 2005 consisted solely of directing questions to the UCI and to Lance Armstrong, seeking to put the burden on them of disproving the reports from the LNDD. There is also the well-known and public feud between WADA president Dick Pound and former UCI president Hein Verbruggen. There are also the public statements of Dick Pound on doping in cycling. There is a statement of Pound in Le Monde of January 28, 2004 that

#### "the public knows that the riders in the Tour de France and the others are doping".

This statement caused Lance Armstrong to write a public letter to Dick Pound that was published in some newspapers in March 2004 and that was, to say the least, not friendly to Dick Pound. Lance Armstrong asked Pound in particular to

"focus (his) efforts on the fight against doping rather than spending (his) time accusing innocent athletes without any evidence other than your own speculation".

5.16 WADA and Pound were apparently surprised that an individual rider had taken it upon himself to respond to Pound's comments, when Pound had apparently been careful not to identify any individual rider by name. Pound responded harshly to Armstrong's letter:

"[Mr. Pound] considers it surprising that Mr. Armstrong has attacked in such virulent fashion someone who he has never met, and who never mentioned his name, not expressed any doubts concerning his exploits," said WADA spokesman Frederic Donze. *Mr.* Pound insists that nobody would be happier than he if cycling became a sport free from doping," the statement continued. "But recent events lead one to believe that there is a certain amount of work to be done."

Pound, for his part, added that "WADA relies on the collaboration of champions like Mr. Armstrong and sporting organizations such as the UCI in the fight against doping in sport."

The UCI, by Hein Verbruggen, echoed Armstrong's criticism of Pound's public statements:

The President of the UCI, Hein Verbruggen, shared Armstrong's concern over the comments made by Pound, which appeared originally in an interview with French newspaper Le Monde on January 28.

"WADA should play the same role as the United Nations," Verbruggen said. "And I have never heard UN boss Kofi Annan talk like Dick Pound. Pound shoots at everything that moves. At the athletes, at the governments, at the European community. But WADA doesn't only stand for repression. With his comments he's giving his organization a bad image."

- 5.17 All these are elements that the investigator feels have to be mentioned. They eventually prove nothing as to the source of the leak of the LNDD reports, but cannot be left unmentioned in the context of this investigation, if only to underline the necessity, in the interest of the proper functioning of the bodies responsible for the fight against doping, for further investigation concerning the leak by authorities with the ability to compel cooperation and more possibilities of investigation than those that have been to this point at the disposal of the investigator.
- 5.18 As for the question of the leak of the LNDD reports, all these are elements that do not allow for definite conclusions to be drawn at this moment, but they underline the need for further investigation.

#### Ad (ii) The forms

- 5.19 It is clear that *L'Equipe* obtained copies of the original doping forms concerning Lance Armstrong from the UCI in the circumstances described above. The investigator feels that there still is some uncertainty concerning the exact number, but on the other hand UCI has accepted that of all 15 forms concerning the testing of Lance Armstrong in the 1999 Tour de France (15 tests), a copy could have been given to the journalist of *L'Equipe*. It is not clear, on the other hand, whether the copies provided by the UCI were the only ones at the disposal of *L'Equipe*.
- 5.20 On page 3 of its August 23, 2005 edition, *L'Equipe* writes that the documents making it possible for matching code numbers and the name of Armstrong, were "kept in different places". The articles in Le Monde of July 21 and 23, 1999, establish that the

press knew the contents of original doping forms of the 1999 Tour de France at that time. Copies of the original forms might have been in the possession of the press as from that time. Besides the UCI, only the Ministry had original forms from the 1999 Tour de France. Dick Pound made statements to the media about a requirement that the forms be destroyed two years after the samples were taken and he made representations about which organizations had destroyed their copies on schedule (in 2000 for the 1998 Tour and 2001 for the 1999 Tour). He never disclosed the basis for his representations about those issues and why he was so interested in establishing that certain organizations had not retained their copies. It is a fact, but not more than that, that at that time M. Garnier, currently director of WADA's office in Lausanne, was responsible for the Ministry's anti-doping department. The articles in Le Monde of July 21 and 23, 1999 indicate that it cannot be excluded that copies may have been made and circulated before the originals, as the Minister has represented to the UCI, were destroyed in 2001 at the latest. It may therefore not be excluded that WADA and/ or L'Equipe possessed copies of original forms before Ressiot came to the UCI and asked for a copy of the UCI's forms. If this were the case, the copy of the UCI forms may be just camouflaging the original scource of the copies of forms, which were already in the possession of *L'Equipe*.

#### Continuance of the investigation

5.21 An investigation needs to focus on the communications between Dick Pound and the media and between Professor De Ceaurriz and the media.

There are a number of troubling facts that raise serious questions.

- a. Dick Pound insisted that the "additional information" be included in the LNDD reports, at about the same time that Mr. Ressiot was engaging in deceptive conduct to secure copies of Lance Armstrong's forms from the UCI. Did Mr. Ressiot already have copies of Lance Armstrong's doping control forms from another source and was he merely seeking to secure those same forms from the UCI in order to protect his initial source of the forms?
- b. Mr. Ressiot explained that he was targeting Lance Armstrong, in part because Lance Armstrong had criticized Dick Pound.
- c. The August 23, 2005, article by Mr. Ressiot suggests that he had been communicating with the LNDD and WADA prior to the publication of his article, and there is reason to believe that in those communications Mr. Ressiot disclosed his awareness that the LNDD had reported positive results from the 1999 Tour de France. What steps did WADA or the LNDD take to protect athlete confidentiality after their communications with Mr. Ressiot?
- d. Professor De Ceaurriz has expressed publicly his disdain for athlete confidentiality and his views, contrary to the applicable laws and regulations, that athletes are not entitled to confidential treatment of their urine samples and the results of testing conducted concerning those samples.
- e. Dick Pound violated his promises of confidentiality made to the LNDD.
- f. Prof. De Ceaurriz, after allegedly insisting that Dick Pound acknowledged the legal

requirement of confidentiality, apparently violated it before or as soon as the first *L'Equipe* article was published.

- g. Both Dick Pound and Professor De Ceaurriz have made statements to the media which have falsely supported the idea that the results reported by the LNDD are reliable indicators that Lance Armstrong used *Prohibited Substances* when Professor Ceaurriz knew and Dick Pound should have known their statements were not true.
- h. The statements by Pound and De Ceaurriz to the media were improper and violated various regulations and laws concerning athlete confidentiality, as well as the promises of confidentiality exchanged between WADA and the LNDD.
- i. WADA and the LNDD have refused to provide the investigator with any documents concerning their dealings with the media or documents to support any of their other assertions in this matter.
- j. Dick Pound apparently received from Mr. Ressiot copies of the doping control forms Mr. Ressiot received from the UCI, and it appears that in September 2005 Mr. Pound knew that Mr. Ressiot had received all of Lance Armstrong's 1999 Tour de France forms from the UCI.
- 5.22 The investigator calls upon WADA, the LNDD and the Ministry to submit themselves to an investigation by an outside independent authority, or where applicable, their statutory body. If these parties involved, will not comply to this request the investigator appeals to the IOC, the WADA Board, or some other organization with the power to compel compliance to order all LNDD and WADA personnel to produce all documents and to cooperate fully with the independent investigator to resolve as many of these unsettling open questions as possible.

#### Conclusions

- 5.23 Although no documentation has been made available, it is the opinion of the independent investigator that it may be accepted that the samples from the 1998 and 1999 Tours de France have been analysed by the LNDD for research purposes. WADA however, while claiming initially that the samples had been analysed for research purposes only, asked the LNDD to provide additional information, in particular the original codes of the samples that were analysed.
- 5.24 It is the conclusion of the investigator that WADA had also the intention that the research results, in combination with the additional information requested by WADA, be used for disciplinary purposes against individual athletes, directly contrary to its representation that the results would not be used "for any sanction purpose". In this sense one can speak of targeting by WADA of the participants of the 1998 and 1999 Tours de France.
- 5.25 The investigator is aware that on the other hand there were the conditions of LNDD that the information contained in its reports was to be kept confidential and was not to be used "for any sanction purpose".

- 5.26 The research was conducted on samples, a great number of which had been opened and analysed before. There is no internal chain of custody. The identity and integrity of the samples is not guaranteed.
- 5.27 The samples were analysed following a non-disclosed and non-validated "accelerated measurement procedure" only, that departed in essential aspects from the mandatory provisions of WADA's laboratory and testing standards in general and *r-EPO* testing requirements in particular. The investigator leaves aside whether these departures are acceptable in view of the research purposes.
- 5.28 The conclusion of the investigator is that the results reported by the LNDD in its research reports on the 1998 and 1999 Tours de France cannot be qualified as constituting Presumptive Analytical Findings, much less *Adverse Analytical Findings* and consequently do not provide proof of an Anti-Doping Rule Violation.
- 5.29 The investigator has had no indication whether the "appropriate exchange of correspondence" or oral contacts between WADA and LNDD might have led to preventing that proper information on the "accelerated measurement procedure" and its limitations was inserted in the reports. The following conclusion should be read with this reservation.
- 5.30 The LNDD failed to include in its reports information on the lack of chain of custody, on the analysis method that was used and on the deviations of the mandatory procedures for analysing urine samples for *r-EPO*. Had the LNDD, as it should have, included such information in its reports, it would have been clear immediately to anyone that a debate regarding the question whether any of the findings might qualify as evidence of doping, would have lacked any ground.
- 5.31 The investigator found no confirmation for WADA's contention that it was made to believe by LNDD that the mandatory required analysis procedures for *r-EPO* had been used. The investigator finds it difficult to reconcile WADA's contention with the fact that it accepted to keep the research results confidential and would not seek to use them for disciplinary purposes.
- 5.32 WADA's request to have the sample codes and other additional information included in the research reports is a violation by WADA of applicable rules, including the *WADA Code*, WADA standards and the stipulation on WADA's doping control form that samples used for research must not be identified as a particular athlete's sample.
- 5.33 The LNDD violated applicable rules on athlete confidentiality by accepting to provide additional information, in particular the sample codes, to WADA. This applies notwithstanding the condition of strict confidentiality stipulated by the LNDD.

- 5.34 The LNDD violated applicable rules on athlete confidentiality by commenting publicly on the alleged positive findings, especially in relation with a particular rider, Lance Armstrong.
- 5.35 WADA violated applicable rules on athlete confidentiality by commenting publicly on the alleged positive findings, especially in relation with a particular rider, Lance Armstrong.
- 5.36 There is no factual basis to find that there has been an Adverse Analytical Finding, let alone that an Anti-Doping Rule Violation could be asserted. There is no way to conduct valid additional analysis of any remaining urine. Consequently, there is no basis for disciplinary action against any rider.

#### Recommendation

5.37 Taking into account the conclusions drawn in this report as at this stage of the investigation, the UCI is recommended to refrain from initiating any disciplinary action whatsoever regarding those riders alleged to have been responsible for causing one or more alleged "Adverse Analytical Findings", on the basis of the confidential reports of the LNDD "Recherche EPO Tour de France 1998" and "Recherche EPO Tour de France 1999", and should inform all of the riders involved that no action will be taken based on the research testing by the LNDD.

Emile N. Vrijman MCL Scholten c.s. Advocaten © The Hague

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