Report

Independent Investigation

Analysis Samples from the 1999 Tour de France



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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 forms1 - 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'. 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.
- 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;'

<sup>2</sup> 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;' 4
- 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.'6

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).

<sup>7</sup> 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 paid8.

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).

<sup>9</sup> 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 years (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

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.

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

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. 17

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'.'

[...]

Ex. 1, Damien Ressiot, "Le mensonge d'Armstrong", L'Equipe, August 23, 2005.

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.

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.''18

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' 19. 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>

[...]

'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.

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

<sup>21</sup> Id.

'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." 22

### 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." 23

[...]

'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>.

<sup>22</sup> 

Ex. 6, Letter from David Howman, Director - General, WADA, to Hein Verbruggen, President, UCI, (August 25, 2005). 23

<sup>24</sup> 

Ex. 7, UCI Press Release, 'Analysis of 1999 Tour Samples: Soon the UCI Conclusions', UCI, (August 29, 2005). 26

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. '28

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...???'29

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

<sup>27</sup> I

<sup>28</sup> Ex. 9, Letter from Hein Verbruggen, President, UCI, to David Howman,, Director – General, WADA, (August 30, 2005).

<sup>29</sup> Ex. 10, Letter from Hein Verbruggen, President, UCI, to David Howman, Howman, Director – General, WADA, (August 30, 2005).

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

 $<sup>{\</sup>tt Q.} \quad \hbox{\it `Wie steht die WADA zu den Anschuldigungen gegen Lance Armstrong?}$ 

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.'31

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.

<sup>31 10</sup> 

 $<sup>{\</sup>tt Q.} \quad \hbox{\it Wie glaubwurdig ist das farnzosische Dopingkontrollabor, in dem die Urinproben nachtraglich getested wurden?}$ 

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.'

<sup>32</sup> Ex. 12, "Pound slammed by WADA's vice-president for Armstrong accusation", www. Bikingbiz. co.uk, September 6, 2005.

<sup>33</sup> Id.

<sup>34</sup> Ex. 13, Letter from Hein Verbruggen, President, UCI, to David Howman, Director – General, WADA, (September 5, 2005).

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."36

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.'38

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Ex. 15, Letter from David Howman Director - General, WADA, to Hein Verbruggen, President, UCI, (September 9, 2005).

<sup>37</sup> Ex. 16, Letter from Richard Pound, President, WADA, to Hein Verbruggen, President, UCI, (September 14, 2005). 38

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.'41

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.

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<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.

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

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. 46

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. 47

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:

<sup>43</sup> 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).

<sup>44</sup> 45 Ex. 20, John Stevenson & Les Clarke, 'UCI denies leaking Armstrong documents', Cycling News, September 20, 2005.

<sup>46</sup> 

<sup>47</sup> 

<sup>48</sup> 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'49,

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'51.

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

<sup>9</sup> Ex. 22, Letter from Hein Verbruggen, President, UCI to David Howman, Director – General, WADA, (September 21, 2005).

<sup>50</sup> Ex. 23, Letter from Hein Verbruggen, President, UCI to David Howman, Director – General, WADA, (September 29, 2005).

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

<sup>52</sup> I

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. 53

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.'54

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. '55

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'57.

'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.'58

### 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

<sup>56</sup> 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> I

<sup>58</sup> Id.

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 60.

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

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

<sup>60</sup> Id

<sup>51</sup> I

<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 prologue 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 prologue 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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<sup>64</sup> ld.

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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, 2005<sup>67</sup>. 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.'73

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.' 75

<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].

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).

<sup>73</sup> Ex. 36, Letter from David Howman, Director – General, WADA, to Emile Vrijman, independent investigator, (October 13, 2005).

<sup>74</sup> 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.'76

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. '78

# 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' 79. According to this letter, the inquiry aims to:

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

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<sup>79</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.'80

### 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.'81

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. 82

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

<sup>82</sup> 

<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. 85

<sup>86</sup> Ex. 41, UCI Press Release, 'Official Statement', UCI, February 27, 2006.

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. '88

- 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 France-it 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 because he was preparing an article dealing with the question whether 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>7</sup> Interview with UCI Vice – President HeinVerbruggen, March 15, 2006.

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. '91

<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> Id

#### **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'95.

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

<sup>92</sup> 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).

<sup>93</sup> 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).

<sup>94</sup> 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' '96.

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'.

<sup>97</sup> 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>

99

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

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

<sup>100</sup> Ex. 50, Emile Vrijman, independent investigator, Preliminary Questions to the LNDD, (November 11, 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>.

#### 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.'104

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 105. 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 questionnaires 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.

<sup>103</sup> Ex. 53, E-mail and attached memo from Richard Pound, President, WADA, to Lance Armstrong, cyclist, (August 30, 2005).

<sup>104</sup> Id.

<sup>105</sup> 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.'106

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 [...].'108

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.'111

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

<sup>107</sup> 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>109</sup> Ex. 57, Letter from Emile Vrijman and Paul Scholten to the legal representative of the LNDD, (January 17, 2006).

<sup>110</sup> Ex. 58, Letter from the legal representative of the LNDD to Emile Vrijman and Paul Scholten, (January 27, 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.' 116

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>.

<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).

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

<sup>116</sup> Id

<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

#### 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.

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"129,

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" 130.

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."

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

<sup>&</sup>quot;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".

<sup>&</sup>quot;Coordination of anti-doping research through WADA is encouraged. Subject to intellectual property rights, copies of anti-doping 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).

<sup>127</sup> 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, 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.

<sup>128</sup> 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.

<sup>129</sup> Supra at 36.

<sup>130</sup> Supra at 36.

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 136. 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." 137

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> Ic

<sup>134</sup> Supra at 94, p. 7.

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

<sup>136</sup> Supra at 94, p. 1 – 2.

<sup>137</sup> 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 139. 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 140.

# 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." 142

"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." 143

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.

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

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." 149

# 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" 150. However, in his interview with "De Volkskrant" 151, 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 152.

# 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  $\mu$ l) 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,

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>147</sup> Supra, at 144.

<sup>148</sup> Supra, at 101.

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

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

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

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> Id.

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 155. 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 156.

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>1</sup>d. "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".

<sup>156</sup> I

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  $^{157}$ . 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" 158 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;

159 Supra, at 141 and 146.

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".

- 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." 161

#### 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."  $^{162}$ 

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:

<sup>&</sup>quot;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.

<sup>162</sup> 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." 164

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." 165

# 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

164 Supra at 101.

165 Id.

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

- 1. 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
- 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" 166.

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" after having been analysed;

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

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

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.

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." 173

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." 174

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", $^{175}$ 

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." 176

<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.

<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." 177

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 178, 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" 179.

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." 180

Furthermore.

"It is our understanding that all analyses were conducted in accordance with the usual EPO method. Furthermore, points  $(d)^{181}$  and  $(e)^{182}$  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."  $^{183}$ 

<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 WADA-accepted 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"-

<sup>179</sup> 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 continuously at a temperature of – 200C during the period of time they were kept in storage at the laboratory?"

<sup>183</sup> 

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." 184

### 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 185.
  - 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." 186

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

<sup>185</sup> Supra, 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.
- 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, [...]." 187

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

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." 188

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." 189

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".

<sup>188</sup> 

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- $EPO^{190}$ .

### 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." 191

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." 194

<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.

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" 195.

# 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 196, 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" 197.

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." 198

Conducting research and having a research program is, however, just as much a mandatory requirement for laboratories wanting to maintain their WADA-accreditation. 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." 1999

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

<sup>&</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, [...]."203

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." 2014

Supra at 196, art. 6.4.5, "Document implemented research activities", p. 40.

Supra at 196, Annex B, "Laboratory Code of Ethics", art. 2.2, "Human subjects", p. 54.

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" <sup>206</sup>.

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"<sup>210</sup>.

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>.

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.

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.

<sup>209</sup> Id

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

<sup>211</sup> Id.

# 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

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.

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

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.

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 $^{217}$ . 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 $^{218}$ . 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 $^{219}$ . 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

- 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

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.

Supra at 196, ANNEX B, "Laboratory Code of Ethics", art. 2, p. 54-56.

<sup>219</sup> Supra at 128.

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."221

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." 222

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?

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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Supra at 75.

<sup>227</sup> 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"228.

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> ld.

<sup>230</sup> 

<sup>231</sup> ld.

### 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." 233

implying that the LNDD had never been obliged to obtain informed 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" Code" 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>232</sup> Supra, at 36.

<sup>233</sup> 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" 241. 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" 242. The IOC Medical Code does not contain a provision regarding the (long-term) storage of "B" specimen corresponding to an analytical negative "A" sample.

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

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

<sup>240</sup> Supra at 238, art.1.3.4, p.37.

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

<sup>242</sup> 

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" 243. 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 question 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." <sup>246</sup>

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." <sup>247</sup>

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

<sup>245</sup> Supra at 202, par. 9, p. 2.

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

<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." 250

### 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.

249 Id.

250 I

<sup>248</sup> Id.

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.

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 quantification and to exclude any technical deficiency in the screening procedure<sup>257</sup>.

#### Urine testing

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  $not^{258}$ . 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 List as appropriate for which there is a WADA-accepted screening method. However, WADA may make specific exceptions to this section.

<sup>257</sup> Id

<sup>258</sup> Supra at 196, art. 5.2.4.1, p. 19.

"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." 260

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" 263.

<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.

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.

A "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.

<sup>269</sup> Id.

<sup>270</sup> Id

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

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"<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" 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.

# 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.

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

1. 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.

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 of calibration certificate;
- k) where relevant, a statement to the effect that the results relate only to the items tested or calibrated."284

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.

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."<sup>285</sup>

# Specific rules and regulations

#### Technical Document - TD2004EPO

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"<sup>286</sup>. 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." <sup>287</sup>

### The Helsinki Declaration

4.64 What has been argued before regarding the applicability of the ISO/IEC 17025 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 WADA-accredited 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", WADA-accredited 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> Id

<sup>288</sup> 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" 289.

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

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).
- 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"292. 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

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" 293.
- 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."294

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>.

Supra at 102.

<sup>294</sup> 295 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" 297.

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." 299

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

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."<sup>300</sup>

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" 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 unofficial-regardless 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.

<sup>303</sup> 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 safeguard their integrity must always be respected"305.

"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.

304

WADA, WADA doping control form, version 3, March 2005.

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

<sup>306</sup> lo

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 safeguards 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

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 "309".

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."310
- 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

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."311

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"313.

## 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."314

#### 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."315

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." 316

## 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:

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

<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."317

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" 18. 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 19.

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

#### The UCI

- 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

<sup>317</sup> Supra at 11, art. 292, "Duty of confidentiality", Chapter XII "CONFIDENTIALITY AND PUBLIC DISCLOSURE", p. 42.

<sup>318</sup> 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" 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"324.

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

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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.

<sup>24</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" 325. 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"326. 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" 328 and "immediately inform the Athlete's International Federation and WADA"329.

#### 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.

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."<sup>334</sup>

#### 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" 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 440. 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 341, as well as the "appropriate disciplinary or Hearing body" 342.

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Id.
Supra at 324, art 3.2.5, p. 9.
Supra at 324, art. 3.3.1, "Therapeutic Use (TUE)", p. 9.
Supra at 324, art. 4.4, "Therapeutic Use", p. 17 – 18.
Supra at 324, article 3.3.1, p. 9.
Supra at 324, art. 3.3.2 and art. 3.3.3, p. 9.
Supra at 324, art. 3.4.1 sub f, "Notification After Initial Review", p. 10.
Supra at 324, art. 3.5.7, p. 12.
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#### 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." 343

#### 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"344.

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.

<sup>344</sup> 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"348.

#### 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.

#### (ii) B Sample Analysis

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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 quarantee 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

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.

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 WADA-accredited 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 quaranteed.
- 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

# vérité sur Armstron

Des traces d'EPO ont été retrouvées à six reprises dans les urines du Texan lors de son premier Tour victorieux, en 1999.

#### « Pas de commentaires à chaud »

Le Texan, par la voix de son avocat, n'a pas souhaité réagir en l'étai. Mis au coman ders le étail de sus infonostions hier en éthut de sokée. Mis au comand ders le étail de sus infonostions hier en éthut de sokée. M's bondé Massas, l'avocat de la bons Armistros, a pu britèrement joindée son client, actuellement aux Étas-Unit, qui n'a pas souhaité les commenter en l'étai.

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CRAWFORD. — À l'heure d'une premenade en VTT bucolique et décontractée en compagnie de son ami et président George W. Bush, samed passé, Lance Armstrong ne se doutait encore de rien. Il n'aura par profile longlemes de la paisible retraite à laquelle il aspirait : le voilò pris dans la grande tourmente...

### « Je ne prends pas et je n'ai jamais pris de drogues qui favorisent la performance »

Depuis son retour à l'issue de sa maladie, Lance Armstrong a mainte fois répondu aux auspicions de dopage à son encontre. Àce jour et alors que ses mensonges sont avérés dans ces colonnes sur su consommation d'EPO en 1999, l'analyse de son discours des sept demières années est éclairant. Morceaux choisis.

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L'Équipe du 20 juillet 1999,

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L'Équipe du B juillet 2001.

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L'Équipe du 12 avril 2001.

L'équipe du 12 avril 2001.

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Communiqué du 21 janvier 2003.

L'ŒIL DU PROFESSEUR AUDRAN (\*)

#### « EPO : l'analyse rétroactive reste efficace »

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Analytical Biochemistry 311 (2002) 119-126

ANALYTICAL BIOCHEMISTRY

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# Detection of isoelectric profiles of erythropoietin in urine: differentiation of natural and administered recombinant hormones

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Received 27 March 2002

#### Abstract

Erythropoietin (EPO) is normally present in urine at a low concentration (about 1 IU/L, i.e., about 10 ng/L) for a total protein concentration of at least 50 mg/L. A method to study the isoelectric profile of this hormone from 20-ml urine aliquots without previous purification was developed. This method involves isoelectric focusing of the retentate from ultrafiltered urine. Both the ultrafiltration and the isoelectric focusing required precautionary measures to prevent EPO degradation by the proteases that are present in urine. Because classical immunoblotting gave rise to an unspecific detection of various urinary proteins in the focused retentate, it was essential to use the "double-blotting" process developed to solve this problem. Sufficient sensitivity was achieved using amplified chemiluminiscent detection after the blotting membrane was treated with dithiotreitol. The patterns that were revealed from various urinary samples proved to be highly heterogeneous as they were composed of more than 10 isoforms in a pI range of 3.7-4.7. Clear transformation of the patterns was observed in the case of treatment by the recombinant hormone, suggesting that this method can be regarded an efficient tool for indicating recombinant EPO misuse in sports. It may also open new investigations in the field of physiologic or pathologic exploration.

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Erythropoietin (EPO)<sup>1</sup> is a glycoprotein hormone produced by the kidney in adult humans. It stimulates red blood cell production by promoting the proliferation and differentiation of erythroid progenitor cells. Since 1985, recombinant human EPO (rHuEPO) has been available for therapeutic use in certain forms of anemia [1]. This hormone, however, quickly became misused as a doping agent for endurance athletes to improve aerobic performances, and the International Olympic Committee officially prohibited it in 1990.

Wide et al. [2,3] reported a lower negative median charge of rHuEPO in comparison with the natural

hormone. In their studies, they used zone electrophoresis, at pH 8.6, of serum and urine in agarose suspension, with subsequent determination of the EPO concentration in the different fractions eluted from the electrophoretic column. These authors proposed this method for antidoping control but, because of considerable practical difficulties, it has never been applied in antidoping laboratories.

It is well known that both the natural and the recombinant form of EPO present extensive microheterogeneity in relation to posttranslational modifications in proteic moiety. Many investigations have focused on the glycosylation of this hormone since it is particularly developed and substantial with respect to its biological properties [4]. All studies have demonstrated that glycosylation is substantially implicated in the hormone's microheterogeneity [5,6]. Other modifications that have not yet been clearly investigated in the case of EPO, however, may also contribute to this heterogeneity. Some of these posttranslational events are influenced by the nature and the environmental conditions of the cell that produces the

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<sup>&</sup>lt;sup>1</sup> Abbreviations used: EPO, erythropoietin; CHO, Chinese hamster ovary; PBS, phosphate-buffered saline; MWCO, molecular weight cutoff; ELISA, enzyme-linked immunosorbent assay; IEF, isoelectric focusing; BSA, bovine serum albumin; DB, double-blotting; DTT, dithiotreitol.

protein. Since human natural and recombinant EPO are synthesized in human kidney and Chinese hamster ovary (CHO) cells, respectively, some of these modifications may be different in the two hormones. In so far as these modifications affect their electrical charge, the resulting molecules can be separated into isoforms by appropriate techniques. Differences in their isoelectric profiles thus seemed to be a potential means to differentiate between natural and recombinant EPO. We report here a method that was developed to investigate the isoelectric profiles of this hormone in urine.

#### Materials and methods

#### Urine samples

Urine samples were obtained from healthy controls and rHuEPO-treated volunteers at different postinjection times during an administration trial (subcutaneous injections of Eprex 4000 from Janssen-Cilag at decreasing doses from 50 to 20 IU/kg, three times per week for 7 weeks). The details of this trial will be published at a later date. All the samples were kept frozen at -20 °C until they were analyzed.

#### Reagents

The recombinant EPO was from Janssen-Cilag (France) as Eprex for Epoetin a, from Roche as NeoRecormon for Epoetin B, and from Amgen as Aranesp for Darbepoetin a. Protease-free Tris and glycine were from Acros Organics, NaCl was from Panreac, and sucrose was from USB. Ampholytes Servalyt 2-4. 4-6, and 6-8 were from Serva. Phosphate-buffered saline (PBS) (0.01 M sodium and potassium phosphate buffer, pH 7.4, containing 2.7 mM potassium chloride and 0.137 M sodium chloride), dithiothreitol (DTT), and N-acetyl-D-glucosamine were from Sigma. Purified Tween 80 was from Pierce. The protease inhibitor cocktail, Complete, and pepstatin were from Roche. Sterislip microfiltration (0.22 µm) units, Centricon-plus 20, and Centricon YM 30 ultrafiltration (molecular weight cutoff (MWCO) 30,000 Da) units, and Durapore (0.65 µm) and Immobilon-P (0.45 µm) membranes were from Millipore. Urea Plus one and wheat germ lectin Sepharose 6MB (WGA Sepharose) were from Amersham Biosciences. The enzyme-linked immunosorbent assay (ELISA) for human EPO Quantikine IVD and monoclonal mouse anti-human EPO (AE7A5) were from R&D. Biotin-labeled purified goat antibodies to mouse IgG were from P.A.R.I.S (France). Streptavidin:biotinylated peroxidase complexes were from Biospa (Italy), nonfat dry milk was from Régilait (France), and chemiluminescent substrate Covalight was from Covalab (France).

#### Ultrafiltration of urine

Urine was kept frozen at -20 °C until it was prepared. After thawing at room temperature, 2 ml of 3.75 M Tris/ HCl. pH 7.4, and 0.4 ml of Complete solution (1 tablet in 2 ml of water) were added to 20 ml of urine. After centrifugation at 2700 RCF and 20°C for 10 min, the supernatant was microfiltered under vacuum through a 0.22-um Steriflip device. This filtrate was then submitted to a first ultrafiltration in a Centricon Plus-20 (MWCO 30,000 Da) by centrifugation at 3570 RCF and 20 °C for 20 min. The retentate was then washed with 20 ml of 50 mM Tris/HCl, pH 7.4, and 0.4 ml of Complete solution in the same Centricon Plus-20 by centrifugation under the same conditions. The washed retentate (about 100-200 µl) was then recovered as indicated by the manufacturer, transferred to a Centricon YM30 having the same MWCO, and further ultrafiltered by centrifugation at 2340 RCF and 20 °C for 1 h to obtain a final volume of 20-80 ul. The final retentate was assayed for its EPO level by ELISA and was kept frozen at -20 °C until isoelectric focusing (IEF). In some experiments, an additional step to reduce the protein content of the final retentate was included in the preparative protocol. In this case, the retentate from the Centricon YM30 device was adjusted to a volume of 400 µl with 50 mM Tris/HCl, pH 7.4, containing 0.2 M NaCl and incubated with an equivalent volume of WGA Sepharose equilibrated with the same buffer. Incubation was performed at room temperature for 2h under rotation. After sedimentation and washing of the pellet, the proteins were eluted from WGA Sepharose by three successive volumes  $(3 \times 400 \,\mu\text{l})$  of  $10 \,\text{g}/100 \,\text{ml}$  Nacetyl-p-glucosamine in this buffer. The three elution fractions were pooled, supplemented with 120 µl of Complete solution, and submitted to a final ultrafiltration in a Centricon YM30 device as described above for samples not treated by WGA Sepharose. All the subsequent steps were identical.

#### Isoelectric focusing of the retentates

The day of the IEF run, the retentates were thawed at room temperature and, if necessary, diluted with 50 mM Tris/HCl, pH 7.4, so that an EPO level of 1500 IU/L was never exceeded. A final volume of 20  $\mu$ l of the different samples was then heated at 80 °C for 3 min and supplemented with 2.2  $\mu$ l of 10% Tween 80. In some experiments, instead of being heated, the samples were supplemented with 2  $\mu$ l of 1.5 mM pepstatin.

The rHuEPO solutions were prepared in 1 g/100 ml bovine serum albumin (BSA) and 50 mM Tris/HCl, pH 7.4, at a final concentration of 600 IU/L. Samples of 20 µl were supplemented with 2.2 µl of Tween 80 before IEF.

IEF was performed in 1-mm-thick 5% T, 3% C polyacrylamide gels containing 7 M urea, 2% (w/v) 2-4 and 2% (w/v) 4-6 ampholytes, and 5 g/100 ml sucrose.

After prefocusing at 250 V and 8 °C for 30 min, using 2% 6-8 ampholytes as catholyte and 0.5 M H3PO4 as anolyte, the samples (20 µl) soaked onto rectangular pieces of filter paper were applied at 0.5 cm from the cathodal edge of the gel. Electrophoresis was run on the Multiphor II Electrophoresis system (Amersham-Pharmacia) at 1 W/cm of the gel length. The migration width was 9 cm. The run was stopped at 4000 Vh.

#### **Immunoblotting**

After the IEF run, the gel was submitted to semidry blotting in 25 mM Tris and 192 mM glycine at 1 mA/cm<sup>2</sup> of membrane for 30 min. An intermediate Durapore membrane was interposed between the blotting Immobilon-P membrane and the gel to prevent sticking. As soon as the transfer was over, the blotting membrane was incubated in 5 mM DTT PBS for 1 h at 37 °C. After a brief rinsing in PBS, the membrane was saturated in 5 g/100 ml nonfat milk PBS for 1 h at room temperature. After it had been incubated in a 1/1000 dilution of the anti-EPO antibody (primary antibody) in 1 g/100 ml nonfat milk PBS for 1h at room temperature, the membrane was washed in six changes of 0.5 g/100 ml nonfat milk PBS. Double-blotting (DB) was then absolutely necessary to prevent nonspecific binding of the secondary antibody to the urinary proteins. This was performed as previously described [7]. Briefly, the blotting membrane was assembled with a second Immobilon-P membrane (DB membrane) and submitted to semidry transfer in 0.7% (v/v) acetic acid, at 1 mA/cm<sup>2</sup>, for 10 min, so that the DB membrane was facing the cathode. All the subsequent steps concerned the DB membrane which was saturated in 5 g/100 ml nonfat milk PBS for 1 h at room temperature and rinsed briefly in PBS. The membrane was then incubated in a 1/4000 dilution of biotinylated anti-mouse IgG antibodies in 1g/100 ml nonfat milk PBS at 4°C for 15h. After washing in six changes of 0.5 g/100 ml nonfat milk PBS, it was incubated in a 1/2000 dilution of streptavidin:biotinylated peroxidase complex in 1 g/100 ml nonfat milk PBS for 1 h at room temperature and washed in six changes of PBS.

In some experiments, classical immunoblotting was performed as described above for double-blotting except that the semidry transfer in acetic acid was omitted.

After its final washing, the membrane was covered by the chemiluminescent substrate (30 µl/cm²), prepared as indicated by the manufacturer, and placed in the dark room of a charge-coupled device camera (Fuji). A first exposure of 3 min was tested to evaluate the obtained intensity. In most of the cases, a second exposure of 20 min was made after a transparent sheet of plastic had been layered onto the membrane. Profiles corresponding to the isoelectric patterns were obtained using "AIDA 1D-Evaluation" software from Fuji.

#### Results

Preliminary experiments to test the behavior of rHuEPO during ultrafiltration had been performed. Solutions of rHuEPO in 0.1 g/L BSA submitted to ultrafiltration at neutral (7.3) and acidic (4.8) pH conditions had shown that, whatever the pH, EPO was recovered in the retentate, whereas the filtrate was devoid of it. The results were quite different when rHuEPO was diluted in urine. Whereas a high recovery of the hormone in the retentate was obtained when ultrafiltration was performed at neutral pH, low to zero (depending on the urine sample) recoveries were observed under acidic conditions (data not shown).

The aspartic proteases present in urine were strongly suspected to be responsible for EPO degradation during ultrafiltration under acidic conditions. From this moment onward, 3.75 M Tris/HCl, pH 7.4, was systematically added to urine samples beforehand. This neutralized the pH of any acidic urine, with the aim being to inactivate the aspartic proteases. Because it was not possible to rule out EPO degradation by proteases active at neutral pH in some urine samples, however, a mixture of antiproteases with broad-spectrum activity (Complete solution) was systematically added to the urine samples before ultrafiltration and to the washing buffer of the retentate.

Under such conditions, EPO was finally concentrated from 200 to 1000 times in the final retentate which was then submitted to isoelectric focusing and immunoblotting of EPO. The sensitivity of the detection was tested using classical immunoblotting following IEF of pure CHO rHuEPO (Fig. 1). This showed that the recombinant hormone was composed of at least five isoforms in a pI range of 4.4-5.1 (in the presence of urea)

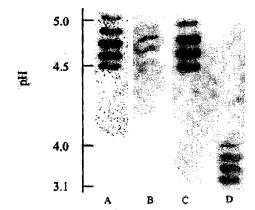


Fig. 1. IEF patterns of pure rHuEPO detected by classical immuno-blotting: Epoetin  $\beta$  (A), Epoetin  $\alpha$  (B, C), and Darbepoetin  $\alpha$  (D). The same quantity of Epoetin  $\alpha$  (10mIU, 84pg) was run in B and C, treatment of the blotting membrane by DTT before probing by the anti-human EPO antibody (C); no treatment (B). Anode is at the bottom of the figure.

for Epoetin a, and one additional more-basic isoform in the case of Epoetin B. The Darbepoetin, due to its two supplementary N-linked oligosaccharide chains, was much more acidic and gave rise to five bands located in a pI range of 3-3.9. Detection was about three times more sensitive if the blotting membrane was incubated in DTT just after the semidry transfer. Using this reducing treatment, the sensitivity achieved was about 0.2 mIU (1.7 pg) per band, which was sufficient to investigate the EPO patterns in the retentates from most of the ultrafiltered urine samples. However, when the retentates obtained from urine samples were analyzed, two kinds of problems were observed. First, as previously described, a strong nonspecific binding of the secondary antibody to some of the urinary proteins was observed after classical immunoblotting, so that the isoforms of EPO were completely masked by unrelated proteins (Fig. 2A). The double-blotting process was thus essential to prevent the urinary proteins from interfering with the detection of EPO [7]. Second, once the nonspecific signal had been eliminated, no EPO was detected following IEF of the retentates—despite sufficient levels—as ascertained by ELISA. This suggested that EPO was degraded during the IEF run. The ultrafiltration experiments had suggested that it was essential to protect EPO from aspartic proteases. Since the pH gradient of the IEF gel was 2-6, it seemed possible that urinary aspartic proteases, present in the retentates that were applied to the gel, were activated during the run and responsible for the disappearance of urinary EPO. Indeed, addition of pepstatin to the retentates just before the IEF step proved to be sufficient to protect EPO from degradation. Heat treatment of the retentates before the run, instead of pepstatin addition, was tested also. As shown in Fig. 2B, whereas "blank" lanes were obtained

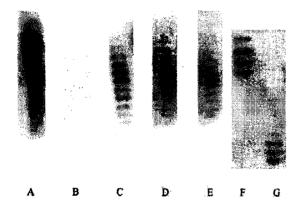


Fig. 2. IEF patterns of natural EPO obtained from urine retentates after classical immunoblotting (A), double-blotting without heat treatment of the retentate before the run (B), and double-blotting with heat treatment of the retentate before the run (C-E). For comparison, the IEF patterns of pure rHuEPO Epoetin α and Darbepoetin α are shown in F and G, respectively. Anode is at the bottom of the figure.

in the case of retentates applied directly onto the IEF gel, clear EPO profiles were observed when the same retentates were added with pepstatin or heated at 80 °C for 3 min before the run (Figs. 2C-E). All subsequent experiments were performed using the heat treatment, which proved to be unfailingly efficient in protecting EPO from degradation during the run.

Under such conditions, the isoelectric patterns of natural EPO observed in urine samples from various individuals proved to be highly heterogeneous, being composed of about 10-15 isoforms in a pI range of 3.8-4.7 (in the presence of urea). Although some differences were noted between individuals, all natural urinary EPO patterns were clearly different from those of the various recombinant patterns. Some patterns comprised minor bands colocated with the recombinant isoforms, but in all cases, the major isoforms presented pIs that were more acidic and more basic than Epoetin and Darbepoetin, respectively (Figs. 2F and G). In some cases where the total protein content of the retentates was particularly high (more than 5 g/100 ml), arc-shaped bands resulted from the gel overloading. This was corrected by treating the retentates with WGA Sepharose, which considerably lowered the protein concentration in the samples applied to the IEF gel. As shown in Fig. 3, the straightness of the bands was significantly improved by this procedure. To be sure that this treatment was not selective for some of the EPO isoforms, a sample with low protein content was prepared according to the two different procedures. In both cases, the corresponding patterns were composed of straight bands that could be easily integrated and compared (Figs. 3c, c', e, and e'). This showed that the distribution of the relative intensities of the bands was not significantly affected by the WGA Sepharose treatment.

A striking transformation in the urinary EPO pattern resulted from the administration of recombinant hormone Epoetin, reflecting the presence of the injected drug in urine. In some cases, during the first week of the rHuEPO treatment, a transitory enlarged microheterogeneity of the banding pattern (pI 3.8-5.1) with additional more basic isoforms (pI 4.4-5.1) was noted, which corresponded to the superimposed patterns of natural and recombinant EPO (Fig. 4B). After 3 weeks of treatment, however, the patterns were very similar to the pattern of the injected hormone, being mainly composed of isoforms in a pI range of 4.4-5.1 and, in some cases, an additional minor more acidic isoform (Fig. 4C). Such characteristic patterns were observed over the 4 days following an injection.

#### Discussion

Several difficulties have to be circumvented to obtain reliable images of the IEF patterns of EPO in urine.

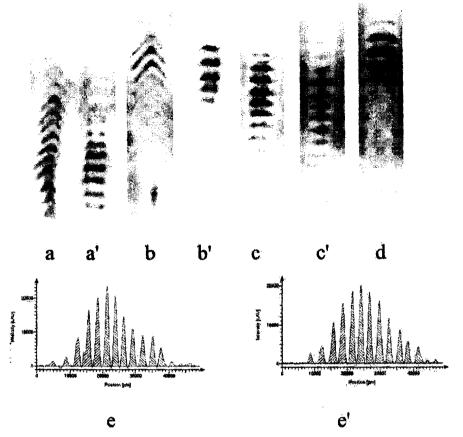


Fig. 3. IEF patterns of urinary EPO obtained from three different samples (A, B, C) prepared by ultrafiltration including (a', b', c') or not including (a, b, c) the treatment by WGA Sepharose. Samples A and B showed the presence of natural and rHuEPO, respectively (see text below), and both presented high protein contents. Sample C, presented low protein content. The integrated profiles corresponding to c and c' are shown in e and e', respectively. For comparison, the IEF pattern of pure rHuEPO (Epoetin α) is shown in d. Anode is at the bottom of the figure.



Fig. 4. IEF patterns of urinary EPO: natural EPO (A), 24 h after a first injection of Eprex (B), 24 h after a seventh injection of Eprex (2-week treatment) (C). For comparison, the IEF pattern of pure rHuEPO (Epoetin a) is shown in D. Anode is at the bottom of the figure.

The level of this hormone in urine is physiologically very low and is not increased by repeated injections of 20 IU/kg (unpublished results). Thus, urine must necessarily be

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concentrated. This is achieved by ultrafiltration through a membrane with a nominal MWCO of 30,000 Da. Though this is just below the molecular weight of EPO (about 34,000 Da), no passage of the hormone through the membrane was observed and thus this MWCO was selected to facilitate the elimination of smaller urinary proteins in the filtrate. Filtrate has no interest for EPO analysis but can be used for antidoping control concerning small molecules such as anabolic agents, diuretics, stimulants, or narcotics, and this may be useful in cases of small volumes of available urine.

This step has to be performed carefully; otherwise EPO may be drastically degraded due to the presence of proteases in urine. Indeed, various proteases have been described in urine: metallo proteases such as MMP-2 and MMP-9 [9], and gelatinase [10], serine proteases such as tonin [11], and aspartic proteases such as napsin A [12] and cathepsin D [13]. Since EPO degradation during ultrafiltration was observed in our experiments when acidic conditions were applied, it appears that aspartic proteases are very likely implicated. The

involvement of cathepsin D in the degradation of \( \beta\_2 \)microglobulin in acidic urine has been reported [13], and it is possible that this protease is involved in the degradation of EPO also. Indeed, two of the specific sites cleaved by this enzyme (Tyr-Phe and Leu-Tyr) are present in the peptidic sequence of EPO and the molecular weight of the enzyme, 45,000 Da, results in its coconcentration with the hormone in the retentate during the ultrafiltration. Whatever aspartic proteases are involved in EPO degradation, they are efficiently inactivated by neutralizing the pH of urine before ultrafiltration. At the same time, an addition of antiserine, -thiol, and -metallo proteases prevents the potential action of other types of proteases. Under such conditions, EPO is sufficiently concentrated for the subsequent IEF step.

The IEF step itself must be performed carefully because of the aspartic proteases reactivated by the acidic pH gradient. If these proteases are not neutralized before IEF, EPO is degraded during the run. This indicates that the respective pI of the proteases and the hormone are close enough to allow sufficient contact during the run. That pepstatin is sufficient to protect EPO from this degradation corroborates the implication of aspartic proteases. Heating the sample at 80 °C for 3 min before the run appears to be an efficient protective measure against EPO degradation by denaturing the proteases. The high thermal stability of EPO has been reported, related to its carbohydrate content [14]. We observed that its pI is not affected by the heat treatment, as shown by the well-preserved profile of the pure recombinant hormone after such treatment. On the other hand, this indicates that the binding of the AE7A5 antibody used for immunoblotting is not affected by the heat treatment of EPO.

The combination of an amplified (biotin:streptavidin) detection and a chemiluminescent signal provides good sensitivity that is further upgraded by incubating the blotting membrane in dithiothreitol before probing with the primary antibody. Since the AE7A5 anti-EPO antibodies used bind to an epitope within the first 26 amino acids of the molecule, it is probable that the reduction of the disulfide bridge between cysteinyl residues Cys 7 and Cys 161 makes this epitope more accessible to the antibody. Finally, a sensitivity of about 0.2 mIU (1.7 pg) per band is achieved. Assuming a mean concentration factor of 500 by ultrafiltration, the minimal concentration of EPO in urine must be about 0.4 IU/L (3.36 ng/L) to be detected.

In addition to sufficient sensitivity, the specificity of the immune detection of EPO proved to be the most difficult goal to achieve. Due to a strong nonspecific adsorption of the secondary antibodies used, it is not possible to get reliable images of the EPO isoforms that are present in urine samples. Only the double-blotting process that has been developed in these circumstances solves this problem [7].

In the case of samples with high protein contents (urine samples for antidoping control are very often taken after an intensive physical exercise that increases proteinuria), treatment by WGA Sepharose during ultrafiltration improves the straightness of the bands composing the pattern without disturbing the distribution of their relative intensities. Indeed, albumin, not being glycosylated, has no affinity for this lectin and is thus eliminated from the final retentate. This step efficiently lowers the protein content of the sample that is applied to the IEF gel, whereas EPO, which presents a very high content in GlcNAc residues, is retained with a recovery of more than 60%. The well-preserved distribution of the bands after this treatment shows that WGA Sepharose has no apparent selectivity for any of the different isoforms of EPO.

The pIs observed for purified Epoetin (4.4-5.1) appeared more basic than those described by Imai et al. (3-4.2) [15]. However, no urea is mentioned in the composition of the IEF gels used by these authors and this may explain the more acidic pI obtained. Under our conditions, the IEF gels contain 7 M urea and the pI observed for the recombinant CHO EPO are closer to those reported by Davis et al. (4.2-4.6) [16] in the presence of urea.

The most striking feature is the clear difference observed between the patterns obtained from untreated subjects (natural urinary EPO) and those from the different recombinant hormones. In comparison with Epoetin  $\alpha$  and  $\beta$ , natural urinary hormone is mainly composed of more acidic isoforms that are missing in the recombinant patterns. This agrees with the greater electrophoretic mobility at pH 8.6, already described for natural urinary EPO in comparison with recombinant CHO hormone by Wide et al. [3]. In contrast, the isoforms of Darbepoetin a are more acidic than the natural isoforms and this can be easily explained by the presence of two additional sialylated oligosaccharidic chains which characterize this recombinant hormone. The origin of the difference between natural urinary EPO and Epoetin  $\alpha$  or  $\beta$ , however, is not clear. Both hormones present the same proteic moiety but it undergoes an extensive posttranslational N-glycosylation at Asn-24, Asn-38, and Asn-83 and an O-glycosylation at Ser-126. The N-glycosylation gives rise to a complex and heterogeneous branching pattern composed of di-, tri-, and tetra-antennary glycans comprising a variable number of acetyllactosamine repeats and terminal sialic acid residues. The heterogeneity in the number of sialic acid residues is reflected in the multibanding isoelectric pattern of the hormone. The maximal possible number of sialic acid residues is 12 on the N-linked (3 tetrasialylated, tetra-antennary) oligosaccharides in both hormones [5] and 1 or 2 on the O-linked oligosaccharides in the case of urinary and recombinant EPO, respectively [17]. The tetrasialylated N-linked oligosaccharides have been shown to be the prevalent forms in recombinant CHO EPO [18-20]. Thus, the more acidic isoforms of natural urinary EPO cannot be imputed to supplementary sialic acid residues. Deamidation may be involved in the microheterogeneity of EPO, which comprises 3 Asn residues not glycosylated and 7 Gln residues. It is well known that some nonenzymatic deamidation may occur during the storage or preparation of samples [21]. However, all the urine samples were submitted to the same analytical procedure, and the differences in the EPO patterns in urine samples treated and untreated subjects cannot be imputed to some different deamidation process occurring during analysis. Furthermore, attempts to deamidate EPO by incubation at alkaline pH at 37°C for 24h did not result in any change in its IEF pattern (data not shown). The presence of small amounts of oligosaccharides containing both sialic acid residues and sulfate groups has been suggested in natural EPO and rHuEPO from CHO cells [22] and sulfation of some of the GlcNAc residues of rHuEPO from baby hamster kidney cells has been recently reported [23]. Furthermore, the sulfated species may be more prevalent in natural urinary than in CHO rHuEPO [24]. This would agree with the more acidic isoforms observed in the case of urinary hormone.

The mechanism of EPO elimination is not well known. Bone marrow [25] and kidney [26] have been shown to contribute, respectively, significantly and to a small extent. Our results indicate that administered Epoetin a (or β) is excreted in urine without noticeable change in its isoelectric profile. This observation is of particular interest for antidoping applications since it allows the detection of recombinant EPO in urine [8]. This method has been thus proposed for antidoping control after having been tested in a large control population study that included different athletes to assess the influence of ethnic origin, sex, age, physical exercise, and erythropoiesisstimulating situations (altitude, hypobaric chambers) on the natural urinary EPO pattern. The results of this study and those of administration trials using the different recombinant hormones will be published at a later date.

By enabling the investigation of the urinary IEF profiles of EPO, this method may also lead to new insights in physiology and pathology.

#### Acknowledgments

We are very grateful to "Amgen" for providing Aranesp. The assistance of "Fuji Raytest France" in the preparation of the photographs is greatly appreciated.

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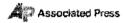
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### Tour Chief: Armstrong Doping 'Proven Fact' Aug 24 7:43 AM US/Eastern





By ANGELA DOLAND Associated Press Writer

#### **PARIS**

The director of the Tour de France said it was a "proven scientific fact" that Lance Armstrong had a performance-boosting drug in his body during his 1999 Tour win, and that the seven-time champion owed fans an explanation.

In a story Wednesday, Jean-Marie Leblanc praised L'Equipe for an investigation that reported that six urine samples provided by Armstrong during the 1999 Tour tested positive for the red blood cell- booster EPO. The French sports daily on Tuesday accused Armstrong of using EPO during his first Tour win in 1999.

"For the first time \_ and these are no longer rumors or insinuations, these are proven scientific facts \_ someone has shown me that in 1999, Armstrong had a banned substance called EPO in his body," Leblanc told the paper.

"The ball is now in his camp. Why, how, by whom? He owes explanations to us and to everyone who follows the tour," Leblanc said. "What L'Equipe revealed shows me that I was fooled. We were all fooled."

Armstrong, a frequent target of L'Equipe, vehemently denied the allegations on Tuesday, calling the article "tabloid journalism."

"I will simply restate what I have said many times: I have never taken performance-enhancing drugs," he said on his Web site.

L'Equipe reported that six urine samples provided by the cancer- surviving American during the 1999 Tour tested positive for the red blood cell-booster EPO. The drug, formally known as erythropoietin, was on the list of banned substances at the time, but there was no effective test to detect it.

The allegations surfaced six years later because EPO tests on the 1999 samples were

carried out only last year when scientists at a lab outside Paris used them for research to perfect EPO testing. The national anti-doping laboratory in Chatenay-Malabry said it promised to hand its finding to the World Anti-Doping Agency, provided it was never used to penalize riders.

Five-time cycling champion Miguel Indurain said he couldn't understand why scientists would use samples from the 1999 Tour for their tests.

"That seems bizarre, and I don't know who would have the authorization to do it." he told L'Equipe. "I don't even know if it's legal to keep these samples."

L'Equipe's investigation was based on the second set of two samples used in doping tests. The first set were used in 1999 for analysis at the time. Without those samples, any disciplinary action against Armstrong would be impossible. French Sports Minister Jean-Francois Lamour said.

Lamour said he was forced to have doubts about L'Equipe's report because he had not seen the originals of some of the documents that appeared in the paper.

"I do not confirm it," he told RTL radio. But he added: "If what L'Equipe says is true, I can tell you that it's a serious blow for cycling."

The International Cycling Union did not begin using a urine test for EPO until 2001, though it was banned in 1990. For years, it had been impossible to detect the drug, which builds endurance by boosting the production of oxygen-rich red blood cells.

Jacques de Ceaurriz, the head of France's anti-doping laboratory, which developed the EPO urine test, told Europe-1 radio that at least 15 urine samples from the 1999 Tour had tested positive for EPO.

Separately, the lab said it could not confirm that the positive results were Armstrong's. It noted that the samples were anonymous, bearing only a six-digit number to identify the rider, and could not be matched with the name of any one cyclist.

However, L'Equipe said it was able to make the match.

On one side of a page Tuesday, it showed what it claimed were the results of EPO tests from anonymous riders used for lab research. On the other, it showed Armstrong's medical certificates, signed by doctors and riders after doping tests \_ and bearing the same identifying number printed on the results.

L'Equipe is owned by the Amaury Group whose subsidiary, Amaury Sport Organization. organizes the Tour de France and other sporting events. The paper often questioned Armstrong's clean record and frequently took jabs at him \_ portraying him as too arrogant, too corporate and too good to be real.

"Never to such an extent, probably, has the departure of a champion been welcomed with such widespread relief," the paper griped the day after Armstrong won his seventh straight Tour win and retired from cycling.

Leblanc suggested that in the future, urine samples could be stashed away for future testing as detection methods improve \_ another possible weapon in the fight against doping.

"We're so tired of doping that all means are good as long as they are morally acceptable," he told L'Equipe.

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OTHER TOP STORIES







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# Armstrong says he's the victim of a 'setup'

From staff and wire reports

Lance Armstrong suggested Thursday that he's the victim of a "setup," saying he doesn't trust the French lab that released test results leading to blood doping allegations against him.

Armstrong's comments came after Dick Pound, head of the World Anti-Doping Agency, said officials had received the lab results and would review them.

"There's a setup here and I'm stuck in the middle of it," Armstrong told The Associated Press. "I absolutely do not trust that laboratory."

The French sports daily *L'Equipe* reported Tuesday that six urine samples Armstrong provided during his first tour win in 1999 tested positive for the red blood cell-booster EPO.

"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."

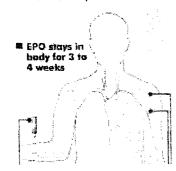
Armstrong, who retired after his seventh straight tour win in July, has angrily denied the *L'Equipe* report. He also said that while Pound might trust the lab that tested the samples, "I certainly don't."

Armstrong also expressed strong feelings on CNN's Larry King Live.

"I don't have trust in that system," Armstrong told the cable show. He cited numerous violations of the anti-doping code in the *L'Equipe* allegations Tuesday that six 1999 samples of his urine tested positive for the blood-boosting banned drug in a 2004 lab study that was supposed to be anonymous.

#### **How EPO works**

Athletes can increase oxygen content in their blood to gain an edge over the competition in endurance sports.



"I had 17 samples taken that year," he told CNN. "Six were positive, but what about the other 11?"

He also questioned the protocols of the testing, especially the violations of anonymity, chain of custody rules and the lack of an A-sample, which was used up in 1999. When a rider's fluids are submitted for testing, they are split into A and B samples.

"This thing stinks," Armstrong said.

Pound said the lab had asked WADA months ago if the agency was interested in reviewing its findings and that he agreed. He said the agency didn't Advertisement



expect names to be connected to the findings, but only wanted to see if the leftover samples from 1999 would show riders used EPO.

"They said it's simply research," Pound said.

Pound said he is waiting for WADA Science Director Olivier Rabin to return from Europe to review the results.

The lab report doesn't name Armstrong, but shows the results of tests on anonymous urine samples. While the French newspaper said it was able to match Armstrong to the positive samples, Pound said the lab and WADA officials cannot do that

The French report appears stronger than previous doping allegations raised against Armstrong, Pound said.

"There's been an awful lot of rumor and accusation 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's got to be taken more seriously," Pound said.

Armstrong and Pound have clashed before on the chairman's comments about athletes who use drugs.

Pound said he's unsure whether WADA would have jurisdiction to take any action against Armstrong if the allegations could be proved. WADA didn't exist until months after the samples were collected in July 1999.

Pound said he was waiting to see if the International Cycling Union would act on the French report.

Armstrong questions the validity of testing samples frozen six years ago, how those samples were handled since, and how he could be expected to defend himself when the only confirming evidence — the 'A' sample used for the 1999 tests — no longer exists.

He also charged officials at the suburban Paris lab with violating WADA code for failing to safeguard the anonymity of any remaining 'B' samples it had.

Pound said the lab is accredited by the International Olympic Committee and that he trusts it handled the samples properly.

"It's one of the top two or three EPO labs in the world," he said. "It's a very competent laboratory."

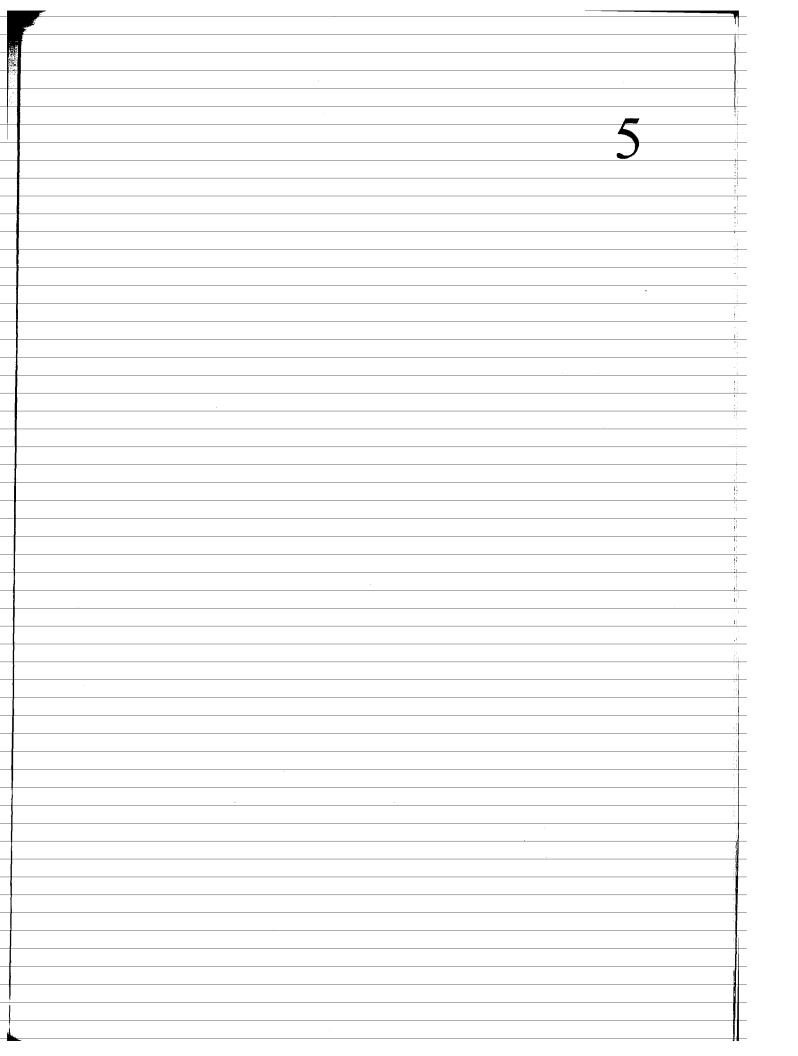
Pound also questioned the need for two samples to confirm a positive test.

"You can count on the fingers of one hand the times a B sample has not confirmed the result of the A sample," Pound said. "It's almost always a delaying tactic."

Armstrong said that contradicts WADA's own drug testing policy.

"For the head of the agency to say he actually doesn't believe in the code .... if your career is riding on the line, wouldn't you want a B sample?," Armstrong said. "The French have been after (me) forever, and 'whoops!' there's no B sample? The stakes are too high."

Contributing: Sal Ruibal, USA TODAY; The Associated Press



Top lab official wonders if delayed testing is possible We are not that lucky here, says Canada's Christiane Ayotte By Charles Pelkey news editor, VeloNews This report filed August 23, 2005

The director of Canada's top anti-doping laboratory on Tuesday said she was "very surprised" over doping allegations raised in a four-page story in the French sports daily *L'Equipe*.



Dr. Christiane Ayotte, Doping Control director at Canada's Institut National de la Recherché Scientifique

photo: AFP (file photo)

Doctor Christiane Ayotte, director of the Doping Control Laboratory at Montreal's Institut National de la Recherché Scientifique, said that the *L'Equipe* story, outlining charges that seven-time Tour de France winner had used EPO at the 1999 edition of the race, raised several important scientific and ethical questions, beginning with the assertion that France's anti-doping lab had tested frozen urine samples five years after the fact.

"We are extremely surprised that urine samples could have been tested in 2004 and have revealed the presence of EPO," Ayotte said in an interview with *VeloNews* on Tuesday. \*EPO - in its natural state or the synthesized version - is not stable in urine, even if stored at minus 20 degrees."

Ayotte, director of the World Anti-Doping Agency-certified lab closest to WADA headquarters in Montreal, said she wasn't surprised that Doctor Jacques de Ceaurriz, director of the French national anti-doping laboratory at Châtenay-Malabry, was confident in the methods, but only that an older sample could be so readily tested.

"I don't dispute their findings," Ayotte said. "If there's residual EPO after five years, it was properly identified. We are not that lucky here."

De Ceaurriz and Ayotte agree that if enough Erythropoletin - synthetic or natural - remains in a sample, distinguishing the two is not an issue. Such degradation, both said, does not lead to false positives.

"One of two things happens," De Ceaurriz said. "Either EPO, which is a protein, degrades as time passes and becomes undetectable. In that case we have a negative test result or, as in this case, the EPO persists as it is. We have therefore no doubt about the validity of our results."

#### Why now?

Ayotte, who has not had the opportunity to speak with De Ceaurriz since publication of the *L'Equipe* story, said that there would have been no logical reason for the lab to have held on to the samples without testing them for as long as it has.

"The lab in Paris, which originally developed the test, would have - should have - retested these samples in 2000 or 2001, in order to develop and validate their methods at the time," she said. "My interpretation is that retesting itself must have been conducted in 2000 or in 2001, but the results were reviewed using the new mathematical model that is now being developed in Paris."

Ayotte explained that as part of WADA's efforts to "harmonize" testing protocols among anti-doping laboratories worldwide, the Paris lab had created the model to allow the application of "qualitative rather than quantitative" standards when interpreting test results.

"That has to be the only explanation, because otherwise, I've been a liar all these years," Ayotte said. "I have been instructing everyone at all of the organizations not to expect to reproduce an EPO adverse finding if more that two or three months has elapsed since the sample was originally taken."

De Ceaurriz and his colleagues at the at Châtenay-Malabry developed the urine test in 2000 as a means of combating EPO use among endurance athletes. The test measures the electrical charge of isoforms released by the body. Isoforms resulting from naturally occurring erythropoietin have a distinctly different pattern of electrical charges than do those that result from the use of artificially produced erythropoietin.

Ayotte noted that earlier standards had called for the application of a "hard-number" interpretation of results, meaning that if a certain percentage of isoforms were positively or negatively charged, a result would be deemed to be an indication of EPO use. Ayotte said research subsequent to the development of the test has suggested that testers understand the reasons behind the formation of positive and negative isoforms and "recognize the presence of distinct populations in a sample."

The development of that model, said Ayotte, may have prompted researchers at Châtenay-Malabry to go back and review existing data - which should include data from the retesting of '99 Tour samples - and apply them to the new model. Suggesting a more recent test, she said, "really makes me wonder."

"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 substance."

#### An ethical breach?

Ayotte said that procedure aside, the Armstrong story in L'Equipe also raises a critical ethical question raised by the release of such 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 now way to have the sample re-tested or verified."

"It seems to me," Ayotte continued, "that this whole thing is 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."

Ayotte said that the lab itself isn't facing questions in the matter.

"It isn't the lab that has the critical bit of information - the link between the code on the sample and the name of the athlete," she noted. "We only get a code at these WADA labs. Someone else must have supplied the paper with the names and their respective codes. So, to me, this whole thing raises a number of questions. 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."

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August 25, 2005

Mr. Hein Verbruggen President International Cycling Union (ICU) CH 1860 Aigle Switzerland

By fax: +41 24 468 58 54, and By e-mail: Hein.Verbruggen@ucl.ch

Subject: L'Équipe and Armstrong

Dear Hein:

I write to you in respect of the articles written recently in L'Équipe, and the information that has been provided by that newspaper. Today I received from the French laboratory the information relating to their studies of stored samples from previous Tours de France. The 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 that it is confidential, and has no information which by itself would identify any individual.

Within the initial article published by L'Équipe, there are copies of doping control forms. Are you in a position to enquire as to how those forms became available to the journalist? If they were provided with the rider's consent, then of course there can be no argument as to appropriate publication.

In the circumstances it would be beneficial if you were in a position, at UCI, to conduct an enquiry to determine what action can be taken. As these matters preceded WADA, and of course the WADA Code, jurisdiction rests with you 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.

Kind regards,

Davis Howman

**David Howman** 

#### Press

Press Release: Analysis of 1999 Tour Samples: Soon the UCI Conclusions

Following the revelations published last week in the press concerning the results of analysis of urine samples from the 1999 Tour de France, the UCI confirms that it is pursuing its global assessment of the situation.

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, the UCI announces that it will communicate its conclusions on this case within the next 10 days.

UCI Press Service



August 30, 2005

Mr. Hein Verbruggen President International Cycling Union (ICU) CH 1860 Aigle Switzerland

By fax: +41 24 468 58 54, and By e-mail: Hein.Verbruggen@uci.ch

#### Dear Hein:

I refer to the letter I wrote to you last week offering WADA's assistance in relation to the recent article in L'Équipe, and thank you for your response which I received this morning.

We note from your press release that UCI is confirming "that it is pursuing its global assessment of the situation". We are not certain what these words mean, particularly as they do not refer to any investigation or inquiry, and therefore we are left with the feeling that you have some other process or protocol in mind.

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 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 much preliminary inquiry to indicate, for example, who held a any confidential information, how it was held, who was responsible for maintaining it, and in what way. Only then can there be inquiries made of those responsible?

We would be interested to hear from you.

Yours sincerely,

David Howman Director General



# COPIE

#### INTERNATIONAL CYCLING UNION

President

World Anti-Doping Agency Mr. David Howman Director General Stock Exchange Tower 800, Place Victoria (Suite 1700) P.O. Box 120 Montreal, Québec H4Z 1B7 Canada

First by fax: +1 514 904 8771 (and email)

Aigle, 30<sup>th</sup> August 2005 Ref: President / HV / az

Dear David,

I refer to your fax dated August 25th last.

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. Ressi of which we know his attitude towards cycling and the UCI (De Galdeano and WADA 10 report).

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

Kind regards,

Hein Verbruggen President



#### INTERNATIONAL CYCLING UNION

President

World Anti-Doping Agency Mr. David Howman Director General

By fax and email

Algle, 30 August 2005 Ref: President / az-j

Your fax of July 25 August 2005

Dear David,

I come back to your fax dated 25 August 2005.

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...???

Best Regards,

Hein Verbruggen President

CC: J. Rogge, IOC President

S. Bubka, IOC Athletes' Commission

Bilder einblenden

## **NETZEITUNG.DE**

URL dieses Artikels: http://www.netzeitung.de/sport/356216.html

# Pound sieht Dopingaktivität bei Armstrong

05. Sep 2005 09:50

Richard Pound glaubt, dass Lance Armstrong gedopt hat. Eine Strafe für den Tour-de-France-Sieger wäre aber rechtlich sehr problematisch, sagte der Chef der Welt-Anti-Doping-Agentur der Netzeitung.

Richard Pound sieht eine hohe Wahrscheinlickeit, dass Lance Armstrong gedopt war. Der Chef der Welt-Anti-Doping-Agentur (Wada) begrüßt zudem Gentests als Beweisgrundlage. «Wir wollen Athleten nicht zu Unrecht beschuldigen, aber schuldige Sportler auch nicht laufen lassen, falls wir das verhindern können», sagte der Kanadier der Netzeitung.

Auch wenn die Schuld des siebenmaligen Gewinners der Tour de France bewiesen werden sollte, weiß Pound nicht, ob der Amerikaner bestraft werden könne. Eine Strafe sei «rechtlich sehr problematisch, weil die Regeln des Weltradsportverbandes UCI aus dem Jahr 1999 mit zu beachten sind», so Pound.

#### Hohe Wahrscheinlichkeit für Dopingaktivität

Netzeitung: Wie steht die WADA zu den Anschuldigungen gegen Lance Armstrong?

Richard Pound, Chef der Welt-Anti-Doping-Agentur (Wada): Nachdem wir all die Unterlagen in dieser Angelegenheit gesehen haben, sehe ich eine sehr hohe Wahrscheinlichkeit, dass es eine Dopingaktivität gegeben hat.

**Netzeitung:** Wie glaubwürdig ist das französische Dopingkontrolllabor, in dem die Urinproben nachträglich getestet wurden?

Pound: Nach meiner Auffassung ist es ein sehr gutes Labor. Es gehört zu den weltweit führenden Labors bei der Erforschung von EPO. Ich habe also keinen Grund zu der Annahme, dass die Analyse der Proben nicht ordnungsgemäß war. Das Labor hat ja die EPO-Spuren in vielen Proben gefunden. Es mag sein, dass EPO-Spuren mit der Zeit aus dem Urin verschwinden, aber es kann doch nicht sein, dass erst kein EPO drin sein soll und dann wie aus dem Nichts doch auftaucht.

#### Informationen nur aus «L'Equipe»

Netzeitung: Könnte es sein, dass in diesem Verfahren am Ende der Athlet bestraft wird, obwohl es gar kein ordentliches Dopingverfahren mit der Öffnung einer B-Probe gegeben hat, wie es vom Sportrecht vorgeschrieben ist?

**Pound:** Das ist eine der Möglichkeiten, mit denen wir uns zu beschäftigen haben. Eine Strafe wäre nach derzeitigem Kenntnisstand natürlich rechtlich sehr problematisch, weil die Regeln des Weltradsportverbandes UCI aus dem Jahr 1999 mit zu beachten sind.

**Netzeitung:** Es soll noch zahlreiche weitere positive Proben aus den Jahren 1998 und 1999 geben. Kennen Sie weitere Namen?

**Pound:** Die Wada hat keine Namen übermittelt bekommen. Wir haben nur den Bericht zu den Analysen aus dem französischen Labor bekommen und darin waren keine Namen enthalten. Unsere Informationen zu Lance Armstrong haben wir auch aus der Sportzeitung «L'Équipe».

Netzeitung: Über möglicherweise betroffene deutsche Fahrer ist Ihnen demnach nichts bekannt?

Pound: Nein, über deutsche Sportler weiß ich nichts. Ich weiß nicht, ob da jemand in Frage kommt.

#### Gentest eine Möglichkeit

Netzeitung: Was halten Sie von der Durchführung eines Gentests, um die Frage zu klären, ob die positiven Urinproben wirklich von Armstrong stammen?

**Pound:** Die Wada begrüßt es, wenn eine solche Möglichkeit zur Verfügung steht. Wir wollen Athleten nicht zu Unrecht beschuldigen, aber schuldige Sportler auch nicht laufen lassen, falls wir das verhindern können.

**Netzeitung:** Der Weltradsportverband UCI prüft derzeit das weitere Vorgehen. Welche Reaktion erwarten Sie?

**Pound:** Wir sind gespannt, wie die Antworten ausfallen werden. Wenn die UCI-Funktionäre jetzt feststellen, dass offenbar eine Reihe von Topfahrern selbst nach dem Desaster um das Festina-Team bei der Tour 1998 positiv auf EPO getestet wurde, demonstriert das klar: Der Radsport hat ein sehr ernstes Problem. Und es zeigt, dass die UCI bei der Lösung des Problems keinen Erfolg hatte.

Das Interview mit Richard Pound führte Hans-Joachim Seppelt

MEHR IN DER NETZEITUNG «L`Equipe» wehrt sich gegen Vorwurf http://www.netzeitung.de/sport/355522.html UCI leitet eigene Nachforschungen ein http://www.netzeitung.de/sport/355352.html Armstrong: Ich habe nie gedopt http://www.netzeitung.de/sport/354880.html Armstrong: Tour-Direktor ist hirnverbrannt http://www.netzeitung.de/sport/354709.html Toursieger Armstrong angeblich gedopt http://www.netzeitung.de/sport/354343.html Humangenetiker Demuth: Gentest über alle Zweifel erhaben http://www.netzeitung.de/sport/356157.html Ex-Profi Järmann: EPO war weit verbreitet http://www.netzeitung.de/sport/355146.html Epo auch in Tour-Proben von 1998 gefunden http://www.netzeitung.de/sport/354849.html Armstrong zweifelt Dopingbefund an

http://www.netzeitung.de/sport/354753.html

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## **Tuesday 6th September 2005**

# Pound slammed by WADA's vice-president for Armstrong accusation

Many in the world of sport have been shocked by the hasty response of WADA boss Dick Pound to L'Equipe's accusations that Lance Armstrong administered EPO in the 1999 Tour de France. The World Anti-Doping Agency's own athlete-protecting protocols were breached by the French doping lab yet Pound immediately went on the offensive against Armstrong. Now, Danish Minister of Culture Brian Mikkelsen - vice president of WADA - has criticised Pound's handling of the affair.

Mikkelsen said the L'Equipe story lacked hard evidence and as such should have been handled with caution.

According to Danish government website, Denmark.dk, Mikkelsen is 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.

"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."

Pound had said the L'Equipe story 'proved' there was a "very high probability" that Armstrong used EPO in 1999, a claim denied by Armstrong.

Mikkelsen said preferred to wait for a report from WADA looking at all the evidence before he offered his opinion.

"Before I have received the report, I won't comment further on the case. I will contact Dick Pound, however, and inform him about my view on the matter," said Mikkelsen.

OTHER NEWS: Lance Armstrong yesterday announced he and Sheryl Crow were engaged to be married.



# COPIE

#### INTERNATIONAL CYCLING UNION

#### President

## BY FAX AND POST

World Anti-Doping Agency Mr. David Howman Director General Stock Exchange Tower 800, Place Victoria (Suite 1700) P.O. Box 120 Montreal, Québec H4Z 1B7 Canada

Aigle, 5 September 2005 Ref: President / az-i

Lance Armstrong - article published in "L'Equipe" on 23 August 2005

Dear David,

I think that you will agree that the first thing that has to be examined is whether there is a basis that is sound enough to proceed further.

The UCI has no other information than the article published in "L'Equipe" on 23 August, which is by itself an obvious breach of confidentiality.

The content of that article indicates that the information it pretends to be available is not a valid basis for an assertion that an anti-doping violation has been committed. We know that results management will have to be conducted in order to know whether it can be asserted if anti-doping violations were committed.

At least the following issues should be clarified:

The reporter, Mr. Ressiot, was in possession of 6 anti-doping control forms regarding one rider: Lance Armstrong. One form has been obtained from the UCI with the consent of Mr. Armstrong. In July 2005, Mr. Ressiot told the UCI that he was preparing an article to confirm that Lance Armstrong never asked the UCI for an authorization to use medication containing prohibited substances. He asked also to see the doping control forms in order to ascertain himself that no medication had been declared. When he had examined the forms, he asked if he could have one copy of them as an example that Lance Armstrong had not declared any medication on doping control forms.

Now we know the reason why he asked for that copy.

It is this form that was reproduced *in extenso* in the press release of 23 August. That form has not been used for the purpose it was asked and given for. It has been extracted under a false pretext with the aim to use it for violating confidentiality.

We do not know how Mr. Ressiot got into possession of the 5 other forms – which come from another source: the French Cycling Federation or the Ministry of Sports (maybe Alain Garnier can tell you which persons in the Ministry may have had access to these forms: the French Minister declared that the forms are destroyed after two years, but copies have been made in 1999-2001; Mr. Garnier might also know to whom it was sent at the French Federation).

In view of the experience with the UCI form – and of other negative experiences the UCI had with Mr. Ressiot – we suspect Mr. Ressiot to have gotten the other forms (or copies of them) in an irregular way.

As Mr. Ressiot is very familiar with the anti-doping rules, he knew that athletes have a right to confidentiality, regardless whether the samples were analysed in the frame of a research project or in the frame of doping control.

The publication of Mr. Ressiot was not only a breach of confidentiality but also an intentional slur on the reputation of the athlete, as he admits himself in his article that no disciplinary action might result from it as it will not be possible to guarantee the rights of the defence.

So, Mr. Ressict has made a public statement that is such as to destroy the reputation of an athlete in the knowledge that the violation cannot be proved and the athlete cannot defend himself.

The question is then whether any disciplinary proceedings is not to be considered as void as from the start, as it would be based on a tort or even a criminal offence.

In any case, the athlete will invoke this kind of argument and it might be rather difficult to have it dismissed.

- 2. Scientists, including heads of WADA-accredited laboratories, have publicly stated that fundamental rules of scientific research concerning ethics and confidentiality have been violated. Therefore it is important to know and hopefully WADA can give us this information:
  - 1) Who initiated the research:
  - 2) What was exactly the object of the research;
  - 3) Did the research specifically include the analysis of samples taken for doping control? If so: which samples? Only samples in the sport of cycling? Only samples from the Tour de France? What is the relation between the scientific object of the research and the fact that the Tour de France samples were to be analysed?
  - 4) Under which rules the research was conducted? WADA rules? French rules?
  - 5) What do these rules say about:
    - a) the use of identifiable samples?
    - b) the need to make the samples anonymous before analysis?

- c) the need to destroy any sign or means (bottle, code, etc...) of identification;
- d) the measures to be taken to make a posteriori identification impossible?
- 6) What do these rules say about the way in which to report on the research results?
- 7) Who was aware of the fact that the research was being conducted?
- 8) Who was aware of the fact that the samples were going to be analysed or had been analysed?
- 9) Which individuals were actually involved in:
  - the storing of the samples?
  - the opening of the samples?
  - the analysis of the samples?
  - the interpretation of the results?
  - the reporting on the results?
- 3. We understood that the research was aimed at improving the EPO-detection method. What kind of conclusion had to be drown in order to know whether at the end of the research project the method was more efficient or not? To what extent was it necessary, in order to come to such conclusions,
  - a) to identify the analysis result of each sample separately;
  - b) to identify each analysis result with the sample code of the doping control;
  - c) to specify that the samples came from the Tour de France 1999 (see the document published in "L'Equipe");

in the report on the research?

Is there any need, created by the scientific research project, to do so and to produce a document as the one that was published in "L'Equipe"?

As we have a difficulty to believe that, some might try to suggest that the above identification was made in order to enable those who are in possession of the names corresponding to the code numbers, including, as we know now, Mr. Ressiot, to identify the athlete(s)?

I.o.w, what is the "scientific" justification for this Identification of the results?

Since this seems to be an at least unusual practice, the question should be answered "who requested this"?

- How did Mr. Resslot get the details he mentions in his article:
  - that a research project was running; apparently he knew this since at least 4 months, as he writes that he has worked for 4 months on his investigation (which means that he had started working on it when he asked to see the forms for other purposes);

- the project was conducted "in collaboration with WADA and the French Ministry":
- the research was done on B-samples only.
- 5. How did Mr. Ressiot know that the result was to be sent to WADA and the Ministry? Obviously he knew in advance that such results, including the sample codes, were going to be sent, as it is not possible that all articles published on 23 August were written not earlier than 22 August, date at which the results were sent to WADA and the Ministry.
- 6. How did Mr. Resslot know, as he writes in his article, published in the morning of 23 August, that WADA was studying the legal possibilities not to let the research results without (disciplinary) consequences, whereas the results had been sent to WADA not earlier than 22 August? Here, Mr. Resslot suggests that WADA knew of these results before 22 August and had the intention to use results that were obtained from a violation of the rules of confidentiality governing scientific research for disciplinary purposes.
- 7.
  The laboratory has published an official statement confirming that it conducted its research "in collaboration with WADA" and that it sent the results to WADA in an "anonymous format" and under the condition that any use for disciplinary purposes was excluded.

On the one hand, the latter condition is normal for scientific results. On the other hand, the condition is strange, because if the results would really have been anonymous, their use for disciplinary purposes was simply impossible. This is, by the way, how it should have been.

In addition, the athletes might invoke that they may avail themselves from this condition that makes any disciplinary proceedings impossible.

\* \* \* \* \*

David, I think it is necessary to get answer to these questions, as the athletes will certainly ask them and maybe many more (see the Hamilton case!). I would appreciate if you – as you have offered – would assist us in this matter.

There has to be an answer to these questions and that answer has to make us confident that we have a valid <u>basis</u> for a case (which does not yet imply that we have a case). If there is no such answer, I am afraid that we cannot go further. There is no sense in doing so if there is no real basis for a final result.

The system has suffered a serious blow by the article published in "L'Equipe" in terms of reliability and ethics. I think it cannot afford another blow if the riders are eventually acquitted on the basis of flows that we would not have identified as from the beginning — and which seem quite obvious.

With the information available now (basically the article), together with the fact that the journalist was prepared to obtain information under false pretexts, we can not avoid anymore to suspect that this whole action was directed against Mr. Armstrong specifically. Legically it could only be done with the help of a person within the laboratory, the Ministry or WADA. You are — obviously — convinced that no WADA-staff is involved. It is therefore crucial that, by obtaining clear answers, we can get as close as possible to what has exactly happened. As expressed on the phone, WADA can be assured of a full cooperation with the UCI.

Sincerely Yours,

Hein Verbruggen President



#### INTERNATIONAL CYCLING UNION

President

World Anti-Doping Agency Mr. David Howman Director General Stock Exchange Tower 800, Place Victoria (Suite 1700) P.O. Box 120 Montreal, Québec H4Z 1B7 Canada

First by fax: +1 514 904 8771 (and email)

Aigle, September 8<sup>th</sup> 2005 Ref: President / HV / az

Dear David,

#### Lance Armstrong - article published in "L'Equipe" on 23 August 2005

I refer to my letter of 5 September, following your letters of 25 and 31 August, in which you state that you are at our disposal for any assistance which we may seek.

In my letter, I set out a number of issues which need to be clarified and information which needs to be provided by WADA, in order that we may investigate this matter. I should be most grateful if you would confirm that you are investigating the issues and also please let me know when we should expect your response. Obviously this matter is extremely urgent and I am looking forward to your response at the earliest possible opportunity.

In addition to the clarifications and information set out in my letter of 5 September, I have the following additional questions, to which I would appreciate WADA's urgent response.

- 1. We need clarification of the full chain of events and timing. In particular, as outlined in item 6 of my letter, we need to know how it is that the article of 23 August in l'Équipe stated that WADA was already studying the "possible legal recourse" relating to the results of the analyses, yet you did not receive the results before 24 August. We also need to know why there appears to have been a delay from the time when the research was initiated and the testing was conducted, to August 2005, when the laboratory provided the results of the analyses to WADA.
- 2. We would like to have full details of WADA's involvement in the French laboratory's research work, as specified in my letter, but also we would like a confirmation of whether WADA directed the French laboratory to "extend" its research and if so, in which ways precisely WADA asked the research to be extended.



- 3. We need documentation relating to the matters listed in item 2 of my letter. In particular, we need to see the correspondence between WADA and the laboratory, and the documentation relating to the rules under which the research was conducted and the purpose and scope of the research. We also need to see any correspondence concerning the testing between WADA any third parties, such as the French Government or Minister of Sports, the French Cycling Federation and other cycling bodies. I assume that being "off the shelf" materials, you will be able to supply these to us by return.
- 4. We need to know how it was that the anonymity of the samples was compromised. To be frank, there are rumours now that the samples which were analysed were originally re-labelled by the laboratory, in accordance with normal practice, to ensure that they were anonymous, but that the laboratory was subsequently requested by a third party to include the doping control numbers in the data. Please confirm whether WADA, or anyone within WADA, requested the inclusion of doping control numbers in the data which were reported. If this is the case, please explain why this request was made.
- 5. We would appreciate if you could help us understand how confidential information came into the public domain. WADA provided documents to the Press?

I repeat that I am very grateful to you for your assistance. It is only with that assistance that we will be able to clarify the many issues and doubts which we have relating to the article in L'Équipe. We may well have further requests.

I am writing separately to the French Ministry of Sports and to the laboratory, in order to gather further information. Perhaps you could telephone me when you receive this letter, in order to update me on progress with regard to the collection and supply to us of all the information we need, as outlined in my letter of 5 September and above.

Sincerely,

Hein Verbruggen President



September 9, 2005

By fax: +41 24 468 58 54, and By e-mail: Hein.Verbruggen@uci.ch

Mr. Hein Verbruggen
President
International Cycling Union (UCI)
CH 1860 Aigle
Switzerland

#### Subject: Lance Armstrong - article published in L'Équipe, 23 August 2005

#### Dear Hein:

I refer to your letter of 5 September in respect of the above-mentioned matter. I understand from that letter and from your statements in the media that UCI is carrying out a "global assessment" in respect of the matter. WADA has offered its assistance to you. WADA's expectation is that, now this matter is one of public record, UCI will fully inquire to ensure that it is appropriately addressed publicly in the interests 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 other riders. It may not be fair that Lance Armstrong is the only rider referred to by name.

In direct response to the questions raised, I say at the outset that the comments and inferences included in your letter also need some response, as it is apparent you are suggesting that somehow WADA should be answering queries directed at the newspaper and its journalists. This is impossible as you will be aware. In addition, WADA does not wish to be associated with a number of the assertions or suggestions contained in your letter. For example, in your introduction, you comment:

- 1. ..."the first thing that has to be examined is whether there is a basis that is sound enough to proceed further".
  - Obviously, 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.
- II. You suggest that the article "is by itself an obvious breach of confidentiality". There is of course no confidentiality resting with the newspaper. I suggest that the question to address, in respect of any breach of confidentiality (and for that purpose alone) is who holds information in confidence, and who, if anyone, has breached that confidentiality.

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It is apparent that UCI held "confidential information" and both disclosed and released it with the consent of Lance Armstrong or his advisers. It appears, from your communication, that the information UCI provided included the code numbers attached to each sample and that such information was not removed or covered prior to the disclosure and release of the documents. That is clear, and not for further inquiry.

iii. You suggest results management will have to be conducted in order to know whether any anti-doping violation occurred. UCI should determine whether under its rules, then and now, there is information which would allow it to proceed with an anti-doping rule violation.

#### I turn now to your specific queries:

1. WADA has no knowledge as to how the reporter obtained the doping control forms. We understand that at least one form was obtained, through his request, from UCI. As we are not in a position to compel the production of any further information, we suggest you inquire elsewhere. If you authorize us to act on your behalf, we would be happy to make further inquiries ourselves. The key matter here, however, is whether the forms are in fact accurate copies. As I have mentioned earlier, and I repeat here, the reporter has no duty of confidence that he has to respect regarding information that is supplied to him.

The issue of the substance, EPO, being found in samples allegedly given by Mr. Armstrong seems to me to be an issue on which you will be inquiring further of the laboratory. The question as to whether, and on what basis, any sanction process vis-à-vs the athlete can follow is a matter for UCI to determine pursuant to its rules.

- 2. By way of background to these questions, we comment and respond:
  - In 1998 and 1999, urine samples were collected from cyclists competing in the Tour de France. We do not know which was the responsible anti-doping organization. It would likely have been CPLD, UCI or the Ministry, or any combination working together. We do not have that information. As the governing international federation, we assume UCI would know this.
  - ii. These samples would have been collected under the then existing protocols, namely the UCI rules, or the CPLD rules. There may have been additional rules for the Tour de France but, we have no information in respect of that. Again, we assume that UCI would be in possession of that information.
  - iii. These samples would have been sent to the French laboratory (accredited at the time by the IOC and subsequently, once WADA became responsible for



laboratory accreditations in 2004, by WADA) for analysis, and that analysis completed on the A samples.

- iv. At the time of the collection of the samples, doping control forms would have been completed by the rider and the doping control officer concerned. It is apparent from the article of L'Équipe, which showed copies of doping control forms, that at least one of these came from UCI. One copy of the forms would have been given to each individual rider, a copy retained by the ADO (we do not know whether this may have been shared) and the laboratory part accompanied the sample to the laboratory. The laboratory part of the doping control form would have had no identifying features, but contained a code number, presumably matching the code number assigned to each sample.
- v. We do not know whether UCI had a protocol in effect at that time requiring riders to give their consent to samples being used for research, post-analysis. This is a matter within the knowledge of UCI.
- vi. 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. We do not have the details.
- vii. 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. 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.
- viii. On 22 August 2005 the laboratory sent the results to WADA, addressed to my attention. The results were contained in two booklets, one for 1998 and one for 1999. The envelope containing the booklets was opened in the WADA office in Montreal on 25 August, upon my return to Montreal from Europe.
- ix. There are no identifying features whatsoever which could lead to the identification of any cyclist within these reports. There are, however, code numbers. Assuming the process was properly carried out at the time, the samples were provided, presumably these code numbers could match the code numbers contained in the doping control forms, or they might have



been new numbers assigned to the samples. We do not have this information.

- x. The WADA Code came into effect for UCI, just prior to the Olympic Games in Athens, in August 2004. Samples collected in that sport subsequently would be subject to the protocols and provisions of the amended UCI rules, which are Code compliant. This would include the necessities for samples collected post August 2004 to have proper consents from the riders before being used for research.
- xi. This provision obviously could not have applied to the samples collected in 1998 and 1999. 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 the samples and therefore would have no way of retrospectively ensuring that any required consent (if any) had been given.
- xii. The rules which applied in 1998 and 1999 were the UCI Rules which you of course have, and the laboratories were accredited by the IOC.

In 1999 it was the IOC Medical Code which governed all doping issues. Included in the IOC Medical Code was Appendix B, which provided for the procedure of the accreditation for laboratories and annexed to that appendix, as Annex II, was a Code of Ethics. This, we understand, provided the only direction to laboratories, accredited by the IOC, in relation to research projects and the only line in the Code, relating to research, stated:

"Laboratories are entitled to participate in programs provided that the Laboratory Director is satisfied with the bona fide nature and they have received proper ethical approval."

Nowhere in the IOC Medical Code, nor in any of the references to laboratories have we found any statement relating to the confidentiality of the sample, the consent of the athlete to research, or the like.

We are not aware whether UCI rules in 1999 reveal any statement in relation to research nor do they have any form or rule for the riders to complete or adhere to in respect to consent to research.

You asked what rules prevailed for the conduct of the research. The only rules in existence in 2004 of which we are aware were the International Standard for Laboratories.

3. Who was aware of the fact that research was being conducted?



As indicated by the WADA Chairman in the press, WADA was informed by the laboratory of the nature of the refinement work conducted and supported the laboratory in that direction.

Who was involved in the samples: storing, opening, interpreting, etc.

This is a question to the laboratory.

What is the scientific justification for the results?

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 microdoses of EPO.

- 4. We cannot answer for Mr. Ressiot. You imply that WADA provided information to him. We did not. Your accusatory approach is most unhelpful.
- 5. Again, we cannot answer for Mr. Ressiot.
- 6. The reports were provided in "anonymous form" and on condition that WADA not use any content for disciplinary purposes. This, of course, was not a problem for WADA, since WADA did not exist in 1999, nor had UCI adopted the Code.

We do not know what rules UCI had in 1998 and 1999 for seeking athletes' consent for samples to be used for research. We suspect there may have been none. We can comment that, although the WADA model doping control form provides for such consent to be given in writing (and has a segment for completion by the athlete), UCI has not yet adopted this in its own forms.

Now we have a further letter from you. We shall reply to that urgently, but wanted you to have our initial answers today.

Sincerely,

David Howman
Director General

Davis Howman



September 14, 2005

By fax: +41 24 468 58 54, and By e-mail: Hein.Verbruggen@uci.ch

Original by courier

Mr. Hein Verbruggen President International Cycling Union (UCI) CH 1860 Aigle Switzerland

Dear Hein,

I have, as you might expect, been following the exchange of correspondence between you and our Director General in relation to some of the facts underlying the story that ran in L'Equipe on August 23, 2005, as well as the public statements made by the UCI and you.

I have seen you quoted as stating that the UCI has received no information in connection with this matter. In the event that this may be true, I am pleased to enclose a copy of the laboratory reports that WADA received. You will, of course, note that there are no names of athletes in these reports. We are advised that the laboratory did not have the names that matched the code numbers. Nor did (or does) WADA. I understand that the UCI has all the names that match the code numbers, so the UCI is now able to identify all the athletes involved, those who tested positive for EPO, as well as those who did not.

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 only one direction, namely how the various elements of the L'Equipe story were obtained by the reporter. Not a single one focuses on the issue of whether or not the allegations made in that 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 interests 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 investigatory 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.

I find this particularly anomalous, since the Information that appears to have allowed L'Equipe to identify one of the athletes in the Tour de France and to match the information with otherwise completely anonymous laboratory data came from the UCI itself. Without the information supplied by the UCI, it would have been impossible to identify any athlete. Unless there is some explanation you may have that could shed further light on this matter, it seems to me, with the greatest if respect, that the UCI appears to be attempting to divert attention from the fact that it was its own actions, not the actions of others, which were directly responsible for the identification of any particular athlete.

If the UCI has any question regarding the ability of the laboratory to analyze the samples, there are means to raise those questions and I hope that as part of the assurances I have requested regarding the UCI investigation, you will do so. I am sure there are means available to re-analyze the samples, or to use DNA verification, to satisfy yourself as to the science involved.

I am confident that we share the same desire to ensure 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 the doping.

If you would like to discuss anything in this letter, I would be pleased to do so.

Sincerely,

Richard W. Pound, Q.C.

## First Edition Cycling News for September 16, 2005

Edited by Hedwig Kröner & Jeff Jones

## Pound: "Verbruggen was the leak"

By Hedwig Kröner

The Chairman of the World Anti-Doping Agency (WADA), Dick Pound, has told reporters in a telephone press conference on Thursday that it was UCI president Hein Verbruggen himself who leaked the doping control protocols of the 1999 Tour de France to French sports paper *L'Equipe*, which in turn provided the basis for the allegations that Lance Armstrong took EPO for the first of his Tour victories.

"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 that information.

"It's 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 a copy of at least one 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). *Cyclingnews* understands that the first sheet of the protocols always goes to the UCI. So it was really Verbruggen himself who gave the documents to the *L'Equipe* journalist? "That's what I understand 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."

Asked if he would be willing to publish the letter, Pound, replied, "If the investigation is thorough and the report is clear, then the exchange of correspondence doesn't mean too much. But if it's not a complete report and we have to comment on it, then the correspondence would probably be quite relevant." Pound also said that WADA was concerned about the way in which the UCI conducted its investigation of the affair. "We're working with the UCI and we're willing to continue to work with them as long as we are convinced that they're going to do a full and complete investigation on this," he continued. "But if it's simply a matter of them looking for some kind of a scapegoat, then that, to us, is not an investigation." Pound's allegations are quite surprising, given that Verbruggen himself has been calling for the head of whoever it was that leaked the information to *L'Equipe*. In light of next week's UCI presidential elections, it doesn't look good for the current president. But in its defence, the UCI told AFP that *L'Equipe* journalist [Damien Ressiot] "came to the UCI on a false pretext and with the approval of Armstrong. He left the UCI with a copy of just one document."

### EPO is not created in frozen urine

Dick Pound also rejected any doubts concerning the age of the tested samples. "If you find EPO in a frozen urine sample, it means that it's been there since the beginning. There might be certain substances that even if the urine is frozen for a number of years that might disappear, but there aren't substances that appear. So if it's there it was there all along."

Finally, Pound didn't rule out that retrospective testing could one day serve in a disciplinary manner. "Within the Anti-Doping Code, we now have a provision that allows us to go back eight years on retesting samples, whether they have been taken in our out of competition. What we have to make sure now is the appropriate legal rule. So that if we do find something in what would then be the B sample, that we have the ability to impose a sanction. But you have to provide the athlete with some means of assuring that it's been properly done - either be keeping enough of the B sample to allow for retesting, or by checking the DNA markers of the urine or blood for identification. We're going to work on that because it is a feature that will become increasingly important."

As far as Cyclingnews understands, the 1999 B samples still provide enough material for yet another test.





## INTERNATIONAL CYCLING UNION

President

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Aigle, September 16<sup>th</sup> 2005 Ref: President / HV / az

Dear David,

Thank you for your letter of 9 September. I look forward to receiving from you the information requested in my letter of 8 September and I repeat that we are grateful to WADA for your offers of assistance. I should be grateful if you would let me know when we will receive a full response to our further request for information. As you know, we are keen to reach a swift conclusion.

With regard to the statements in your letter of 9 September, two issues, in particular, are not adequately answered and I trust that you will answer them, alongside your response to my letter of 8 September. The issues relate to: (i) jurisdiction; and (ii) the breach of confidentiality.

With regard to jurisdiction, even though the samples apparently relate to the Tour de France in 1998 and 1999, before WADA was established, I do not accept that you may distance yourself from the laboratory, without vigorously investigating the sequence of events yourselves. Even if you do not believe you have jurisdiction over any disciplinary matters which might possibly arise regarding the athlete concerned (although I emphasise that such matters may not arise), the laboratory's apparent work since 2004 clearly comes within your jurisdiction.

I cannot see any basis on which WADA may distance itself from the laboratories' work, given that it falls under your jurisdiction. Moreover, you have stated that the laboratory informed WADA that it was undertaking the research, WADA asked to be informed of and it has reviewed the results which the laboratory sent to it (the laboratory also states that it undertook the research in collaboration with WADA; see the enclosed Press statement from the laboratory). I am sure that WADA would not wish to be associated with any work of one of its accredited laboratories, unless WADA was satisfied that its rules had been strictly followed.



In any event, you state that it should be determined whether there is any basis of truth in the allegation. Part of that determination has to be whether WADA's rules, under which the laboratory operated when conducting the apparent research, were followed. WADA could not have any interest in, or give any credence to, a research project by a WADA-accredited laboratory, unless WADA was satisfied that the research project had been undertaken in full compliance with WADA's rules. I would expect that you would make full enquiries of the laboratory as your highest priority, in order to ensure that it had complied with all of WADA's requirements. As you know, we have sent an initial questionnaire to the laboratory and it would also be helpful if you would ensure that the laboratory responds to us without delay.

With regard to the breach of confidentiality, the resolution of this question remains critical to our enquiry with all the ramifications which any breach will have for the authorities concerned. I agree with you that the questions to address are: (i) who holds information in confidence; and (ii) who has breached that confidentiality.

You will see, from the enclosed statement issued by the laboratory, that the laboratory acknowledges having undertaken the research (as mentioned above, in collaboration with WADA), and that the laboratory agreed to supply the anonymous data to WADA on condition that the data would not be used in disciplinary proceedings. The statement also confirms that the laboratory was not in a position to match the samples with any individuals.

Why would the laboratory insist that the samples should not be used in any disciplinary proceedings? This would normally be the case in any event, because the laboratory would re-label the samples to ensure anonymity. The third party must have requested that the laboratory include the doping control numbers in the data. In that case, why did the laboratory risk its reputation by agreeing to such a request?

We need to know who requested the laboratory to include the doping control numbers in the data. You will be able to tell us whether it was anyone within WADA and, if so, why such a request was made. If it was a third party, then WADA will no doubt wish to pursue this matter with the laboratory. The laboratory operates under WADA rules, and it did so at the time the data were transmitted. By stating that the laboratory "accepted" to supply the data to WADA as they were, the laboratory indicates that WADA asked for such data. If a third party has procured the laboratory to include the doping control numbers in the data, then WADA will no-doubt want to know the circumstances and to take such action as is necessary against the laboratory.

I look forward to your response to the above and to the issues set out in our previous correspondence. We continue to need to take such action as we deem necessary in relation to this matter. Thank you once again for your assistance.

Hein Verbruggen President



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President

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First by fax: +1 514 904 8771 (and email)

Aigle, September 16<sup>th</sup> 2005 Ref: President / HV / az

Dear Dick.

It is only after reading the statements you made, that I fully understand the extremely negative consequences for myself and the UCI.

I was not fully aware of that when I called you yesterday.

I want to inform you that I feel obliged to come out with an official reaction; this is no longer acceptable.

Sincerely yours,

Hein Verbruggen President

## First Edition Cycling News for September 20, 2005

Edited by John Stevenson & Les Clarke

## **UCI denies leaking Armstrong documents**

## Accuses WADA of blocking investigation



WADA chairman Dick Pound Photo: © AFP

Responding to comments by Dick Pound, the head of the World Anti-Doping Authority, the UCI has denied supplying French newspaper L'Equipe with the doping control forms necessary to link Lance Armstrong with the 1999 Tour de France urine samples that L'Equipe alleges indicate Armstrong used EPO in winning the Tour.

"Mr. Verbruggen [UCI president] has never been involved personally, contrary to what Mr. Pound said in another statement," said the UCI in a press release yesterday. "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."

The UCI has admitted that it 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," it said.

The UCI initiated an investigation into the L'Equipe allegations on August 29, and said at the time it would announce its findings within ten days. On September 9 it announced that it had been unable to find out anything because WADA had not responded to all its questions about the research and testing being conducted by the anti-doping lab at Châtenay-Malabry.

Since then, Dick Pound has cast doubt on the UCI's motives in investigating the case. "We're waiting to see whether they have a commitment to get at the truth and the whole truth before we decide to participate further in the investigation, "he said. "We are prepared to help further if one of the issues that the UCI wants to explore is how some of this information became public, that's fine. But we're not prepared to sit by and participate in an investigation that only looks at how the information became public."

In response, the UCI says it is attempting to conduct "a comprehensive examination of all issues related to the reported testing" including, "the reasons for the testing; the testing protocol; funding; the approval of the testing; how samples were selected; how the testing was conducted; the accuracy of the tests; the results reported; the use made of the results; and all other issues related to the L'Equipe article and the allegations contained therein."

"It has been three weeks since we initiated the investigation at WADA's request," the UCI statement continues, "and WADA has failed, to date, to provide all the documents and information we have requested, which we need to conduct the investigation, even though WADA has stated its willingness to assist the UCI."



September 22, 2005

By fax: +41 24 468 58 54, and By e-mail: Hein.Verbruggen@uci.ch

Mr. Hein Verbruggen President International Cycling Union (UCI) CH 1860 Aigle Switzerland

Dear Hein,

I have your recent letters. As you will have seen from the letter sent to you directly by my President on 14 September, and from which I quote:

"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."

Until we receive such assurance, I am not in a position to respond to your further requests.

Yours sincerely,

David Howman Director General

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## INTERNATIONAL CYCLING UNION

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## **FAX MESSAGE**

To

WADA

**David Howman** 

Fax nbr

+1 514 904 8650

From

Hein Verbruggen

Date

21 September 2005

Ref

President / HV / gpo

Total pages

Subject

(including this one)

#### Dear David,

Thank you very much for your letter of 9 September. I look forward to receiving from you the information, as requested in my previous correspondence, relating to the allegations in the French press relating to research apparently carried out by a French laboratory. I have received a letter from Mr. Pound on 14 September. In his letter he referred to a courier containing documents relating to our investigation. We have not yet received this courier and I would be grateful if either you or Mr. Pound would kindly let me know when we will receive it, which I trust will be as soon as possible.

As you are aware from my letters of 5, 8 and 16 September, the investigation we are conducting is both thorough and complete. Can you please now confirm that you will provide all the information requested.

Thank you for your assistance.

Yours sincerely,

Hein Verbruggen President



## INTERNATIONAL CYCLING UNION

#### President

World Anti-Doping Agency
Mr. David Howman
Director General
Stock Exchange Tower
800, Place Victoria (Suite 1700)
P.O. Box 120
Montreal, Québec H4Z 1B7
Canada

First by fax: +1 514 904 8771

Aigle, 29 September 2005 Ref: President / az-j

## Tour de France samples

Dear Mr. Howman,

We refer to your letter of 22 September 2005.

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

In the meantime, we received the copy of the two laboratory reports and we thank you for that.

We were somewhat surprised that the reports are not called "Study on the improvement of the EPO detection method" or something of the kind. They are called "Recherche EPO Tour de France 1998/1999" Each report contains nothing else but the analysis result of each sample and the survey that was published in L'Equipe. There is nothing on the purpose, principles, implementation, or conclusions of any scientific research.

The Paris laboratory wrote to us that it "a accepté de transmettre à l'AMA la totalité des informations dont il disposait de façon à permettre à cette Autorité de vérifier a postériori, si elle le souhaitait, la cohérence des résultats obtenus. Il a d'ailleurs subordonné cette acceptation à l'engagement de l'AMA d'exclure toute action disciplinaire eu égard aux conditions de réalisation de ces travaux de recherche et en particulier à l'ouverture des flacons B ".

This wording indicates that the data found in the report were included at WADA's request. This request was accepted by the laboratory on the condition that disciplinary action be excluded.

r. 2/2

This condition is, of course, important for the further investigation of the case and is particularly relevant for the following data:

- name and date of the competition;
- the laboratory's sample series number (corresponding to the whole of samples delivered to the laboratory at the same time on a given day);
- the sample code numbers;
- the remaining volume of urine;
- the remaining volume of "retentat".

So can you confirm that it was not WADA or someone within WADA who asked for one or more of these data to be included in the reports?

Thank you for your prompt reply.

Sincerely Yours,

Pat McQuaid President





Mr. Richard W. Pound, Q.C. President World Anti-Doping Agency Stock Exchange Tower 800 Place Victoria, Suite 1700 P.O. Box 120 Montréal (Québec) H4Z 1B7 Canada

Lausanne, 20 September 2005

#### Dear President,

The ASOIF Council, on behalf of the Summer Olympic IFs and the IOC Athletes Commission, on behalf of the athletes of the world, wish to protest in the strongest possible terms the irregularities committed in the so-called doping revelations against the cyclist Lance Armstrong.

The IFs 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 in this case 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.

Even if it was not yet in force in 1999, the International Standard for Laboratories, which must be applied by all anti-doping laboratories accredited by WADA, recommends with regards to storage of samples that "the laboratory shall maintain a policy pertaining to retention, release and disposal of samples and aliquots". Does this mean therefore that the Châtenay-Malabry Laboratory has kept all the samples in its possession during all these years? If so, then other samples taken during international competitions held in France since 1998 have also been stored (e.g. 1998 Football World Cup, Roland Garros Tennis tournaments in 1998 and 1999, etc.) If this is not the case, can you please explain how the lab took the unilateral initiative to preserve samples from the 1998 and 1999 Tour de France without the authorisation of the International Cycling Union?

WADA's International Standard for Laboratories goes on to say that laboratories must use a unique internal code for each sample, that no information that could link an athlete with an individual result may be included in its reports to WADA and, in general, that "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" (5.2.6.13).

However, in this case, the results of the analysis that have been done for research purposes – not even anti-doping control purposes – have been reported not with the internal laboratory code (which was not even necessary for reporting research results), but with the sample code! The results have been reported in a way so as to be able to identify the race, the day other samples were taken and, based on the doping control form containing the sample code, the identity of the athletes tested!

This is simply unacceptable, of course, since it is widely known that, within the context of scientific research, if any study is not completely anonymous (that is, there can be no way to identify the person concerned), then the subject in question must give his or her clear consent. Moreover, any scientific study worthy of this term must be the subject of an agreement in advance of a scientific ethics commission.

All analyses must be done in strict confidentiality. The laboratory does not know the names corresponding to the codes identifying the samples. Therefore, one of the parties to these names must have violated his obligation of confidentiality — and this was not UCI since they have indicated that they learned the first time themselves from the article in l'Equipe that these samples had been tested. This says a lot about the complicity and the professional ethics of those involved.

Obviously, the lab itself does not have the right to publicly confirm or comment upon analyses considering these were done illegally and their identification was made in violation of the guarantee of confidentiality.

These events not only cast serious doubt on the credibility of the French anti-doping system, but also on the entire world-wide anti-doping fight if such blatant transgressions are not rectified and those responsible properly disciplined.

Athletes will surely be reticent and anxious about participating in international competitions in France in the future if their due rights are so carelessly disregarded and there is the possibility that they too could find themselves facing accusations at the end of procedures to which they were not a party.

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.

Sincerely,

Denis Oswald ASOIF President Sergey Bubka

President, IOC Athletes Commission

cc: Jacques Rogge, IOC President

International Olympic Federations

IOC Athletes Commission



play true

September 23, 2005

By e-mail: rjf@asoif.com

Mr. Denis Oswald President ASOIF Avenue de Cour 135 CH-1007 Lausanne SWITZERLAND By e-mail: bubka@dn.farlep.net

Mr. Sergey Bubka Chairman IOC Athletes' Commission c/o 7, Avenue Princesse Grace Houston Palace MC-98000 Monaco MONACO

#### Dear Presidents,

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Your letter dated 20 September addressed to me, but copied to the IOC President, all International Olympic Federations, and the IOC Athletes' Commission, was tabled at the WADA Executive Committee meeting on Tuesday. 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. That 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 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.

As you are aware, the World Anti-Doping Code and its ancillary International Standards came into effect on 1 January 2004, and were implemented throughout that year by the International Federations. Prior to changes in rules, international federations, in general, adopted the Olympic Movement Anti-Doping Code and/or had rules of their own.

The situation in relation to the information which we at WADA have is quite simple. I outline it chronologically from our information:

1. We were informed, by the French Laboratory that they were conducting tests on stored samples in their efforts to refine the quality of the EPO test. I am certain that you would encourage such efforts in view of your support of the fight against doping in sport.

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- 2. All of the WADA accredited laboratories are required to undertake continuing internal research. The French Laboratory has been at the forefront, over the years, in its particular efforts to refine the analysis for EPO. Indeed, a paper from that Laboratory based on samples collected, inter alia, from the 1998 Tour de France was published in 2000 in "Nature".
- 3. WADA was informed of the refinement progress, we encouraged its continuation as you would expect, and asked to be apprised of the findings.
- 4. The French Laboratory sent to WADA findings in relation to its research conducted on samples from the 1998 and 1999 Tours. This was sent by courier to our headquarters in Montreal. The package was opened on 25 August, 2005.
- 5. The article in L'Equipe was published on 23 August 2005.
- 6. The information contained in the Laboratory reports to WADA was anonymous.
- 7. WADA has no other information in relation to the samples, no information in relation to the riders from whom the samples were taken, and no means of identifying any sample as coming from any rider. We have sent the research documents to UCI as requested.
- 8. WADA has been told by UCI that confidential information relating to the rider, and held by UCI, was given with the rider's consent to the journalist. This of course was a doping control form, and maybe more.

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

Further in your letter, you ask of us a series of questions which ought best to be directed to those responsible. For example, you ask WADA to explain: "how the lab took the unilateral initiative to preserve samples for the 1998 and 1999 Tour de France without the authorisation of the International Cycling Union?" To help you in answering that, we refer to the rules of UCI in existence at that time. We are certain you will have read these prior to writing and circulating your letter, but we take the liberty to refresh your memory by quoting directly from those rules:

Article 130. "Other than undisputed 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."

We are not aware of any requests from the UCI in relation to those samples, and quite obviously the property in them did not pass back to the federation. We



should emphasize that, so far as we are aware, there was no analysis done for the purpose of doping control.

9. You are adamant in expressing factual situations and then commenting on them. Perhaps I might politely ask on what factual basis you have formed your analysis of the facts and how you suggest the identity of the athletes tested is so obvious from the Laboratory report on its research.

Finally, I must express my astonishment that not only have you written a very public statement on behalf of two well-known organizations without taking elementary precautions to ensure the factual base is correct, but you have also launched into invective and insults which go far beyond any professional or sensible critique or criticism.

The hyperbolic nature of your attacks indicates a serious lack of understanding of the situation, which is all the more surprising, coming as it does from 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 objective, you may have lost sight of the essential purpose for the existence of WADA and the role of all stakeholders in it.

The sentiment you were careful to express in your second paragraph is vastly undermined by the content of the succeeding paragraphs. I might also point out that the ASOIF and athlete representatives on the WADA Executive Committee had not been consulted regarding the contents of your letter.

In conclusion, you say: "the IFs and the athletes do not intend to make any other comments about this matter, which includes other troubling elements...' and you suggest: "that all those involved in the fight against doping are called upon to respect the rules." As I said at the outset, it is intriguing to read your colourful letter which makes numerous references to breach of rules without quoting them. It would have been helpful (and more professional) for you to have identified, at the outset, each of the specific rules which you claim to have been breached, but I invite you now to do so, and in detail.

You demand that WADA suspend the accreditation of the Chatenay-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.

You have also made some most unfortunate comments regarding a particular country. I do hope you will reconsider those comments forthwith and issue a public apology on behalf of all of the IFs and athletes in whose name you have purported to speak. You



will understand the concern with which the governmental members, in particular, of WADA read these accusations. I should say that the concern was not limited to the governmental members.

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.

In conclusion, for the moment, I invite you to reassess, forthwith, both the facts and rules upon which you purport to rely as well as your position and, if you can, review your original letter with dispassion in regard to the real facts, you might care to remedy the damage you have done by the publication of your letter of 20 September.

Unlike you, I will not circulate this letter to the IFs and members of the Athletes Commission, since I hope it will elicit a significantly different letter from you in response, although I reserve the right to do so, depending upon your response. Since I am a representative of the IOC on the WADA Foundation Board, it is, however appropriate for me to provide a copy to the IOC President, as part of my stewardship report in that capacity.

Yours sincerely,

Richard W. Pound, QC

President

c.c. Jacques Rogge, IOC President (by e-mail: christophe.de kepper@olympic.org)





Mr. Richard W. Pound, Q.C. President World Anti-Doping Agency Stock Exchange Tower 800 Place Victoria, Suite 1700 P.O. Box 120 Montréal (Québec) H4Z 1B7 Canada

Lausanne, 06 October 2005

## Dear President.

We are in receipt of your response to our letter of September 20<sup>th</sup> and find your approach and tone both surprising and puzzling.

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 antidoping 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 recognise 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 or regulatory standards so as to obtain a result, which leaves serious doubts as to the truth?

We hope the answer to this question is obvious.

We also find it rather strange that the WADA Chairman should recriminate us for not being sufficiently specific in reference to the World Anti-Doping Code, created by WADA, when this would appear to be your responsibility to ensure the Code has been respected.

In any case, to satisfy your request, we have provided in the document attached the specific references to the Code which we believe to have been violated in this case as well as some further commentary in relation to these rules.

We return again to what is, for us, the fundamental issue: The credibility of the Paris lab has come into question. Instead, WADA seems to want to place the burden of responsibility for investigating the lab on an International Federation (UCI) saying "...the situation presently being investigated by 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." Since when is it the responsibility of an IF to investigate a lab?

When questioned on the lab's responsibilities regarding the storage and testing of 6 year-old samples without UCI's consent, you attempt to deflect the responsibility from the lab by citing UCI's rules in force at the time. We appreciate your efforts to 'refresh our memory' but you apparently did not read UCI's rules very carefully yourself since, in fact, you misquote the 1999 version of UCI Rule 130. The correct text reads:

"Other than <u>in disputed</u> 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." (See attached)

In other words, in your opinion, the fact that UCI did not make a specific request for these samples means that they waive all their rights in relation to said samples, which therefore remain the property of the lab and that the lab can do whatever it wants with them? But in reality, this rule actually supports our argument that UCI did not authorize the storage and analyses of these samples, since there was no dispute at the time, and therefore the lab acted in violation of these rules.

So, the next time you are so quick to accuse us of getting our facts wrong, perhaps you should be a bit more diligent in checking your own facts.

You claim we use "strong accusatory language" and that we have "launched into invective and insult which go far beyond any professional or sensible critique or criticism." You say the "hyperbolic nature of your attacks indicates a serious lack of understanding of the situation". And still the most spectacular statement of all: "It causes me to wonder whether, in the pursuit of some different objective, you may have lost sight of the essential purpose for the existence of WADA and the role of all stakeholders in it."

Again we must ask the question, why is WADA being so defensive and who are you trying to defend? As key stakeholders or 'owners' of WADA, we expected WADA to react to the contrary; objectively, impartially and promptly in addressing our concerns. Whereas you are so concerned about the truth and the real facts, we expected WADA to take great pains over finding out the truth about the missteps of the laboratory and the reasons for its particular way of reporting research results and to provide us with the real facts in answer to our questions.

All of this kind of sensational language seems to have just one objective: to avoid the point. The point is: Why would one of the most experienced anti-doping laboratories in the world disregard WADA's rules and make the results of internal research available in such a way as to breach the confidentiality of the athletes? In doing so, the lab must have known that it would risk undermining the confidence and trust the sport movement has in its ability to work fairly, objectively and transparently in the fight against doping.

And when considering your rhetorical and patronising spin in order to draw attention away from this point, one begins to have the same doubt about WADA.

As a result, and seeing your reluctance to carry out an investigation yourselves, we believe the best way to address the above questions is to call for an independent investigation of these circumstances, completely outside WADA's control and under the auspices of a CAS mediator.

We regret that such an investigation is necessary and that WADA is apparently unwilling, for some reasons unknown to us, to accept this responsibility itself. For the sake of all the 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.

In line with your wishes, we have refrained from circulating this letter to our members, however, we reserve the right, based on your satisfactory response to our questions, to circulate this correspondence at a later date.

Sincerely,

Denis Oswald ASOIF President Sergey Bubka President, IOC Athletes Commission

Encl.2

cc: Jacques Rogge, IOC President

# Specific references to the World Anti-Doping Code contained in the letter from Denis Oswald and Sergey Bubka on 20 September 2005 and Further commentary

1) Our letter, Paragraph 7: "... laboratories must use a unique internal code for each sample, that no information that could link an athlete with an individual result may be included in its reports to WADA and, in general, that 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."

Code References: 5.2.2.1, 5.2.6.11, 5.2.6.13

WADA Comment: You claim this last article is not relevant since it applies to doping control and you state, "...you will realize these were not analyses conducted for doping control."

Our response: How can confidentiality not be relevant, regardless of the context? Are you saying that confidentiality should be less stringent for research? The fact is, a journalist had access to the analytical results — even before WADA (!) and, regardless of the purpose of analysis, this means that the above rule was breached by the laboratory or WADA since, as you indicate in your letter, only the lab and WADA were aware of their "internal" analyses on stored samples. The fact that UCI or the athlete may have authorised the journalist to have a copy of the athlete's doping control form is entirely irrelevant since, without access to the lab's original analyses, this form, and the Sample code numbers, would be absolutely meaningless.

As the analyses were not conducted for doping control there was no need at all to enable an association with the collection document or other external chain of custody (5.2.2.1), regardless the persons or bodies that are in possession, rightfully or wrongfully, of a copy of the collection document. Confidentiality should also protect the athlete against wrongful or mistaken use by third parties of information enabling the athlete to be identified. There was no need to include the sample code numbers in the report to WADA since you were not in possession of the matching doping control forms. The circumstance that the information was irrelevant for its purpose, adds to the seriousness of the breach of confidentiality and again leads us to ask, why carry out the research in this specific way?

2) Our letter, Paragraph 8: "However, in this case, the results of the analysis that have been done for research purposes — not even anti-doping control purposes — have been reported not with the internal laboratory code (which was not even necessary for reporting research results), but with the sample code! The results have been reported in a way so as to be able to identify the race, the day other samples were taken and, based on the doping control form containing the sample code, the identity of the athletes tested!"

## Code Ref:

i) Article 4.5 – Monitoring programme: "...Such reports shall not contain additional information regarding specific Samples...WADA shall implement

measures to ensure that strict anonymity of individual Athletes is maintained with respect to such reports.

ii) Article 6.3 – Research on Samples: "No Sample may be used for any purpose other than the detection of substances ... on the Prohibited List, or as otherwise identified by WADA pursuant to Article 4.5 without the Athlete's written consent."

<u>WADA Comment</u>: You claim information received from the lab was anonymous and that no other information received from the lab could identify the athlete.

Our response: The wording "no additional information regarding specific samples" and "strict anonymity" imply that there may be no individualization at all of the results. This excludes the use of the Sample codes. Article 4.5 implies that IF's shall not receive the Sample codes of Samples in which substances on the monitoring list have been found: otherwise the monitoring results are no longer anonymous.

While we expect WADA's interpretation of art. 6.3 is that the athlete's consent is not needed if a prohibited substance is looked for in a research project, we would beg to differ also based on the specific reference on the Doping Control Form where Section 3 states:

## "Consent for research (optional)

In order to help combat doping in sport, by signing below I 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 of any type, provided that it can no longer be identified as my sample."

3) Our letter, Paragraph 9: "...any scientific study worthy of this term must be the subject of an agreement in advance of a scientific ethics commission"

<u>Code Ref</u>: Laboratory Standards, Annex B (Code of Ethics), Art. 2, **Research**: "Laboratories are entitled to participate in research programs provided that the Laboratory director is satisfied with the bona fide nature and the programs have received proper ethical (e.g. human subjects) approval."

WADA Comment: No reference.

<u>Our response</u>: Other than receiving WADA's encouragement, did the lab obtain the proper ethical approval to do this research? Were all the athletes whose samples were analysed in this research consulted?

4) Our letter, Paragraph 11: "...the lab itself does not have the right to publicly confirm or comment upon analyses considering these were done illegally and their identification was made in violation of the guarantee of confidentiality."

<u>Code Ref</u>: Laboratory Standards, Annex B (Code of Ethics), Art. 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."

WADA Comment: You generally defend the actions of the lab, but make no reference of concern to the fact confidential laboratory records appeared in the media.

<u>Our response:</u> The director of the Paris Lab, Dr. Jacques de Ceaurriz, is repeatedly quoted in l'Equipe and other media outlets (AFP, 23.08.05) as confirming publicly that the samples were positive for EPO. This is in clear violation of WADA's Code of Ethics in the International Standards for Laboratories regarding confidentiality regardless of whether for research or doping control purposes.

5) Our letter, Paragraph 15: "...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."

## Code Ref: (2)

- Laboratory Standards, Article 6.4.8.2: Suspension of accreditation: "Whenever WADA has reason to believe that Suspension may be required and that immediate action is necessary in order to protect the interests of WADA and the Olympic movement, WADA may immediately suspend a Laboratory's accreditation. If necessary, such decision may be taken by the Chairman of the WADA Executive Committee."
- Laboratory Standards, Annex B (Code of Ethics), Art. 4; Conduct detrimental to the Anti-doping Program: "The Laboratory personnel shall not engage in conduct or activities that undermine or are detrimental to the anti-doping program of WADA, an International Federation...or the International Olympic Committee"

WADA Comment: "You demand that WADA suspend the accreditation of the Chatenay-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."

<u>Our response</u>: Not only does the WADA ExCo have the authority to suspend labs, but the WADA Chairman himself has this power. And WADA has already set a precedent by suspending other labs (e.g. Seoul) for much less visible and serious violations.

### An interview with L'Equipe's Damien Ressiot, September 7, 2005

### The author of it all

After August 23, 2005, L'Equipe's Damien Ressiot, already a busy journalist, was hard to get hold of. The author of several articles published in the first three pages of the paper that day that claimed there was proof Lance Armstrong took the banned doping substance EPO to win the 1999 Tour de France. Ressiot based his claim on the results of the French WADA-accredited laboratory Châtenay-Malabry, which had conducted retrospective testing of the leftover B samples from 1999 and 1998 in order to improve its methods of detecting EPO, as well as Lance Armstrong's doping test protocols of the first of his seven Tour victories.

While the French journalist has not revealed the sources of his information - and shouldn't be forced to do so - many have questioned Ressiot's approach on handling his alleged revelations: Armstrong himself called the course of action a witch-hunt, as four of the eight positive samples associated with his name, and no others were identified. Why didn't this happen? This was just one of the questions *Cyclingnews' Hedwig Kröner* was finally able to ask Damien Ressiot, when she got a hold of him on the phone last week.



Copies of L'Equipe that ignited a fire Photo ©: AFP

**Cyclingnews:** 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 your newspaper, *L'Equipe*, which is owned by the same organisation as Tour de France organiser ASO, did not want to publish the information too soon.

"I did focus on him as a person, on the challenge that he threw at the journalists."

 Damien Ressiot on his motivation for identifying only Lance Armstrong

Damien Ressiot: 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 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 Antidoping 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 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 truth, and in order to obtain the information, I couldn't avoid the delay.

**CN:** Why did you identify only Lance Armstrong and not the other six 1999 positive samples as well?



Photo ©: AFP

DR: 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 Could Armstrong's 1999 Tour victory ("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 in my habit to protect anybody.

CN: Did you not think of the possibility that people would reproach you for this - not publishing all of the names? The fact that you concentrated on Armstrong only gave him some arguments against your investigation.

DR: Some of my colleagues have already reproached me for this, and many readers interpreted it negatively. But Armstrong's Prologue time in 1999 Photo @: AFP complaints are inadmissible: He made several declarations in the past that he would open his medical dossier, respond to all of the questions concerning the doubts surrounding him - basically, act like a champion with a clear conscience - and that never was the case. While I was working on the current revelations, I asked him to, and he didn't want to. He didn't do it for Walsh and Ballester either [authors of the book L.A. Confidentiel - ed.]. You can't say that you're ready to do it if you really are not. Of course, the information we published is very personal, but then you shouldn't announce that you're ready to reveal it any time if you're not going to!

CN: Where are the official protocols of the Tour de France antidoping tests stored? At the UCI, at the French Cycling Federation...?

"He made several declarations in the past that he would open his medical dossier...and that never was the case."

- Ressiot calls Armstrong's bluff

DR: The protocols are not public, and they were very hard to get. Within the institutions, some say that they don't have them any more and I don't know if one has to believe them. The UCI has them, that's for sure. Of course, I can't give you my sources. All I can tell you is that it wasn't Sylvia Schenk, as French magazine L'Express put it in last week's edition of their paper. I can assure you of that. [Meanwhile, Cyclingnews contacted]

Schenk, who is complaining against the UCI over the legitimacy of its upcoming presidency elections, and she has also denied this firmly - ed. 1

CN: How can you know that four of the positive samples in 1999 were taken after the prologue?

DR: When you read the results table of the laboratory, you see that the first series of samples that arrived in Chatenay-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.

CN: But the names of the four riders tested at the prologue 1999 are no secret.

**DR:** Yes, that's true. If you take the book *L.A.* Confidential, on page 202, the names of the riders that were tested after the prologue are listed. [Cyclingnews 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 prologue 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.



1999 - the year it all started Photo ©: AFP

CN: Is there still enough urine left in the B samples to carry out another test?

**DR:** Yes, there is still enough material left for another analysis. So Armstrong could, if he wanted, ask another lab to test the samples again - of course, these are the B samples, so it wouldn't be the classic procedure where you need an A and a B sample.

CN: Will you publish the names of the other six positives?

**DR:** At the moment, no, but I'm working on it. I can imagine that a number of my French colleagues who reproached me that I didn't are also working on it. If they succeed, I will gladly feed off their revelations. Some of their letters weren't exactly pleasing. In fact, I have also received threats already for my work.

## ANALYSIS OF SAMPLES FROM THE 1999 TOUR: INDEPENDENT INVESTIGATOR APPOINTED BY THE UCI

Within the frame of measures aiming to clarify facts linked to the analysis of urine samples taken during the 1999 Tour de France, the UCI has appointed last Friday 30<sup>th</sup> of September, Mr. Emile Vrijman and his law firm Lamsma Veldstra & Lobé attorneys in Rotterdam, the Netherlands, as independent investigator to be in charge of this case.

Lawyer and former Director of the National Anti Doping Agency in The Netherlands (NeCeDo), Mr. Vrijman has a large experience in those qualities in the in the field of anti - doping.

The UCI has entrusted Mr. Vrijman and his law firm the task to undertake a comprehensive investigation regarding all issues concerning the testing conducted by the French laboratory of urine samples from the 1999 Tour de France.

As WADA has informed the UCI of its intention to open an investigation, the UCI is concerned that such an investigation from WADA as an involved party, would be based on aspects out of its competencies.

The UCI's decision to appoint an independent investigator is supported by numerous authorities, both in sports, as well as in Anti – Doping. The UCI expects all relevant parties to fully co-operate with the investigation.

Finally, the UCI wishes to express its full confidence in both the capabilities, as well as the integrity, of Mr. Vrijman and his law firm to conduct the investigation in a thorough and proper manner and is looking forward to the conclusions of their investigation.

**UCI Press Service** 



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Mr. W.F. Veldstra / Mr. G.P. Lobé / Mw. Mr. D.A. Wahid - Manusama / Mr. G. Hoyng / Mr. E.N. Vrijman, MCL / Mr. R.A. van Winden / Mr. A.N. Broekhoven / Mw. Mr. H.C. Aalders-van Vuren / Mr. J.H. Lamsma, adviseur

ADVOCATED EN PROCUREURS

World Anti-Doping Agency
Mr. Richard W.Pound Q.C., President
Stock Exchange Tower Suite 1700
800 Place Victoria
P.O.Box 120
Montreal (Quebec) H4Z 1B7
CANADA

FAX 001 514 904 86 50

Uw ref.

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Onze ref.

: 252101

PY20051006LA/ev/as

Inzake

: UCI/Independent Investigation

**Datum** 

: October 6, 2005

Dear Mr. President,

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Stichting Beheer Derdengelden Lamsma Veldstra & Lobé advocaten ABN-AMRO 45 97 69 626 BTWnr. NL007159961B01

As you may know already, my law firm has been requested by the Union Cycliste Internationale (UCI) to undertake an independent investigation regarding all relevant facts and circumstances concerning the testing conducted by the French Doping Control Laboratory (LNDD) of urine samples from the 1998 and 1999 Tours de France. This investigation is intended to be comprehensive and to cover all aspects of the matter at hand. In order to be able to commence with the investigation, the UCI has handed over to us her entire file for review and study.

Given the fact that the matter in question resolves around alleged Adverse Analytical Findings, we have decided to structure the procedural aspects of our investigation accordingly.

Taking into account the position of WADA as coordinating body in the international fight against doping in sport and it's involvement in the current matter so far, we expect WADA to fully co-operate with our investigation, as it has already confirmed to be prepared to do so. Upon completion of our review of the UCI file, we intend to contact all relevant parties forthwith, in order to obtain a further classification regarding those issues, which might have remained unclear to us so far. Further details about the manner in which our investigation will continue will be communicated to you at that time.

In the meantime, we expect all relevant parties, including WADA – in the interest of the impartial and unbiased nature of the investigation – to maintain absolute confidentiality regarding all aspects of our investigation, as well as all information WADA might actually have in its possession regarding this matter.

Yours sincerely

-Emile N. Vríjman

Wilfred Veldstra

Lamsma Veldstra & Lobe advocaten en procureurs is een maatschap die mede beroepsvennootschappey omvat. Iedere aansprakelijkheid is beperkt tot het bedrag dat in het desbetreflende geval onder onze beroepsaansprakelijkheidsverzekering wordt uitbetaald. Een kopie van de huidige beroepsaansprakelijkheidsverzekeringspolis met



Mr. W.F. Veidstra / Mr. G.P. Lobé / Mw. Mr. D.A. Wahid - Manusama /
Mr. G. Hoyng / Mr. E.N. Vrijman, MCL / Mr. R.A. van Winden /
Mr. A.N. Broekhoven / Mw. Mr. H.C. Aalders-van Vuren / Mr. J.B. Lamsma, adviseur



Per telefax: 0033 - 1 40 45 90 47

Ministere de la Jeunesse et du Sport att. of the Honorable mr. Jean-François Lamour Esq. 95, Avenue de France 75650 Paris-Cedex 13 FRANKRIJK Postbus 23320

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PY20051006LC/ev/as

inzake

: UCI/Independent investigation

**Datum** 

: October 6, 2005

### Your Excellency,

With this letter I would like to inform you, that my law firm has been retained by the Union Cycliste Internationale (UCI) to undertake an independent investigation regarding all relevant facts and circumstances concerning the testing conducted by the WADA Accredited Doping Control Laboratory in Châtenay-Malabry, France, of urine samples from the 1998 and 1999 Tours de France. This investigation is intended to be comprehensive and to cover all aspects of the matter at hand. In order to be able to commence with the investigation, the UCI has handed over to us her entire file for review and study.

Given the fact that this matter resolves around alleged Adverse Analytical Findings, we have decided to structure the procedural aspects of our investigation accordingly.

Taking into account the important role your Ministry is fulfilling – both nationally and internationally – in the fight against doping in sport and it's involvement in the doping control procedures at both Tours de France, we have no doubt whatsoever that your Ministry will fully co-operate with our investigation. Would you please be so kind as to inform us regarding the manner in which you would like us to communicate with your Ministry in this matter and provide us with the identity and further details of an authorized contact person within your Ministry in order to facilitate future communication regarding this matter. Upon completion of our review of the UCI file, we intend to contact all relevant parties forthwith, in order to obtain a further clarification regarding those issues which might have remained unclear to us so far. Further details about the manner in which our investigation will continue, will be communicated to you at that time.

In the meantime, we expect all relevant parties, including the Ministry – in the interest of the impartial and unbiased nature of the investigation – to maintain absolute confidentiality regarding all aspects of





our investigation, as well as all information the Ministry might actually have in its possession regarding this matter.

Yours-sincerely,

Emile N. Vrijman

Wilfred F. Veldstra

Mr. W.F. Veldstra | Mr. G.P. Lobé | Mw. Mr. D.A. Wahid - Manusama |
Mr. G. Hoyng | Mr. E.N. Vrijman, MCL | Mr. R.A. van Winden |
Mr. A.N. Broekhoven | Mw. Mr. H.C. Aalders-van Vuren | Mr. J.H. Lamsma, adviseur



Direction Laboratoire National de Depistage du Dopage Mr.J. de Ceaurriz 143, Avenue Roger Salengro 92290 Chatenay-Malabry FRANCE

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PY20051006LB/wv/is
: UCI/Independent investigation

Datum

: October 6, 2005

Dear Mr. Director,

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As you may know already, my law firm has been requested by the Union Cycliste Internationale (UCI) to undertake an independent investigation regarding all relevant facts and circumstances concerning the testing conducted by your laboratory of urine samples from the 1998 and 1999 Tours de France. This investigation is intended to be comprehensive and to cover all aspects of the matter at hand. In order to be able to commence with the investigation, the UCI has handed over to us her entire file for review and study.

Given the fact that this matter in question resolves around alleged Adverse Analytical Findings, we have decided to structure the procedural aspects of our investigation accordingly.

Taking into account the involvement of your laboratory in the current matter so far, we expect the LNDD to fully cooperate with our investigation, as it has already confirmed to be prepared to do so. Upon completion of our review of the UCI file, we intend to contact all relevant parties forthwith, in order to obtain a further clarification regarding those issues, which might have remained unclear to us so far. Further details about the manner in which our investigation will continue will be communicated to you at that time.

In the meantime, we expect all relevant parties, including LNDD – in the interest of the impartial and unbiased nature of the investigation – to maintain absolute confidentiality regarding all aspects of our investigation, as well as all information and (research) data LNDD might actually have in its possession regarding this matter.

Yours sincerely.

Emile N. Vrijman

Wilfred F. Veldstra

Lamsma Veldstra & Lobé advocaten en procureurs is een maatschap die mede/beroepsvennootschappen omvat. Iedere aansprakelijkheid is beperkt tot het bedrag dat in het desbetreffende/geval onder onze beroepsaansprakelijkheidsverzekering wordt uitbetaald. Een kople van de huidige beroepsaansprakelijkheidsverzekeringspolis met de voorwaarden ligt ter inzage bij ons secretariaat.



# Ministère de la Jeunesse, des Sports et de la Vie Associative

Le Ministre

Paris 6 110 007 2005

Messieurs.

Vous avez bien voulu informer M. Jean-François LAMOUR, Ministre Français de la Jeunesse, des Sports et de la Vie Associative de la mission qui vous a été confiée par l'Union Cycliste Internationale.

Votre cabinet ayant été mandaté par cette dernière, j'ai l'honneur, pour clore cet échange, de vous transmettre copie de la correspondance adressée au Président de l'Union Cycliste Internationale en réponse à sa lettre du 9 septembre dernier, dans le respect des responsabilités et compétences respectives de l'UCI ou de son mandataire et des autorités gouvernementales françaises.

Je vous prie de croire, Messieurs, en l'assurance de ma considération distinguée.

Pour le Ministre et par délégation, Le Directeur du Cabinet,

Jean-François VILOTTE

Messieurs Emile N. VRIJMAN et Wilfred F. VELDSTRA Lamsma Veldstra & Lobé Postbus 23320 3001 KII Rotterdam Hollande

CAB/JFV/MV

## Ministère de la Jeunesse, des Sports et de la Vie Associative

Le Ministre

Personnelle et Confidentielle

Paris. 6 16 SEP. 2005

Monsieur le Président,

Après avoir pris connaissance de votre correspondance du 9 septembre dernier, il m'a semblé utile de vous faire part des informations suivantes :

1- Le Laboratoire national de dépistage du dopage français (LNDD) est un établissement public à caractère administratif (EPA) dont la spécialité statutaire est, notamment, ainsi que le précise le texte réglementaire (article R 3632-19 du code de la santé publique) relatif à ses missions « de mener des travaux de recherche en vue de l'adaptation du contrôle destiné à lutter contre le dopage au progrès technique et scientifique et d'assurer la valorisation de leurs résultats ».

L'étude conduite par le LNDD sur les échantillons prélevés lors du Tour de France en 1998 et en 1999 s'inscrit dans le cadre de cette mission de recherche. Cette recherche porte sur des produits interdits à la date du prélèvement. En 1998 et en 1999, l'EPO, même si elle ne pouvait être détectée, constituait un produit interdit.

C'est donc dans son domaine de compétence que le LNDD a agi sans qu'il n'y ait eu besoin d'une quelconque intervention ou validation de la part du Ministère français en charge des sports.

Les résultats de l'étude sur les échantillons de 1998 ont d'ailleurs fait l'objet d'une publication scientifique dans « Nature » en 2000 (n° 405 : 635 Lasne F. et de Ceaurriz J.) sans susciter d'observations particulières.

Le L NDD continuera à exercer cette compétence dans l'avenir en tant que département des analyses de la future Agence française de lutte contre le dopage (AFLD) dont la création est prévue par le projet de loi n° 2181 relatif à la lutte contre le dopage et à la protection de la santé des sportifs, voté à l'unanimité en première lecture par l'Assemblée Nationale le 6 avril 2005. L'article 1<sup>er</sup> de ce projet garantit l'indépendance de l'agence qui est une « Autorité publique indépendante dotée de la personnalité morale ».

.../...

M. Hein VERBRUGGHEN
Président de l'Union Cycliste Internationale
Ch 1860 Aigle
SUISSE

95. avenue de France - 7.56.50 Paris cedea 13 - Tel. : 01 40 45 91 18 - Fax : 01 40 45 90 47

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 antidopage qui charge l'AMA d'une mission spécifique de coordination dans le domaine de la recherche.

Je ne peux que me réjouir de la contribution efficace du laboratoire français à la lutte contre le dopage au plan international, ses travaux de recherche a yant a insi permis la mise au point et l'amélioration du test de l'EPO.

2- La levée effective de l'anonymat des échantillons n'a pu être faite que par rapprochement avec les bordereaux de prélèvement qui mentionnent le numéro d'échantillon et le nom du coureur.

Je m'étonne qu'un tiers ait pu se procurer le bordereau complet de prélèvement du coureur (à supposer établie l'authenticité du document publié).

En effet, à eux seuls, les résultats d'analyse des échantillons, même comportant les numéros des échantillons, n'ont pu être à l'origine de la rupture de la confidentialité des études menées par le laboratoire, rupture que je regrette comme vous.

Ni le LNDD (qui ne détient que des documents anonymés), ni le ministère chargé des sports (qui ne détient depuis 2000 que des documents anonymés et qui, pour l'année 1999, a détruit, au plus tard en 2001, les bordereaux négatifs dont il était destinataire), n'ont pu être à l'origine de ces fuites.

3- Je vous informe qu'une suite favorable et immédiate serait donnée à toute requête d'un coureur qui, connaissant son numéro d'échantillon 1998 ou 1999 et prenant la décision de le révéler, demanderait que le LNDD confie à un laboratoire d'expertise tiers, selon les voies juridiques appropriées, les produits conservés pour analyse ADN et recherche de substances dopantes interdites en 98/99 éventuellement présentes. Avant de répondre à votre lettre je me suis assuré auprès du Directeur du LNDD que, pour 1999, douze sur quinze des échantillons positifs à l'EPO sont réanalysables et, pour 1998, 24 sur 39 le sont (sur la base de 20 μl pour les retentats et de 20 ml pour les urines).

Telles sont les informations que je souhaitais vous communiquer eu égard aux compétences et prérogatives respectives de l'UCI et du ministère dont j'ai la responsabilité.

Je ne peux en conclusion que vous faire part de ma surprise quant à la nature des questions que vous avez cru bon de me poser dans le cadre de ce que vous qualifiez « d'enquête ». Vous savez la détermination du Gouvernement français à agir aux côtés du mouvement sportif et de l'AMA pour améliorer les techniques et procédures de lutte contre le dopage, et ce, sans qu'il puisse être suspecté d'agir dans le but d'attenter à l'image d'une discipline ou d'un sportif.

Sachez que je suis aussi déterminé que vous à ce que les études et recherches qui ont été conduites par le LNDD servent la lutte engagée avec le concours de l'AMA contre le recours aux procédés et produits dopants.

Je vous prie de croire, Monsieur le Président, à l'assurance de ma considération distinguée.

Jean-François LAMOUR



Châtenay-Malabry, le 19 octobre 2005

Lamsma Veldstra and Lobé
Westzeedijk 140
3016 AK Rotterdam
HOLLANDE
A l'attention de Me. Veldstra et de Me. Vrijrnan

Chers Maîtres,

Par votre lettre en date du 6 octobre 2005, vous avez informé le laboratoire de Châtenay-Malabry (LNDD) qu'une enquête indépendante à été confiée à votre cabinet par l'UCI à propos des faits et des circonstances relatifs à l'analyse EPO des échantillons des « Tours de France 1998 et 1999 » et je vous en remercie.

Le laboratoire a adressé récemment un courrier sur cette question à l'UCI que je me permets de vous adresser.

En vous souhaitant une bonne réception de cette information, je vous prie de croire, Chers Maîtres, en l'assurance de mes salutations distinguées et respectueuses.



Châtenay-Malabry, le 15 septembre 2005

M. Hein Verbruggen Président UCI CH 1860 AIGLE SUISSE

Fax N° 00.41.24.468.58.54

Monsieur le Président.

En réponse à votre courrier du 9 septembre 2005, je tiens à vous apporter dans l'immédiat les précisions sulvantes :

- 1°) Les reliquats des échantillons A des Tours de France 1998 et 1999 et les flacons B correspondants anonymés ont bien été utilisés par le laboratoire à l'occasion de travaux de recherche qui visaient à mettre à l'épreuve un nouveau critère de positivité à l'EPO moins restrictif que celui utilisé précédemment et mieux adapté à la détection de la prise d'EPO à des faibles doses.
- 2°) Cette recherche a été menée en collaboration avec l'AMA qui a pris en charge une partie des travaux notamment ceux qui avaient trait à l'administration d'EPO recombinante à des volontaires selon un protocole qui intégrait l'administration de fortes doses d'EPO suivies de l'administration de faibles doses.
- 3°) Le laboratoire a travaillé en toute indépendance et avec l'unique objectif d'améliorer la version înitiale du standard international EPO qui sert de guide aux laboratoires antidopage.
- 4°) Le laboratoire a accepté de transmettre à l'AMA la totalité des informations dont il disposait de façon à permettre à cette Autorité de vérifier à posteriori, si elle le souhaitait, la cohérence des résultats obtenus. Il a d'ailleurs subordonné cette acceptation à l'engagement par l'AMA d'exclure toute action disciplinaire eu égard aux conditions de réalisation de ces travaux de recherche et en particulier à l'ouverture des flacons B.
- 5°) Le laboratoire a réagi à la sortie de l'article du journal l'Equipe par le communiqué de presse ci-joint.

Je vous prie de recevoir, Monsieur le Président, l'expression de mes sentiments distingué

J. de Calvolation

### **COMMUNIQUE DE PRESSE**

Suite à l'article paru dans le journal l'Equipe du mardi 23 août intitulé « LE MENSONGE ARMSTRONG » le Laboratoire National de Dépistage du Dopage de Châtenay-Malabry (LNDD) précise qu'il a bien mené des travaux de recherche impliquant l'analyse EPO rétrospective des échantillons du Tour de France 1998 et 1999 en collaboration avec l'Agence Mondiale Antidopage (AMA), qu'il a accepté de transmettre toutes les informations anonymées dont il disposait à cette Autorité sous réserve d'exclure leur utilisation dans une procédure disciplinaire. Le laboratoire n'a pas la possibilité de raccorder ses résultats à un sportif et n'est donc pas en mesure de confirmer la filiation qui a été faite entre ses résultats de recherche et les procès-verbaux nominatifs publiés par le journal l'Equipe.



### WORLD ANTI-DOPING AGENCY

play true

October 13, 2005

By fax: +31 10 436 36 91 (Original by mail)

Mr. Emile N. Vrijman Mr. Wilfred F. Veldstra Lamsma Veldstra & Lobé Postbus 23320 3001 KH Rotterdam **NETHERLANDS** 

#### Dear Sirs:

We have received your letter in which you indicate you have been appointed to conduct an independent inquiry by UCI. No doubt UCI has legally appointed you or your firm under powers within UCI's Constitution or Rules. It would accordingly be normal, and indeed most beneficial, if such a letter were to have been accompanied by an official mandate indicating both jurisdiction and terms of reference in relation to any such "inquiry" that you may have been asked to conduct.

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.

Yours sincerely,

David Howman

Director General

Howman



October 5, 2005

By e-mail: c/o Audrey.Zuttel@uci.ch

By fax: +41-24 468 58 54

Mr. Pat McQuaid President International Cycling Union (UCI) CH 1860 Aigle Switzerland

Dear Mr. McQuaid:

Subsequent to the publication of the story in the issue of L'Equipe dated August 23, 2005 of possible positive samples for EPO during the 1998 and 1999 Tours de France, there have been requests from WADA stakeholders and others for an investigation into the facts as alleged.

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 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 analyzed by the laboratory in France.

WADA has therefore 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.

Please provide your written response by October 17, 2005.

Very truly yours,

David Howman Director General

Enclosure

World Anti-Doping Agency Stock Exchange Tower 800 Place Victoria Suite 1700 PO Box 120 Montreal (Quebec) H4Z 1B7 Canada

Phone: + 1 514 904 9232 Fax: + 1 514 904 8650

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### **Questions for UCI**

- 1. Can you confirm, for the record, that UCI is the governing International Federation for the Tour de France?
- 2. Can you confirm that this was the case, *inter alia*, for the 1998 and 1999 Tours de France?
- 3. Can you confirm that EPO was a prohibited substance under UCI and Tour de France rules for 1998 and 1999?
- 4. Can you confirm that samples provided by riders in the 1998 and 1999 Tours de France were provided in the context of the UCI anti-doping rules?
- 5. Can you confirm that there was not a generally accepted test for EPO in place during 1998 and 1999?
- 6. Can you confirm that UCI was always of the view that the combination of blood testing and urinalysis was not necessary for the detection of EPO and that urinalysis alone was sufficient (a position subsequently confirmed by CAS)?
- 7. Can you confirm that the doping control forms purporting to be signed by Lance Armstrong which appeared in L'Equipe are copies of the originals in UCI's possession pertaining to the 1999 Tour de France?
- 8. Can you confirm that there have been no alterations made to such forms?
- 9. Can you confirm that copies of such doping control forms were provided to L'Equipe with the consent of the appropriate UCI authorities?
- 10. Can you confirm that the disclosure and provision of copies of such doping control forms to L'Equipe were done with the consent of Lance Armstrong?
- 11. Were any written commitments obtained from L'Equipe regarding the use of such doping control forms?
- 12. Could you bring to our attention all UCI rules that may bear on this particular case?
- 13. Have any written requests or instructions been given by UCI to the laboratory regarding the 1998 and 1999 Tour de France samples?



- 14. Can you confirm the receipt, from WADA, of the laboratory analyses of the samples retained from the 1998 and 1999 Tours de France?
- 15. Can you confirm that it is not possible to identify any particular athlete on the basis of the information contained in the laboratory analyses?
- 16. Can you confirm that all samples provided by riders in the 1998 and 1999 Tours de France were provided in the regulatory context of UCI's anti-doping rules?
- 17. Can you confirm that UCI has duly accepted and adopted the World Anti-Doping Code and that it came into effect immediately prior to the 2004 Olympic Games in Athens?
- 18. Can you confirm that UCI also acknowledges the eight-year retrospective period in the World Anti-Doping Code in respect of possible doping offences?
- 19. Can you confirm whether UCI has internal rules about the retention of doping control forms from past doping controls? And, if so, what are these rules?
- 20. Can you confirm whether UCI adopts the facts, positions and arguments in the ASOIF letter dated 20 September 2005? [We assume that UCI is in receipt of a copy of this letter, but would be happy to supply a copy, should this assumption be incorrect.]
- 21. Should the facts regarding the positive samples prove to be correct, what does UCI propose to do?
- 22. Does UCI have any facts upon which it believes that there has been:
  - a. any failure at the laboratory in the chain of custody of the 1999 samples;
  - b. any technical shortcoming in the analysis of such samples;
  - c. any alteration of such samples; or
  - d. any manipulation of such samples?

If so, please provide us with details, to enable us to follow up on your concerns.

- 23. Has UCI requested any further analysis of the samples in the possession of the laboratory?
- 24. Is there any applicable UCI rule that would prevent subsequent analysis of the samples in question (i.e., analysis in 2005 of 1998 and 1999 samples)?
- 25. Can you confirm whether UCI has kept Lance Armstrong informed as to its actions in this matter? (Has there been anything which has not been provided to Armstrong?)



### INTERNATIONAL CYCLING UNION

President

World Anti-Doping Agency
Mr. David Howman, Director General
Stock Exchange Tower
800, Place Victoria (Suite 1700)
P.O. Box 120
Montreal, Québec H4Z 1B7
Canada

Sv fax: +1 514 904 8771 and email

Aigle, October 6th 2005 Ref: President / PMQ / az

Dear Mr. Howman,

I am writing in response to your letter of October 5th

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

I would also like to inform you that the UCI has already started the results management of this case.

We have, following calls for an independent investigation by, amongst others, the President of the IOC Jacques Rogge, passed over the responsibility of this investigation to Mr. Emile Vrijman whose credentials in this matter you will not, I am sure, question. We have, likewise passed over all of our files in relation to this matter to him.

As he has no connection with the UCI or indeed any of the other parties pertaining to this case, we are sure his report will be completely independent and we are asking everyone involved to cooperate fully with his investigation.

In relation to a possible WADA investigation, I must say that I cannot accept this. We feel that 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 29th.

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 and other means of identification to be included in the laboratory report.

I take note of that.

Yours sincerely,

Pat McQuaid

President

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### LETTER OF AUTHORITY TO Mr. E. VRIJMAN

The International Cycling Union (UCI) is the international federation for the sport of cycling. UCI is the responsible anti-doping organization for testing, results management, hearings and sanctions in relation with anti-doping violations that are committed in cycling races on UCI's international calendar of cycling races.

On August 23, 2005, the French newspaper L'Equipe, published an article titled "Armstrong's lie" which accuses Lance Armstrong of having used the Prohibited Substance EPO during the 1999 Tour de France. In the article it was alleged that at least six urine samples from Armstrong had tested for EPO, when tested by the French Laboratoire National de Depistage du Dopage in Châtenay – Malabry (LNDD). In addition, six urine samples of other cyclists were alleged to have tested positive for EPO as well. According to the article and statements the article attributed to the LNDD, the tests conducted on the urine samples from Armstrong and the other riders were part of a scientific research program, intended to improve the existing testing method for EPO.

Responding to the allegations made in the aforementioned article, Armstrong denied having ever used banned substances and questioned the manner in which the LNDD had conducted the testing. Within days, a public debate was taking place regarding the accuracy of the article's reporting, the nature and reliability of the tests conducted by the LNDD, as well as their purpose and findings and the manner in which the UCI was to proceed with respect to the alleged positive urine samples and the cyclists who allegedly provided them. The article in L'Equipe raised many other questions as well. Why did the LNDD report contain the original doping control codes? How was it possible for a journalist of L'Equipe in 2005 to be in possession, not only of confidential research conducted by the LNDD, but of copies of the doping control forms of the 1999 Tour de France of Lance Armstrong as well?

In order to clarify all of the facts and circumstances surrounding the analyses conducted by the LNDD of urine samples collected during the 1998 and 1999 Tour de France in general and the subsequent alleged adverse analytical findings in particular, the UCI has decided to request Mr. Emile Vrijman, attorney-at-law at Rotterdam, to undertake an independent and comprehensive inquiry regarding this matter and, in particular, to:

- determine what the reason(s) has/have been for the LNDD to analyze, in 2004 and/or 2005, the urine samples of the 1998 and 1999 Tour 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;
- 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 Doping Control Laboratories regarding the research on and analysis of urine samples collected for doping control purposes in general and for the Prohibited Substance of EPO in particular;
- 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; 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 UC";
- examine how confidential research reports and doping control documents came in the possession of an unauthorized third party; and

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

The mission of Mr. Vrijman does not include an examination of the LNDD's accreditation status or the reliability of the EPO test as such.

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. Mr. Vrijman will draft a report on his findings and will send a copy of his report to the President of the UCI, the President of the IOC, the President of WADA, the head of LNDD and the French Minister of Youth and Sports.

To the extent that in the opinion of Mr. Vrijman, certain findings should remain confidential under applicable anti-doping rules, these findings will be laid down in a separate confidential document that will be sent to UCI and WADA only.

The UCI requests 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 all coaches, administrators, officials, cyclists and other individuals associated with international cycling and/or international cycling events, shall cooperate fully and completely with Mr. Vrijman and his investigation.

Done at Aigle, on November 2005

Jean-Pierre Strebel

Treasurer

Pat Mc Quaid.

President

## Pound says Armstrong faces further investigations

# Thursday, December 22, 2005 12:44:06 PM ET

By Steve Keating

TORONTO (Reuters) - Investigations into doping allegations against seven-times Tour de France winner Lance Armstrong will continue into the New Year, World Anti-Doping Agency (WADA) president Dick Pound said.

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

"There is no urgency because he is not going to be in another race but there are some explanations that are going to have be given."

After Armstrong's seventh Tour victory last July the French sports daily L'Equipe published a story alleging Armstrong had taken the banned blood booster EPO (erythropoietin) in 1999.

Armstrong, 34, who retired after the race, has denied ever taking performance-enhancing drugs.

In the interview Pound was also critical of the role played by the International Cycling Union (UCI).

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

"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.

"And there are another 15 or so positive tests on which they refuse to comment."

L'Equipe's report said the newspaper had gained access to laboratory documents which reported that six of Armstrong's urine samples collected on the 1999 Tour showed "indisputable" traces of EPO.

The newspaper published what it said was a results sheet from the laboratory which appeared to show six figures revealing traces of EPO.

The newspaper also published documents from the French cycling federation showing exactly the same figures under Armstrong's name.

Investigations into the allegation, however, soon stalled as WADA, the UCI and the French cycling federation engaged in a bitter public debate on how to proceed.

Armstrong, who overcame testicular cancer to become the most successful rider in cycling history, briefly threatened to return to France to race in one more Tour.

But he said in a recent interview that, "race organisers can sleep peacefully, they won't have to look at Armstrong eye to eye."

Armstrong, however, will be making an appearance in an Italian court in March when he will go on trail for defamation, a charge that carries a maximum six-year prison sentence.

The charge stems from another interview Armstrong gave to the French daily Le Monde in which he called fellow rider Filippo Simeoni a liar.

Simeoni gave evidence in 2002 during the trial of Armstrong's former coach Michele Ferrari saying Ferrari had given him doping substances.

## OFFICIAL STATEMENT

Date: 27 février 2006 / 27 February 2006

When they met at the Olympic Winter Games in Torino, WADA's Chairman Dick Pound told UCI's Vice-President Hein Verbruggen that WADA had in its possession copies of the 15 doping control forms signed by Lance Armstrong during the 1999 Tour de France and that those copies originated from the UCI.

The UCI has immediately carried out an internal investigation and found to its disappointment that this information appears to be correct. The UCI had previously made public statements that only a photocopy of one form had been given to Mr. Ressiot from L'Equipe based upon the assurances of the staff member concerned.

In July 2005 Damien Ressiot from L'Equipe informed UCI that he wanted to write an article on Lance Armstrong confirming that since his return to competition in 1999, he had never taken any medicine in relation with possible consequences of the cancer he had overcome. It was agreed with Mr. Armstrong that Mr. Ressiot could come and see the doping control forms at the UCI office and ascertain for himself that no such medication had been mentioned on the forms by Mr. Armstrong. While at the UCI office Mr. Ressiot asked for and was authorized to have a copy of one doping control form as an example, in order to prove to his readers that he had effectively had consulted the forms.

However, Mr. Ressiot's article of 23 August in L'Equipe was about the confidential report of the anti-doping laboratory of Paris containing results of research conducted on 1999 Tour de France samples. The laboratory had sent this confidential report the day before to WADA and the French Ministry of Sports. Oddly enough, and notwithstanding the condition set by the French laboratory that it could not be used for disciplinary purposes, this research report contained the original codes of the samples collected back in 1999.

Mr. Ressiot got a copy of this confidential report and published it in L'Equipe with six doping control forms signed by Lance Armstrong. He linked the forms to the code numbers contained in the report. At the same time he published three pages of comments and related articles, including a small article on Mr. Armstrong's medication. He wrote that he had been working on this publication for four months.

It is evident to the UCI that Mr. Ressiot had used a dishonest pretext in order to accessing the doping control forms of Mr. Armstrong which were in the possession of the UCI.

However, based upon the assurances of the staff member concerned, UCI made public statements that only a photocopy of one form had been given to Mr. Ressiot. Mr. Ressiot refused to say where he got the other forms from, invoking the confidentiality of his sources (which



#### **Union Cycliste Internationale**

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#### Service de Presse Press office

Tél.: +41-79-337.00.30 Fax: +41-91-966.98.76 did not prevent him from revealing his source to others and distributing copies of these documents also to third parties).

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 his inquiry for the purpose of writing an article proving that Mr. Armstong 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.

The UCI regrets that it was not correctly informed as from the beginning and apologizes for any misunderstanding to the public. However it also regrets the dubious practices used by certain journalists. For its part UCI has immediately taken the appropriate internal measures.

For the rest the UCI awaits the results of the independent investigation on the doping allegations against Lance Armstrong.

Service de Presse UCI



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# BEGSPORT

## Wada boss warns Armstrong inquiry

By Matt Catchpole

The World Anti-Doping Agency has warned cycling's governing body it may carry out its own investigation into allegations against Lance Armstrong.

The International Cycling Federation (UCI) has set up an independent inquiry to investigate claims Armstrong doped during the 1999 Tour de France.

"If it is not a thorough investigation we will decide accordingly what to do," Wada chairman Dick Pound said.

"(That) may include our own investigation."

Last August, French newspaper L'Equipe published allegations that samples Armstrong had given during the 1999 Tour de France contained traces of the banned blood-boosting substance EPO.

Armstrong, who has won a record seven Tours de France, has always vehemently denied the allegations.

The UCI says it is fully investigating the matterour view is to let them do it Dick Pound

Wada chairman

The American has described them as "persecution" and part of a "witch-hunt", and also criticised the manner in which L'Equipe obtained the samples from a French laboratory.

Last October, the UCI set up an independent inquiry, headed by Dutch lawyer Emile Urijman, to look into the allegations.

"We will wait and see what the outcome of that investigation is," Pound told BBC Sport.

"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, which may include our own investigation."

Pound has frequently been at odds with both the UCI and Armstrong in the past.

When the allegations were first made, Pound said: "It's a pretty serious story if it is true."

A UCI spokesman criticised him for making "public statements about the likely guilt of an athlete on the basis of a newspaper article and without all the facts being known".

The UCI also said, "a Wada inquiry would be based on areas out of its competence".

In 2004, Armstrong wrote an open letter to European newspapers saying that Pound should not be in charge of Wada.

Story from BBC SPORT:

http://news.bbc.co.uk/go/pr/fr/-/sport2/hi/other\_sports/cycling/4768904.stm

Published: 2006/03/03 11:42:15 GMT

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Mr J.P.R. Scholten

Mr E.N. Vrijman

Mr M.G. Suermondt

World Anti-Doping Agency Mr. David Howman Esq. Director - General Stock Exchange Tower Suite 1700 800 Place Victoria Montreal H4Z 1B7 CANADA

By telecopier: 00 1 514 904 8650

The Hague, March 15, 2006 Re: Independent investigation

Ref.: 206.242.07

Dear Mr. Howman,

Further to my letter dated October 6, 2005, I would like to inform you in more detail regarding the current status of the independent investigation I have been asked by the UCI to conduct concerning all facts and circumstances related to the analyses of the urine samples of the 1998 and the 1999 Tours de France by the French WADA-accredited doping control laboratory, the "Laboratoire Nationale De Dépistage Du Dopage" (hereinafter: the "LNDD") in Chatenay–Malabry, France.

At this time, I have finished evaluating all available information and documentation on file with the UCI, including certain material previously gathered by the UCI from other Parties, as well as the information and documentation subsequently received from both the French Ministry de la Jeunesse, Sports et Vie Associative, the LNDD and Lance Armstrong.

Having arrived at this stage of the investigation, WADA's cooperation is needed in order to be able to further clarify some of the relevant facts and issues regarding the matter at hand, which so far have remained unclear. Given WADA's recent contribution to the investigation regarding the issue of the doping control forms, I trust WADA to be willing to provide further assistance to the investigation by answering the questions contained in the (preliminary) questionnaire, attached hereto. Depending on your reaction I might address you in the future with some more questions.

I look forward to receiving WADA's reply within ten days time.

Attachment: 1

ING Bank Den Haag Rek. nr 65.75.51.147 t.n.v. Stichting Beheer Derdengelden Scholten c.s. F. van Lanschot Bankiers Rek. nr 22.70.04.442 t.n.v. Stichting Beheer Derdengelden Scholten c.s.

Op al onze transacties zijn de Algemene Voorwaarden, gedeponeerd op 21 juni 2004 bij de Kamer van Koophandel Haaglanden onder nummer 26522, onverminderd van toepassing. .

Scholten c.s.

### PRELIMINARY QUESTIONNAIRE WADA

#### INDEPENDENT INVESTIGATION

#### **MARCH 2006**

In your letter to the UCI, dated September 9, 2005, the following statement has been made with regard to the research conducted by the LNDD, including the analyses of urine samples from the 1998 and the 1999 Tours de France:

"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."

- Q1. When exactly (specific date) in 2004 did WADA become aware that the LNDD "had, in its possession, retained B samples from the 1998 and 1999 Tours that could be used for further research"?
- Q2. How did WADA become aware that the LNDD "had, in its possession, retained B samples from the 1998 and 1999 Tours that could be used for further research"?
- Q3. Having become aware of the fact that the LNDD had, in its possession, retained B samples from the 1998 and 1999 Tours that could be used for further research, was it WADA that subsequently asked the LNDD to be informed, or was it the LNDD's initiative to inform WADA?

Q4. What information and documentation did WADA actually receive about (a) the ongoing refinement of the process for a better EPO test and (b) the fact that the LNDD "had, in its possession, retained B samples from the 1998 and 1999 Tours that could be used for further research"?

If available, could you please provide me with copies of the relevant correspondence between WADA and the LNDD regarding this issue?

Q5. At the time WADA received information and/or documentation from the LNDD about the ongoing refinement process for a better EPO test and the fact that the LNDD "had, in its possession, retained B samples from the 1998 and 1999 Tours that could be used for further research", had the LNDD already started analyzing these urine samples? If not, did the LNDD discuss with WADA the use these urine samples for research purposes, before starting to analyze them and what issues were raised?

If available, could you please provide me with copies of the relevant correspondence between WADA and the LNDD regarding this issue?

- Q6. When the LNDD informed WADA regarding the use of the "B" samples from the 1998 and the 1999 Tours de France for research, did WADA at any time discuss with the LNDD whether or not it would be allowed to use these urine samples for conducting research, or such issues as the "ownership of biological samples", the necessity of obtaining "informed consent" when conducting research, "confidentiality" or "privacy"?
- Q7. Did WADA at any time discuss with the LNDD whether or not the UCI should be informed about the research it was conducting, as the urine samples from the 1998 and the 1999 Tours de France had originally been collected by the UCI in its capacity as Testing Authority for these competitions?

Q8. After having been informed by the LNDD that it "was using these stored samples to refine their EPO test", WADA "asked to be informed". Could you specify what WADA asked the LNDD to be informed about? Was there any specific information regarding the analyses of the urine samples from the 1998 and the 1999 Tours de France WADA wanted to be informed about?

If available, could you please provide me with copies of the relevant correspondence between WADA and the LNDD regarding this issue?

According to the French Ministry for Youth and Sports in its letter to the UCI, dated September 16, 2005, the analyses of the urine samples from the 1998 and the 1999 Tours de France were conducted "in cooperation with WADA". However, in your letter to the UCI, dated September 9, 2005, you explicitly state that:

"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."

Q9. Could you please inform me whether WADA has been involved in any manner whatsoever in these research activities, either financially, or otherwise?

In your letter to the UCI, dated September 9, 2005, the following remark has been made with regard to the reporting of the analysis results of the urine samples from the 1998 and the 1999 Tours de France:

"On 22 August 2005 the laboratory sent the results to WADA, addressed to my attention. The results were contained in two booklets, one for 1998 and one for 1999. The envelope containing

the booklets was opened in the WADA office in Montreal on 25 August, upon my return to Montreal from Europe."

I have been informed however that, prior to the reports it sent to WADA in August 2005, the LNDD had already sent a report to WADA in January 2005 regarding the analysis results of the urine samples of the 1998 and the 1999 Tours de France.

Q10. Can you confirm whether or not this is correct? If so, could you provide me with a copy of this report?

If have also been informed that WADA, after having received the January 2005 report, subsequently asked the LNDD for "additional information" with regard to the analyses of the urine samples from the 1999 Tour de France.

- Q.11 Can you confirm whether or not this is correct? If so, could you explain what "additional information" WADA requested from the LNDD? Could you provide me with a copy of your correspondence with the LNDD regarding your request for additional information?
- Q12. Did the LNDD provide any information to WADA, or, alternatively, did WADA request the LNDD for any further information regarding the interpretation of the reports in general and the results in particular?
- Q13. Assuming your statement regarding the receipt of the reports of the LNDD in August 2005 to be correct, that WADA had no knowledge of the contents of these reports prior to August 25, 2005, can you explain why the article in L'Equipe mentioned that WADA had already studied the reports with respect to the possibility of legal sanctions pursuant the research conducted by the LNDD?
- Q14. What documents or other relevant information has WADA gathered in the course of its investigation of issues related to the positive tests reported by the LNDD

concerning frozen urine samples from the 1998 and 1999 Tours de France? Would WADA be willing to provide copies of these documents in order to assist me with the investigation?

Emile N. Vrijman Scholten c.s. Attorneys The Hague, March 15, 2006 Scholten c.s.

Denneweg 124 2514 CL 's-Gravenhage Tel. 070 362 44 04 Fax 070 345 84 29 E-mail: scholten.cs@planet.nl

Mr J.P.R. Scholten

Mr E.N. Vrijman

Mr M.G. Suermondt

World Anti-Doping Agency Mr. David Howman Esq. Director - General Stock Exchange Tower Suite 1700 800 Place Victoria Montreal H4Z 1B7 CANADA

By telecopier: 00 1 514 904 8650

The Hague, March 20, 2006 Re: Independent investigation

Ref.: 206.242.07

Dear Mr. Howman,

In addition to the "preliminary questionnaire" send to WADA on March 15, 2006, please find attached for your attention an "additional questionnaire", containing further questions regarding the analyses of the urine samples of the 1998 and the 1999 Tours de France by the French WADA-accredited doping control laboratory, the "Laboratoire Nationale De Dépistage Du Dopage" (hereinafter: the "LNDD") in Chatenay–Malabry, France.

These questions specifically address the manner in which the LNDD reported the findings of the research it conducted with regard to the aforementioned urine samples and, as well the interpretation of both research reports.

I look forward to receiving WADA's reply on or before Monday, March 27, 2006.

Yours sincerely,

Attachment:

ING Bank Den Haag Rek. nr 65.75.51.147 t.n.v. Stichting Beheer Derdengelden Scholten c.s. F. van Lanschot Bankiers Rek. nr 22.70.04.442 t.n.v. Stichting Beheer Derdengelden Scholten c.s.

Op al onze transacties zijn de Algemene Voorwaarden, gedeponeerd op 21 juni 2004 bij de Kamer van Koophandel Haaglanden onder nummer 26522, onverminderd van toepassing. Scholten c.s.

## ADDITIONAL QUESTIONNAIRE WADA

#### INDEPENDENT INVESTIGATION

#### **MARCH 2006**

The research reports WADA received from the LNDD in August 2005, each have a similar format, comprising of:

- a summary table, listing the laboratory codes, 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 results of the different detection methods apparently applied, possible remarks, as well as the urine samples' remaining volume of urine and/or "retentate" after having been analysed<sup>2</sup>;
- an overview of the analysis results having used the new mathematical model; and
- a series of prints of the integration results of the equipment.

According to the LNDD, the summary table of both reports had been printed in different colors, in order to indicate whether or not a particular urine sample did contain the prohibited substance r-EPO. However, the copies of both reports send by WADA to the UCI only contained a summary table printed in black and not in color.

Q15. Did the reports WADA received from the LNDD regarding the analyses of the urine sampled of the 1998 and the 1999 Tours de France contain a print of the aforementioned summary table in color?

2 Id..

<sup>1</sup> This is the French expression for 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.

Q16 If so, why did WADA send a copy of the aforementioned summary table printed in black only, given the fact that the LNDD used different colors in order to provide further information regarding its findings, i.e. to indicate whether or not a particular urine sample did contain the prohibited substance r-EPO. to as the colors used?

Could you provide us with color copies of the summary tables of both research reports?

- Q.17 Did the LNDD, when sending both research reports to WADA, inform WADA of any of the following facts:
  - a) that it had used some kind of "accelerated measurement procedure", a non WADA-validated screening procedure, when analyzing the urine samples from the 1998 and the 1999 Tours de France?;
  - b) that the "accelerated measurement procedure" does not comply with the required mandatory rules and regulations for conducting doping control testing, as laid down in WADA's "ISL", nor with the principles as detailed in the ISO/IEC 17025 international standard, in particular its failure to use both positive and negative controls and the absence of any confirmation testing?;
  - c) that the "accelerated measurement procedure" does not comply with the mandatory requirements regarding the testing of urine samples for the prohibited substance r-EPO, as specified in WADA's technical document "TD2004EPO", in particular the failure to conduct the mandatory stability test?;
  - d) that it could not provide the required mandatory internal chain of custody?; and

- e) that it could not guarantee that the urine samples from both Tours de France had been kept stored under continuously at a temperature of  $-20^{\circ}$ C during the period of time they were kept in storage at the laboratory?
- Q18. If so, when did the LNDD supply this information to WADA and in which manner?

If available, could you please provide me with copies of the relevant correspondence between WADA and the LNDD regarding this issue?

- Q19 If not, did WADA ask the LNDD whether:
  - a) it had used the WADA-validated screening procedure and confirmation procedure, when analyzing the urine samples from the 1998 and the 1999 Tours de France?;
  - b) the screening procedure and confirmation procedure used complied with the required mandatory rules and regulations for doping control testing, in particular with WADA's "ISL", as well as requirements for testing contained in the ISO/IEC 17025 international standard?
  - c) the screening procedure and confirmation procedure used complied with the required mandatory rules and regulations complied with the mandatory requirements regarding the testing of urine samples for the prohibited substance r-EPO, as specified in WADA's technical document "TD2004EPO", in particular whether or not the mandatory stability test hd been conducted?;
  - d) it could provide the required mandatory internal chain of custody?; and

- e) it could guarantee that the urine samples from both Tours de France had been kept stored continuously at a temperature of 20°C during the period of time they were kept in storage at the laboratory?
- Q20. If so, when did WADA ask these questions and in which manner?

If available, could you please provide me with copies of the relevant correspondence between WADA and the LNDD regarding this issue?

The article "Recombinant erythropoietin in urine. An artificial hormone taken to boost athletic performance can now be detected" from Prof. De Ceaurriz and Dr. Lasne regarding the detection of the prohibited substance r-EPO analysis in urine samples from the 1998 Tour de France was published in the issue of the scientific magazine "Nature", dated June 8, 2000. According to the article 102 frozen urine samples from participants in the 1998 Tour de France were analyzed by using an enzymelinked immunosorbent assay, 28 of which were considered to have EPO levels "above the normal range".

- Q21 Did WADA have any knowledge of this scientific publication?
- Q22 Did WADA know, when being informed by the LNDD regarding the analyses of the urine samples from the 1998 and the 1999 Tours de France, that the urine samples from the 1998 Tour de France had already been opened and analyzed at least once before, prior to the current research being conducted?
- Q23 Did the LNDD inform WADA that it had already opened and analyzed the urine samples from the 1998 Tour de France at least once before, prior to it's current research?

Q24. What documents or other relevant information has WADA gathered in the course of its investigation of issues related to the positive tests reported by the LNDD concerning frozen urine samples from the 1998 and 1999 Tours de France? Would WADA be willing to provide copies of these documents in order to assist me with the investigation?

Emile N. Vrijman Scholten c.s. Attorneys The Hague, March 15, 2006

# WADA ANSWERS TO UCI INDEPENDENT INVESTIGATION QUESTIONS OF MARCH 15 AND MARCH 20, 2006

#### Q 1.

When exactly (specific date) in 2004 did WADA become aware that the LNDD "had, in its possession, retained 8 samples from the 1998 and 1999 Tours that could be used for further research"?

Initially, on October 19<sup>th</sup>, 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. It was not discussed whether they were A or B samples. Communication took mainly place through phone conversations between the LNDD and WADA Science Director, Dr Olivier Rabin.

Q2. How dld WADA become aware that the LNDD "had, in its possession, retained B samples from the 1998 and 1999 Tours that could be used for further research"?

See answer to question (1). However, there was no specification as to whether it was left over from A or B samples. Further research is expected of laboratories-under the ISL- as a matter of course. This is not a project financed by WADA grants.

Q3.
Having become aware of the fact that the LNDD had, in its possession, retained B samples from the 1998 and 1999 Tours that could be used for further research, was it WADA that subsequently asked the LNDD to be informed, or was It the LNDD's initiative to inform WADA?

By the time WADA was informed of the research project by the LNDD, the project was already in progress. WADA confirmed, at that time, that 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, were of interest to WADA. From that point on, WADA asked to be kept informed of the results of the project. As indicated under question (2) WADA felt that such project was in line with the ISL requirements and within the objectives of the fight against doping.

Q4.
What information and documentation did WADA actually receive about (a)
the ongoing refinement of the process for a better EPO test and (b) the fact
that the LNDD "had, in its possession, retained B samples from the 1998
and 1999 Tours that could be used for further research?

On February 25, 2005, a meeting took place between Dr. Rabin and Pr. de Ceaurriz and Dr. Lasne from the LNDD in Paris. 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.

#### 05.

At the time WADA received information and/or documentation from the LNDD about the ongoing refinement process for a better EPO test and the fact that the LNDD "had, in its possession, retained B samples from the 1998 and 1999 Tours that could be used for further research", had the LNDD already started analyzing these urine samples? If not, did the LNDD discuss with WADA the use these urine samples for research purposes, before starting to analyze them and what Issues were raised?

Yes the project had already started, see above.

#### 06.

When the LNDD informed WADA regarding the use of the "B" samples from the 1998 and the 1999 Tours de France for research, did WADA at any time discuss with the LNDD whether or not it would be allowed to use these urine samples for conducting research, or such issues as the "ownership of biological samples", the necessity of obtaining "Informed consent" when conducting research, "confidentiality" or "privacy"?

WADA was not part of any discussion prior to the project being started. The only discussion that took place between WADA and the Laboratory was of a general nature.

#### Q7.

Did WADA at any time discuss with the LNDD whether or not the UCI should be informed about the research it was conducting, as the urine samples from the 1998 and the 1999 Tours de France had originally been collected by the UCI in its capacity as Testing Authority for these competitions?

WADA recommended that the LNDD inform the IF if all samples were from the same sport.

#### 08.

After having been informed by the LNDD that it "was using these stored samples to refine their EPO test", WADA "asked to be informed". Could you specify what WADA asked the LNDD to be informed about? Was there any specific information regarding the analyses of the urine samples from the 1998 and the 1999 Tours de France WADA wanted to be informed about?

If available, could you please provide me with copies of the relevant correspondence between WADA and the LNDD regarding this issue?

In February 2005 WADA confirmed its interest in the results of the project. Furthermore, WADA made sure that such results would be of use to UCI. WADA can not imagine that 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. WADA ensured that UCI would have all elements to be in a position to act in accordance with its rules.

On 27<sup>th</sup> July 2005 WADA confirmed its willingness of receiving the final report indicating clearly that such results were outside the scope of the World Anti Doping Code and that WADA had no intention to look into any disciplinary action. Furthermore, WADA indicated that it had no way of linking any sample with the name of any rider. This element was confirmed recently by UCI who acknowledged that all doping control forms originated from its office.

According to the French Ministry for Youth and Sports in its letter to the UCI, dated September 16, 2005, the analyses of the urine samples from the 1998 and the 1999 Tours de France were conducted "In cooperation with WADA". However, in your letter to the UCI, dated September 9, 2005, you explicitly state that:

"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."

Q9.

Could you please inform me whether WADA has been involved in any manner whatsoever in these research activities, either financially, or otherwise?

See question (3), WADA was not in any manner involved in the initiation of this research and did not support it financially.

In your letter to the UCI, dated September 9, 2005, the following remark has been made with regard to the reporting of the analysis results of the urine samples from the 1998 and the 1999 Tours de France:

"On 22 August 2005 the laboratory sent the results to WADA, addressed to my attention. The results were contained in two booklets, one for 1998 and one for 1999. The envelope containing the booklets was opened in the WADA office in Montreal on 25 August, upon my return to Montreal from Europe."

I have been informed however that, prior to the reports it sent to WADA in August 2005, the LNDD had already sent a report to WADA in January 2005 regarding the analysis results of the urine samples of the 1998 and the 1999 Tours de France.

#### Q10.

Can you confirm whether or not this is correct? If so, could you provide me with a copy of this report?

WADA has no knowledge of a report from January 2005. Perhaps you could indicate the source of your information.

If have also been informed that WADA, after having received the January 2005 report, subsequently asked the LNDD for "additional information" with regard to the analyses of the urine samples from the 1999 Tour de France.

#### 011

Can you confirm whether or not this is correct? If so, could you explain what "additional Information" WADA requested from the LNDD? Could you provide me with a copy of your correspondence with the LNDD regarding your request for additional information?

As indicated above no such report was ever received and therefore your statement is incorrect. As indicated in question (3) WADA asked to be kept informed of the progress and final result of the project and as indicated in question (8) asked the laboratory 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.

#### Q12.

Did the LNDD provide any information to WADA, or, alternatively, did WADA request the LNDD for any further information regarding the interpretation of the reports in general and the results in particular?

The report showed that old samples could still reliably be analyzed for the presence of recombinant or endogenous EPO. The report of August 2005 being self-evident, WADA did not need to request further information. Furthermore, the results from the project are being used in the current refining of the decision criterion for the EPO test.

#### Q13.

Assuming your statement regarding the receipt of the reports of the LNDD in August 2005 to be correct, that WADA had no knowledge of the contents of these reports prior to August 25, 2005, can you explain why the article in L'Equipe mentioned that WADA had already studied the reports with respect to the possibility of legal sanctions pursuant the research conducted by the LNDD?

We cannot answer on behalf of the newspaper.

#### 014.

What documents or other relevant information has WADA gathered in the course of its investigation of issues related to the positive tests reported by the LNDD concerning frozen urine samples from the 1998 and 1999 Tours de France? Would WADA be willing to provide copies of these documents in order to assist me with the investigation?

We are still waiting for Mr. Armstrong and the UCI to answer our questions.

Q15.
Did the reports WADA received from the LNDD regarding the analyses of the urine sampled of the 1998 and the 1999 Tours de France contain a print of the aforementioned summary table in color?

Yes.

Q15

If so, why did WADA send a copy of tile aforementioned summary table printed in black only, given the fact that the LNDD used different colors in order to provide thither information regarding its findings, i.e. to indicate whether or not a particular urine sample did contain the prohibited substance r-EPO to as the colors used?

Could you provide us 4th color copies of the summary tables of both research reports?

There is no particular reason why it was sent in black and white. A color copy of the report is sent to you under separate cover.

#### Q.17

Did the LNDD, when sending both research reports to WADA, inform WADA of any of the following facts:

- a) that it had used some kind of "accelerated measurement procedure", a non WADA-validated screening procedure, when analyzing the urine samples from the 1998 and the 1999 Tours de France?;
- b) that the "accelerated measurement procedure" does not comply with the required mandatory rules and regulations for conducting doping control testing, as laid down in WADA's "ISL", nor with the principles as detailed in the ISO/IEC 17025 international standard, in particular its failure to use both positive and negative controls and the absence of any confirmation testing?;
- c) that the "accelerated measurement procedure" does not comply with the mandatory requirements regarding the testing of urine samples for the prohibited substance r-EPO, as specified in WADA's technical document "TD2004EPO", in particular the failure to conduct the mandatory stability test?;
- d) that it could not provide the required mandatory internal chain of custody?; and
- e) that it could not guarantee that the urine samples from both Tours de France had been kept stored under continuously at a temperature of— 20C during the period of time they were kept in storage at the laboratory?

As indicated above, WADA was not involved in the design of the research protocol and therefore, in answer to your question, did not discuss with the lab

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the specific elements you mention. This was, in addition, not mentioned either at the time of reception of the final report.

However, we would be interested to know where you have obtained these elements that you are presenting as "facts".

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.

#### 018.

If so, when did the LNDD supply this information to WADA and in which manner?

If available, could you please provide me with copies of the relevant correspondence between WADA and the LNDD regarding this issue?

As indicated above some of this information was provided ex post facto in answer to our questions.

# Q19 If not, did WADA ask the LNDD whether:

- a) it had used the WADA-validated screening procedure and confirmation procedure, when analyzing the urlne samples from the 1998 and the 1999 Tours de France?;
- b) the screening procedure and confirmation procedure used complied with the required mandatory rules and regulations for doping control testing, in particular with WADA's "ISL", as well as requirements for testing contained in the ISO/IEC 17025 International standard?
- c) the screening procedure and confirmation procedure used compiled with the required mandatory rules and regulations compiled with the mandatory requirements regarding the testing of urine samples for the prohibited substance r-EPO, as specified in WADA's technical document "TD2004EPO", in particular whether or not the mandatory stability test hd been conducted?;
- d) it could provide the required mandatory internal chaln of custody?; and
- e) it could guarantee that the urine samples from both Tours de France had been kept stored continuously at a temperature of -20°C during the period of time they were kept in storage at the laboratory?

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 the samples under the project. Some of the

other points were part of ex post facto questions as indicated under questions (17) and (18).

#### Q20.

If so, when did WADA ask these questions and in which manner?

If available, could you please provide me with copies of the relevant correspondence between WADA and the LNDD regarding this issue?

As indicated under question (19), during the course of the project, this was done orally.

The article "Recombinant erythropoietln in urine. An artificial hormone taken to boost athletic performance can now be detected" from Prof. De Ceaurriz and Dr. Lasne regarding the detection of the prohibited substance r-EPO analysis in urine samples from the 1998 Tour de France was published in the issue of the scientific magazine "Nature", dated June 8, 2000. According to the article 102 frozen urine samples from participants in the 1998 Tour de France were analyzed by using an enzyme-linked immunosorbent assay. 28 of which were considered to have EPO levels "above the normal range".

#### 021

Did WADA have any knowledge of this scientific publication?

Yes.

#### 022

Did WADA know, when being informed by the LNDD regarding the analyses of the urine samples from the 1998 and the 1999 Tours de France, that the urine samples from the 1998 Tour de France had already been opened and analyzed at least once before, prior to the current research being conducted?

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 the A samples had already been opened.

#### 023

Did the LNDD inform WADA that it had already opened and analyzed the urine samples from the 1998 Tour de France at least once before, prior to it's current research?

WADA dld not discuss the specifics of the samples with the LNDD

#### Q24.

What documents or other relevant information has WADA gathered in the course of its investigation of issues related to the positive tests reported by the LNDD concerning frozen urine samples from the 1998 and 1999 Tours de France? Would WADA be willing to provide copies of these documents in order to assist me with the investigation?

WADA has not yet received any response from UCI and Lance Amstrong to the enclosed questions which pertain to issues we expect you will address in your inquiry and to which we suspect you might have answers already.



April 3, 2006

By fax 31 70 345 84 29

Mr. Emile N.Vrijman Scholten c.s. Denneweg 124 2514 CL's Gravenhage

Dear Mr. Vrijman,

You will find attached WADA's answers to your questions as raised in your letters of March 15 and March 20.

We are somewhat surprised by some of the facts in your questions, which to our knowledge, are inaccurate.

Furthermore, we have attached to our answers the questions we sent to both UCI and Lance Armstrong and which, to this day, remain unanswered. 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.

Yours Sincerely,

David Howman

David Howman Director General

World Anti-Doping Agency Stock Exchange Tower 200 Park Victoria Subsectivity PO Section Montrest (Quotise) H1Z 187

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Mr. W.P. Veldstra | Mr. G.P. Lobé | Mw. Mr. D.A. Wahid - Manusama | Mr. G. Hoyng | Mr. E.N. Vrijman, MCL | Mr. R.A. van Winden | Mr. A.N. Broekhoven | Mw. Mr. H.C. Aalders-van Vuren | Mr. J.H. Lamsma, adviseur



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Per Facsimile 00 33 1 46 60 30 17 and separately by mail

Laboratoire National de Depistage du Dopage Prof. Dr. J. de Ceaurriz 143, Avenue Roger Salengro 92290 Chatenay-Malabry FRANCE

Uw ref.

• ...

Onze ref.

: 252101

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Inzake

: UCI/Independent investigation

Datum

: November 14, 2005

Dear Prof. De Ceaurriz,

Thank you very much for your letter in the abovementioned matter, dated October 19, 2005, informing me of the response of the Laboratoire Nationale de Depistage du Dopage (LNDD), dated September 15, 2005, regarding various questions posed by the Union Cycliste Internationale (UCI).

Please find enclosed - for your information – a copy of the so-called "letter of authority" from Mr. McQuaid, the President of the UCI, confirming formally the mandate I received verbally from the UCI on September 30, 2005. According to this letter, I have been requested by the UCI to conduct an independent and comprehensive inquiry "regarding all facts and circumstances surrounding the analyses conducted by the LNDD of urine samples collected during the 1998 and 1999 Tour de France in general and the subsequent alleged adverse analytical findings in particular". In addition further details as to both the nature and scope of the inquiry are provided as well.

At this time, I'm trying to establish a timetable for conducting the aforementioned inquiry, allowing me to obtain the relevant information and documentation as soon as reasonably possible, while, at the same time, providing sufficient opportunities for evaluating the information and documentation already obtained. In order to be able to accomplish this, I would like to use this opportunity to present you with a number of so — called "preliminary questions". A separate attachment, containing these questions, has been enclosed with this letter. Naturally a speedy reply is very much appreciated, as this will assist me in finalizing the aforementioned timetable for conducting the inquiry, in particular in so far as it will be regarding the LNDD.

Finally, I would like to stress once more — in the interest of the impartial and unbiased nature of the inquiry — the need for all relevant parties, including the LNDD, to maintain absolute confidentiality





# PRELIMINARY QUESTIONS LNDD NOVEMBER 11, 20051

- 1. What is the exact total number of urine samples from both the 1998 and the 1999 Tour de France which have been and/or still are in the possession of the LNDD?<sup>2</sup>
- 2. Have all urine samples from both the 1998 and the 1999 Tour de France, which have been and/or still are in the possession of the LNDD, been analyzed at this time by the LNDD?<sup>3</sup>
  - 2.1 If not, how many of the urine samples from the 1998 and the 1999 Tour de France have remained unused?
  - 2.2 If so, are all analysis results contained in the reports issued by the LNDD?
- 3. Did you report your findings regarding the analysis of the urine samples from both the 1998 and the 1999 Tour de France to the UCI?<sup>4</sup>
  - 3.1 If not, why not?
  - 3.2 To whom did you report these findings?
- 4. The UCI received a copy from WADA of each of the reports issued by the LNDD regarding the analysis of urine samples from both the 1998 and 1999 Tour de France. These reports however, have been marked as "confidential". In order to be able to determine whether or not certain of your findings might indeed qualify as constituting a so called "adverse analytical finding" necessitating the commencement of the result management process as laid down in the current UCI Anti Doping Rules and Regulations, I would like to ask you if you could provide me with two additional sets of copies of the reports issued by the LNDD regarding the analysis of urine samples from both the 1998 and 1999 Tour de France?
- 5. Could you please inform me whether or not "laboratory documentation packages" are available regarding each of the separate alleged adverse analytical findings reported by the LNDD in it's report regarding the analysis of urine samples from the 1999 Tour de France?
  - 5.1 If so, could you confirm whether or not the aforementioned laboratory documentation packages contain all of the documents as specified in WADA Technical Document (TD2003LDOC), dated June 5, 2003, "Laboratory Documentation Packages" and WADA Technical Document (TD2003LCOC), dated June 5, 2003, "Laboratory Internal Chain of Custody"?
- 6. Could you please inform me in case one or more of the riders concerned should choose to do so whether or not it will be possible to have a B sample analysis conducted for each of these alleged adverse analytical findings individually, if so requested?
  - 6.1 If not, why is this?

<sup>&</sup>lt;sup>4</sup> In answering this question, you are kindly requested to provide separate answers regarding the urine samples from the 1998 and the 1999 Tour de France.



<sup>&</sup>lt;sup>1</sup> In order to facilitate the investigation and the subsequent reporting, you are kindly requested to answer these questions in the English language.
<sup>2</sup> In appropriate this greation, you are kindly accurated to appropriate the union complete from the 1998.

<sup>&</sup>lt;sup>2</sup> In answering this question, you are kindly requested to provide separate answers regarding the urine samples from the 1998 and the 1999 Tour de France.

<sup>&</sup>lt;sup>3</sup> In answering this question, you are kindly requested to provide separate answers regarding the urine samples from the 1998 and the 1999 Tour de France.



- 7. If I have been informed correctly, a number of samples from both the 1998 and 1999 Tour de France have been listed in the aforementioned reports as "manquant". Does this mean that these urine samples are "missing"?<sup>5</sup>
- 8. If these samples are indeed "missing", does this mean that they simply have not been found stored, as you expected on the basis of the LNDD's internal chain of custody for these samples, or that these samples have 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?<sup>6</sup>
- 9. Could you inform me whether or not the LNDD will be closed during the upcoming holidays in December and if yes, could you provide me with the relevant dates of closure?

and the 1999 Tour de France.

6 In answering this question, you are kindly requested to provide separate answers regarding the urine samples from the 1998 and the 1999 Tour de France.



<sup>&</sup>lt;sup>5</sup> In answering this question, you are kindly requested to provide separate answers regarding the urine samples from the 1998



regarding all aspects of the inquiry, as well as all information, documentation and (research) data, the LNDD might actually have in its possession regarding this matter.

Yours sincerely,

Emile N Vrijman attorney – at – law

attachment

Vrijman, Emile
Van: email direction [direction@Indd.com]
Verzonden: donderdag 8 december 2005 16:00
Aan: Vrijman, Emile
Onderwerp: answers to the preliminary questions



E. VRIJMAN.tif



# Châtenay-Malabry, le 8th december 2005

## TRANSMISSION DE TELECOPIE

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Nombre de pages y compris celle-ci : 2

Dear Emile N. Vrijman,

Please, find here our answers to the preliminary questions:

1:

## Tour de France 1999

Among the 91 urine samples from TDF 1999 (A and B), 87 were retrospectively analysed for EPO. The remaining biological material concerns 72 out of these 87 samples. These 72 samples could be reanalysed either on the basis of a sufficient volume of retentate (20  $\mu$ l) or a sufficient volume of urine (20 mL). The 4 samples missing have been used for other research purposes.

#### Tour de France 1998

Among the 102 urine samples from TDF 1998 (A et B), 60 were retrospectively analysed for EPO. The remaining biological material concerns 42 out of these 60 samples. These 42 samples could be reanalysed either on the basis of a sufficient volume of retentate  $(20 \mu)$  or a sufficient volume of urine  $(20 \mu)$ . The 42 samples missing have been used for other research purposes.

2.1 : None

2.2 : Yes

1/2



<u>3:</u>

3.1: No. UCI did not request these analyses and was not concerned by our research project.

3.2: The findings were reported to two different institutional Authorities.

4:

No additional copies will be made by LNDD. However, LNDD can check the results which are in the possession of UCI.

**5**:

The samples were analysed for EPO in the framshift of a research program without applying the rules of WADA for anti-doping controls. So, no laboratory documentation packages are available.

<u>6:</u>

No.

6.1: All the B samples were opened for the need of our research on EPO.

<u>7:</u>

Yes. Some samples were missing. See answer to question 1.

<u>8:</u>

Research samples were managed differently from the chain of custody used for anti-doping controls. The missing samples have been used for other research purposes.

<u>9 :</u>

The LNDD is closed for the last week of December 2005.

Sincerely yours,

T. de CEAURRIZ

2/2

Vrijman, Emile

Van: Vrijman, Emile

Verzonden: woensdag 21 december 2005 18:44

Aan: 'f.lasne@Indd.com'

Onderwerp: Request for further information

Urgentie: Hoog

Gevoeligheid: Vertrouwelijk

Dear Dr. Lasne,

Further to our telephone conversation of yesterday afternoon, Tuesday, December 20, 2005, I would like to inform you – as requested – by e-mail regarding the following.

#### 1. Draft report visit to LNDD

At this time, Dr. Van der Veen and I are busy completing the draft version of the report of our visit to the LNDD on Friday, December 9, 2005. Upon completion, we will send both Prof. De Ceaurriz, as well as you – as promised —according to draft report for your comments and observations. I would like to stress however, that this (draft) report is intended only for recording the content of the conversation we have had, as well as our own personal observations. As such the report can only accessed by Dr. Van der Veen and myself and will not be part of the final report of the investigation itself. We expect to have the draft report complete at the end of this week;

### 2. Request for additional data/bottle codes

As you may recall, one of the issues addressed during our meeting at the LNDD, on Friday, December 9, 2005, concerned the inclusion in your report "Recherche EPO Tour de France 1999" of the code numbers engraved on the original glass bottles containing the urine samples collected at the 1999 Tour de France. According to the explanation provided by the LNDD, a relevant public authority (in a country far away from Europe) specifically requested this information, as part of its overall request to the LNDD to be provided with all "remaining additional data" regarding the analyses of the 1999 Tour de France urine samples. This request subsequently resulted in a discussion between the French relevant public authority and this relevant public authority regarding the conditions, under which the requested data might be provided, which lasted approximately six (6) months. Copies of the correspondence between both relevant public authorities relating to this issue are in the possession of the LNDD.

Having returned to the Netherlands, both Dr. Van der Veen and I decided to see whether or not the documentation currently in our possession - especially copies of the correspondence between the UCI and this relevant public authority - might actually confirm the explanation provided by the LNDD. This however, appears <u>not</u> to be so. As a matter of fact, in one of its letters to the UCI, this relevant public authority even seems to suggest that the additional data had been volunteered by the LNDD and not (specifically) requested. This would mean that – at least for now – Dr. Van der Veen and I are being confronted with two conflicting explanations regarding the abovementioned issue.

Whilst neither Dr. Van der Veen, nor I, have yet found any reason to doubt the explanation given by the LNDD, the simple that a different explanation regarding this issue has been provided by one of the other relevant parties involved, forces us to request the LNDD either to provide documentation supporting its explanation(s), or to allow access to such documentation in order to enable us to verify the contents of such documentation personally. As you will understand, this request is not made solely in the interest of the investigation itself, but also in the interest of the LNDD as well. In order to be able to present the position of the LNDD in this matter correctly and objectively, verification and confirmation of its explanation(s) regarding the aforementioned issue are required.

In light of the above, I would therefore respectfully like to ask you to let me know – as soon as possible – whether or not the LNDD is willing and able to either provide the documentation supporting its explanation(s) or allow access to such documentation. As the LNDD will be closed between Christmas and New Year's day, I would like to receive your reply Friday, December 23, 2005, at the latest. This would allow me sufficient time to plan and organize my schedule for conducting the investigation during the first months of 2006. Should you have any questions or remarks regarding this e-mail, please do not hesitate to contact me at once, either by telephone, or by e-mail.

With kind regards, also on behalf of Dr. Van der Veen,

Yours sincerely,

Emile N. Vrijman

----Original Message----From: "Richard Pound" <... Date: Tue, 30 Aug 2005 11:01:15
To: "lance" Subject: RE: Best time to tall

I have attached a memo with the answers (to the best of my present knowledge and

belief) to the questions you asked.

----Original Message----

From: lance [

Sent: Wednesday, August 24, 2005 6:15 PM

To: Richard Pound Cc: Bill Stapleton

Subject: Re: Best time to call

Dick,

Thanks for taking the time tonight to talk.

We look forward to your responses.

Take care,

Lance

----Original Message----From: "Richard Pound" Date: Wed, 24 Aug 2005 14:47:07
To: "lance"

Subject: RE: Best time to call

Whenever you want. RWP

----Original Message----

From: lance '

Sent: Wednesday, August 24, 2005 10:34 AM To: Richard Pound (CIO)

Subject: Best time to call

DICK,														
When would be	the bes	t time	for mys	self, m	y agent,	and	my	lawyer	t.o	call	and	speak	to	you?
Please advise.														
Thanks.														
Lance														
		======	*****	====										
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1. What role, if any, did WADA have in the research project?

This is not research conducted by the French laboratory pursuant to any specific WADA funded research project. The French laboratory has been one of the leading laboratories in advancing and improving the test to detect EPO. In that regard, it has routinely continued in its internal study and research. During the course of refining the EPO test in an appropriate fashion, findings were made as a result of analyses of 98 samples retained from the 1998 and 1999 Tours de France, following the process and timelines outlined in the answer to your second question, the French laboratory shared this information with WADA. This information is confidential and does not have any connection to any individual.

2. When results were positive, how did that get posted out?

The French laboratory is a government-funded laboratory. In July 2005 WADA was informed by the French Government that the Laboratory had this 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. After an appropriate exchange of correspondence, the laboratory forwarded the information to WADA on 22 August 2005. It was received the following day, but not opened until the Director General's return from Europe on 25 August. We are not aware of distribution to anyone else.

3. Chain of custody - did WADA ever have the information? UCI? French Government? - Who was in charge of the samples and the codes in relation to them?

These samples were collected in 1998 and 1999. They were collected during the Tours de France, over which both the UCI and French Government had some jurisdiction for doping controls. The doping control forms, which include the codes or numbers that relate to the samples, would have been held by either or both responsible anti-doping organizations. We do not know whether either or both had such copies. WADA has none.

4. Does a WADA-accredited laboratory have any obligation to follow a minimum WADA Code procedures re confidentiality, and so on?

There is an International Standard on Laboratories. There are normal protocols in relation to research projects. Both have requirements of confidentiality. In this particular situation the French laboratory, on the information presently provided to us, adhered to the principles of confidentiality. The samples used in their work were collected under UCI rules in existence in 1998 and 1999, and not pursuant to the Code nor any WADA protocols. WADA was not in existence at the time. Ownership, retention and use for research are matters for those responsible for the testing in 1998 and 1999.

Vrijman, Emile

Van: Lasne [f.lasne@wanadoo.fr]

Verzonden: donderdag 22 december 2005 11:19

Aan: Vrijman, Emile

Onderwerp: RE: Request for further information

Gevoeligheid: Vertrouwelijk

Dear Mr Vrijman,

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

Best regards,

Françoise Lasne

----Message d'origine----

De: Vrijman, Emile [mailto:vrijman@lamsma-veldstra.nl]

Envoyé: mercredi 21 décembre 2005 18:44

À: f.lasne@Indd.com

**Objet:** Request for further information

Importance: Haute

Critère de diffusion : Confidentiel

Dear Dr. Lasne,

Further to our telephone conversation of yesterday afternoon, Tuesday, December 20, 2005, I would like to inform you – as requested – by e-mail regarding the following.

#### 1. Draft report visit to LNDD

At this time, Dr. Van der Veen and I are busy completing the draft version of the report of our visit to the LNDD on Friday, December 9, 2005. Upon completion, we will send both Prof. De Ceaurriz, as well as you – as promised - a copy of the draft report for your comments and observations. I would like to stress however, that this (draft) report is intended only for recording the content of the conversation we have had, as well as our own personal observations. As such the report can only accessed by Dr. Van der Veen and myself and will not be part of the final report of the investigation itself. We expect to have the draft report complete at the end of this week;

## 2. Request for additional data/bottle codes

As you may recall, one of the issues addressed during our meeting at the LNDD, on Friday, December 9, 2005, concerned the inclusion in your report "Recherche EPO Tour de France 1999" of the code numbers engraved on the original glass bottles containing the urine samples collected at the 1999 Tour de France. According to the explanation provided by the LNDD, a relevant public authority (in a country far away from Europe) specifically requested this information, as part of its overall request to the LNDD to be provided with all "remaining

additional data" regarding the analyses of the 1999 Tour de France urine samples. This request subsequently resulted in a discussion between the French relevant public authority and this relevant public authority regarding the conditions, under which the requested data might be provided, which lasted approximately six (6) months. Copies of the correspondence between both relevant public authorities relating to this issue are in the possession of the LNDD.

Having returned to the Netherlands, both Dr. Van der Veen and I decided to see whether or not the documentation currently in our possession - especially copies of the correspondence between the UCI and this relevant public authority - might actually confirm the explanation provided by the LNDD. This however, appears <u>not</u> to be so. As a matter of fact, in one of its letters to the UCI, this relevant public authority even seems to suggest that the additional data had been volunteered by the LNDD and not (specifically) requested. This would mean that – at least for now – Dr. Van der Veen and I are being confronted with two conflicting explanations regarding the abovementioned issue.

Whilst neither Dr. Van der Veen, nor I, have yet found any reason to doubt the explanation given by the LNDD, the simple that a different explanation regarding this issue has been provided by one of the other relevant parties involved, forces us to request the LNDD either to provide documentation supporting its explanation(s), or to allow access to such documentation in order to enable us to verify the contents of such documentation personally. As you will understand, this request is not made solely in the interest of the investigation itself, but also in the interest of the LNDD as well. In order to be able to present the position of the LNDD in this matter correctly and objectively, verification and confirmation of its explanation(s) regarding the aforementioned issue are required.

In light of the above, I would therefore respectfully like to ask you to let me know – as soon as possible - whether or not the LNDD is willing and able to either provide the documentation supporting its explanation(s) or allow access to such documentation. As the LNDD will be closed between Christmas and New Year's day, I would like to receive your reply Friday, December 23, 2005, at the latest. This would allow me sufficient time to plan and organize my schedule for conducting the investigation during the first months of 2006. Should you have any questions or remarks regarding this e-mail, please do not hesitate to contact me at once, either by telephone, or by e-mail.

With kind regards, also on behalf of Dr. Van der Veen.

Yours sincerely.

Emile N. Vrijman

Wanadoo vous informe que cet e-mail a ete controle par l'anti-virus mail. Aucun virus connu a ce jour par nos services n'a ete detecte.

# E.N. Vrijman

Van:

"E.N. Vrijman" <en.vrijman@planet.nl>

Aan:

<direction@Indd.com>

Verzonden:

dinsdag 10 januari 2006 13:10

Onderwerp:

Request for further information and/or access to documentation

Dear Prof. De Ceaurriz,

Even though it is already January 10, 2006, I would nevertheless like to start this e-mail to you by wishing you a happy, healthy and successful 2006.

As you may know already, during your absence from the LNDD in December 2005, I contacted Dr. Lasne on December 21, 2005, by e-mail requesting access to the documentation mentioned at our last meeting at the LNDD on December 9, 2005. The reason for this request is the fact that the explanation provided by the LNDD for including additional data in it's research reports, so far has <u>not</u> been confirmed by the relevant public authority concerned. As a matter of fact, the relevant public authority concerned even seems to suggest that the additional data had been volunteered by the LNDD itself, instead of (specifically) having been requested. The fact that there are now two different – conflicting – explanations regarding this issue leaves me with no other choice then to request the LNDD either to provide (copies of) documents supporting it's explanation or allow access to such documentation in order to be able to verify the contents of such documentation personally. The importance of this issue for the investigation as a whole increases the necessity for verification only further.

In light of the above, I'm therefore happy that Dr. Lasne informed me by e-mail, dated December 22, 2005, that the LNDD would allow access to the documentation I asked for, "as soon as consent from the official authorities of the laboratory is obtained". When trying to contact you by telephone on Monday, January 9, 2006, to inquire whether or not such consent had already been obtained from the official authorities, your secretary informed me that a meeting has been scheduled for Wednesday, January 11, 2006, precisely for this very purpose.

As this issue represents a key element of the investigation itself and consequently will — to a very large extent — be responsible for determining in which direction and in what manner the investigation will be conducted further, I would like to visit the LNDD immediately after consent has been obtained. In other words, should consent indeed be given at the meeting this coming Wednesday, I would like to visit the LNDD immediately the day after – i.e. on Thursday, January 12, 2006, alternatively on Friday, January 13, 2006. At the same time, I would like this opportunity also to discuss the draft text of the report of our visit to the LNDD on December 9, 2005 and to ask additional questions as well. Dr. Van der Veen of the NMI and my colleague, Mr. Paul Scholten, will accompany me this time.

In order to be able to actually be present at the LNDD on Thursday, January 12, 2006, I would propose to you to contact me by telephone this Wednesday, January 12, 2006 - as soon as possible after the aforementioned meeting - to let me know whether or not the necessary consent has been obtained and access will be allowed. You can contact me at the offices of my law firm in The Hague at 0031 - 70 - 362 4404 or at my mobile phone at 0031 - 6 - 30 36 49 90. I will prepare the necessary travel arrangements accordingly.

I look forward to receiving your reply and/or your telephone call tomorrow, Wednesday, January 11, 2006.

With best regards,

Yours sincerely,

Emile N. Vrijman

Scholten c.s. Advocaten Denneweg 124 2514 CL 's Gravenhage Telefoon : 0031 70 362 4404 Fax : 0031 70 345 8429

E-mail: en.vrijman@planet.nl

02-03-2006

## E.N. Vrijman

Van:

"email direction" <direction@lndd.com>
"E.N. Vrijman" <en.vrijman@planet.nl>

Aan: Verzonden:

donderdag 12 januari 2006 8:44

Onderwerp:

RE: Request for further information and/or access to documentation

Dear M. Vrijman,

Thank you very much for your greetings. In our turn we wish you a very happy new year.

Regarding the access to the documentation of the LNDD you asked for, 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 who is Me RANOUIL from the law firm:

August et Debouzy 6 avenue Messine 75008 PARIS FRANCE

Tél: + 33.1.45.61.51.80 fax: + 33.1.45.61.51.99

Sincerely yours,

#### J. de CEAURRIZ

----Message d'origine----

De: E.N. Vrijman [mailto:en.vrijman@planet.nl]

**Envoyé:** mardi 10 janvier 2006 13:11

A: direction@Indd.com

**Objet:** Request for further information and/or access to documentation

Importance: Haute

Dear Prof. De Ceaurriz,

Even though it is already January 10, 2006, I would nevertheless like to start this e-mail to you by wishing you a happy, healthy and successful 2006.

As you may know already, during your absence from the LNDD in December 2005, I contacted Dr. Lasne on December 21, 2005, by e-mail requesting access to the documentation mentioned at our last meeting at the LNDD on December 9, 2005. The reason for this request is the fact that the explanation provided by the LNDD for including additional data in it's research reports, so far has <u>not</u> been confirmed by the relevant public authority concerned. As a matter of fact, the relevant public authority concerned even seems to suggest that the additional data had been volunteered by the LNDD itself, instead of (specifically) having been requested. The fact that there are now two different - conflicting - explanations regarding this issue leaves me with no other choice then to request the LNDD either to provide (copies of) documents supporting it's explanation or allow access to such documentation in order to be able to verify the contents of such documentation personally. The importance of this issue for the investigation as a whole increases the necessity for verification only further.

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I look forward to receiving your reply and/or your telephone call tomorrow, Wednesday, January 11, 2006.

With best regards,

Yours sincerely,

Emile N. Vrijman

Scholten c.s. Advocaten Denneweg 124 2514 CL 's Gravenhage Telefoon: 0031 70 362 4404 Fax: 0031 70 345 8429

E-mail: en.vrijman@planet.nl

Wanadoo vous informe que cet e-mail a ete controle par l'anti-virus mail. Aucun virus connu a ce jour par nos services n'a ete detecte. Scholten c.s.

Denneweg 124
2514 CL 's-Gravenhage
Tel. 070 362 44 04
Fax 070 345 84 29
E-mail: scholten.cs@planet.nl

Mr J.P.R. Scholten

Mr E.N. Vrijman

Mr M.G. Suermondt

August et Debouzy Me Ranouil 6 Avenue Messine F - 75008 PARIS

Aussi par télécopie: 00 - 33 - 1 - 45.61.51.99

La Haye, 17 janvier 2006

Re: LNDD

Dossier: 206.242.07

Cher confrère.

Comme vous savez probablement, le journal L'Equipe a publié dans son édition du 23 août 2005 un article nommé 'Le mensonge d'Armstrong' dans lequel le journal a accusé Lance Armstrong, sept fois vainqueur de Tour de France, d' usage de l' EPO dans le Tour de France 1999.

Dans l'article on suggère que six échantillons d' urine prélevé sur Lance Armstrong pendant ce Tour auraient étés positives. Les analyses d'urine a effectués par le laboratoire Nationale De Dépistage Du Dopage (LNDD) à Chatenay-Malabry. Ce laboratoire a été accréditer auprès l'AMA. Six autres coureurs auraient étés positive de prendre EPO aussi.

Selon l'article les analyses des échantillons d'urine d' Armstrong et des autres coureurs auraient formés une part de la recherche scientifique du LNDD en vue d' améliorer les méthodes de détection de l'EPO.

En conséquence de cet article et le débat public suivant, l'Union Cycliste Internationale (UCI) -en qualité de fédération internationale de coordination du cyclisme- m' a prié d' exécuter une recherche objective concernant tous faits et toutes circonstances relevantes dans cet affaire. Pour votre information ci-joint vous trouverez une copie du lettre d' autorisation, soi-disant 'Letter of Authority' d'UCI. Dans ce lettre l'UCI a défini l'étendue de la recherche à exécuter.

Comme vous pouvez conclure de ce lettre ma recherche se faut se diriger en premier instance à la recherche de LNDD en général et les résultats de ce recherche en particulier. A ce regard, ensemble avec Dr A. van Veen de l' Institut de Mesure Hollandais, j'ai eu un rendez-vous au LNDD le 9 décembre 2005 en vue d'une entretien avec Professeur De Ceaurriz, le directeur de LNDD et Madame Dr. Lasne, cadre de LNDD.

ING Bank Den Haag Rek. nt 65.75.51.147 t.n.v. Stichting Beheer Derdengelden Scholten c.s. F. van Lanschot Bankiers Rek. nr 22.70.04.442 t.n.v. Stichting Beheer Derdengelden Scholten c.s.

Op al onze transacties zijn de Algemene Voorwaarden, gedeponeerd op 21 juni 2004 bij de Kamer van Koophandel Haaglanden onder nummer 26522, onverminderd van toepassing. Pendant ce rendez-vous on a parlé du contenu des rapports de recherche émis par LNDD. Particulièrement on a parle à la mention par LNDD des numéros de code originaux lesquels sont imprimés sur les bouteilles lesquelles on a usées à l'époque chez la réalisation du contrôle antidoping pendant le Tour de France 1999. A cause de l'existence de cet information spécifique dans le rapport du LNDD concernent l'échantillons d'urine du Tour de France 1999, le journaliste de L'Equipe a été en mesure de réduire les résultats de recherche anonymes aux coureurs spécifiques. Selon le LNDD c'est fait sur la demande pressante d'une 'Autorité Publique' et sous des conditions plus précis. Maintenant j'ai constaté que la déclaration de l''Autorise Publique' diffère énormément de la déclaration de LNDD. L'Autorité Publique a fait savoir que le LNDD a l'offert l'information concernent volontairement

Puisque il 's agit d' un problème crucial par rapport du recherche dans cet affaire et les résultats au fait sont pour le besoin de la cause exceptionnelles, comme aussi le déroulement du recherche, j'ai demandé le LNDD en écrit de m' accorder la communication des correspondance relevante au fait et des toutes autres pièces vérificatoires, concernent la recherche scientifique du LNDD en général et les résultats de ce recherche en particulier. Notamment, je suis intéressé dans les rapports, rédigés par le LNDD, et dans le correspondance entre (i) le Ministère de la Jeunesse, des Sports et de la Vie Associative et l'AMA, (ii) le Ministère et le LNDD et (iii) le LNDD et l'AMA.

En vue de ces demandes pour des informations, Professeur De Ceaurriz a m'avisé de les présenter conforme les règles judiciaires françaises et de me diriger à vous. Je saisi l'occasion de vous prier de satisfaire mon demande susmentionné ou de me donner l'information nécessaire d'obtenir ces documents autrement.

Enfin, je vous demande de m'informer si, dès ce moment, il est nécessaire de me diriger à vous dans l'avenir ou si ce serait possible de me diriger au LNDD directement concernent des demandes pour l'information analytique ou technique.

Je vous prie de croire, cher confrère, à l'assurance de ma considération distinguée.

Scholten c.s. Advocaten

Paul Scholten

Emile Vrijman

# august & debouzy avocats

6-8, avenue de Messine 75008 Paris - France Tél. 33 (0) 1 45 61 51 80 - Fax. 33 (0) 1 45 61 51 99 www.august-debouzy.com

January 27, 2006

Emile Vrijman Attorney at law Scholten c.s Advocaten Denneweg 124 2514 CL's Gravenhage

By mail and fax: 0031703458429

Re.: <u>Laboratoire National de Dépistage du Dopage - Request for further information</u> and/or access to documentation

Dear Sir.

As you know, we are acting as the legal counsel to the Laboratoire National de Dépistage du Dopage (LNDD) and refer to your letter of January 17, 2006. In this respect, we appreciate that you wrote to us in French.

We understand that you wish to obtain documentation regarding the facts and circumstances surrounding the LNDD's analyses of urine samples collected during the 1998 and 1999 Tour de France, in general, and the subsequent alleged adverse analytical findings, in particular. We also understand that you would like to visit LNDD as soon the LNDD official authorities' consent has been obtained.

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 that 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.

Finally, your letter of January 17, 2006 states that the content of the reports issued by the Laboratoire National de Dépistage du Dopage's, particularly the reference to the original codes, is allegedly the source of the information contained in the article published by *L'équipe* newspaper in its August 23, 2005 issue. We consider that such statement lacks grounds and objectivity. Please note, in this respect, that if these allegations were public, it would constitute, under French law, a defamatory accusation. We would therefore be grateful if you would, in the future, refrain from making such allegations which might compromise our client's interests and adversely affect the quality of our exchanges.

Yours sincerely

Pierre-Charles Ranouil / Isabelle Vedrines

PRIVILEGED & CONFIDENTIAL COMMUNICATION BETWEEN ATTORNEYS

Scholten c.s.

Advocaten

Denneweg 124 2514 CL 's-Gravenhage Tel. 070 362 44 04 Fax 070 345 84 29 E-mail: scholten.cs@planet.nl

Mr J.P.R. Scholten

Mr E.N. Vrijman

Mr M.G. Suermondt

Ministère de la Jeunesse, des Sports Et de la Vie Associative Le Directeur du Cabinet Monsieur Jean-François Vilotte 95 Avenue de France F - 75650 PARIS cedex 13

Par téléfax: \*33 – 1 – <del>40.45.90.47</del>

45 82 13 70

La Haye, 24 janvier 2006

Ref.: 206.242.07 Re: UCI/Investigation

## Cher monsieur Vilotte,

Par lettre de 6 octobre 2005, j'ai informé son Excellence Ministre Français de la Jeunesse, des Sports et de la Vie Associative, Mr. Lamour par rapport du demande de l' Union Cycliste Internationale (UCI) -en qualité de la fédération internationale de coordination du cyclisme-pour instituer une recherche objective concernant tous faits et toutes circonstances relevantes dans cet affaire à propos de la publication dans le journal française L' Equipe d' article 'Le mensonge d'Armstrong'. En conséquence de cet article et le débat public suivant, l'UCI m' a prié d'exécuter une recherche objective concernant tous faits et toutes circonstances relevantes dans cet affaire. En vue de l'exécuter vraiment, à la fin de novembre l'UCI m'a envoyé un lettre, soi-disant 'Letter of Authority'. Dans ce lettre l'UCI a défini l'étendue de la recherche à exécuter. Pour votre information ci-joint vous trouverez une copie du lettre d' autorisation.

En réaction à ce lettre, daté le 6 octobre 2005, vous m'avez envoyée de la communication ultérieure en nom du Ministre par lettre du 13 octobre 2005 à propos du contenu du correspondance par rapport de cette affaire entre votre Ministère et l'UCI. Dans ce cadre j'ai reçue une copie du lettre du Ministre à l'UCI daté le 16 septembre 2006.

Non seulement à propos de ce lettre, mais plus aussi à propos de l'état actuel de la recherche, ie voudrai volontiers avoir un rendez-vous avec vous ou avec des autres représentants de votre

ING Bank Den Haag Rek. nr 65.75.51.147 t.n.v. Stichting Beheer Derdengelden Scholten c.s. F. van Lanschot Bankiers Rek. nr 22.70.04.442 t.n.v. Stichting Beheer Derdengelden Scholten c.s.

Op al onze transacties zijn de Algemene Voorwaarden, gedeponeerd op 21 juni 2004 bij de Kamer van Koophandel Haaglanden onder nummer 26522, onverminderd van toepassing. Ministère, désignés pour cela, par rapport de (i) la politique française d'anti-dopage entre 1998 et aujourd'hui, (ii) la manière on a exécuter cette politique, (iii) la position du LNDD dans le cadre de cette politique en général et dans cet affaire en particulier, (iv) le rôle lequel votre Ministère a joué et joue sans cesse à l'exécution de cette politique, notamment par rapport de votre engagement à l'exécution des contrôles antidoping pendant des événements sportives et des compétitions importantes en France en général et le Tour de France en particulier et (v) votre coordination avec l'UCI et l'AMA en général et dans cet affaire en particulier.

Pouvez-vous m'informer si, et si possible à court terme, on peut délibérer avec votre Ministère à propos des choses susmentionnés?

Je vous prie de croire, monsieur Vilotte, à l'assurance de ma considération distinguée.

Scholten c.s. Advocaten

Paul Scholten

Emile Vrijman



## MINISTÈRE DE LA JEUNESSE, DES SPORTS ET DE LA VIE ASSOCIATIVE

Le Directeur du Cabinet 000017

27 JAN 2006

Messieurs,

Vous avez bien voulu, dans le cadre d'une mission d' »investigation » confiée à votre cabinet d'avocats par l'union cycliste internationale, me faire part de votre souhait d'un entretien pour évoquer la politique française d'anti-dopage et la manière dont elle aurait été exécutée par les autorités ministérielles et publiques françaises.

S'agissant des contrôles effectués pendant le Tour de France, vous ne pouvez ignorer que ces derniers font l'objet de protocoles dont votre mandant, l'UCI, est signataire et destinataire.

En ce qui concerne la politique française anti-dopage, celle-ci s'inscrit dans le cadre légal défini par la loi n° 89-432 du 28 juin 1989, puis par la loi n° 99-223 du 23 mars 1999, toutes deux relatives à la lutte contre le dopage.

Je ne peux, dans ces conditions, que vous confirmer les informations transmises par la lettre du ministre de la jeunesse, des sports et de la vie associative à l'UCI en date du 16 septembre 2005.

Je vous prie de croire, Messieurs, à l'assurance de ma considération distinguée.

Messieurs Paul Scholten et Emile Vrijman Scholten c.s . Advocaten Denneweg 124 2514 CL's Gravenhage

Jean François Vilotte

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Scholten c.s.

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Mr E.N. Vrijman

Mr M.G. Suermondt

August et Debouzy Me P-C. Ranouil et Me I. Vedrines 6-8 Avenue Messine F - 75008 PARIS

Also by telefax: 00 - 33 - 1 - 45.61.51.99

The Hague, January 30, 2006

Re: LNDD file: 206.242.07

Dear colleagues,

Acknowledging receipt of your letter dated 27 instant and your preference for the English language I would like to clear the air.

Apparently you see us as representatives of the UCI, but we like to point out that we are in the process of delivering an objective and completely independent report. Therefore we see the lab not as an opposing party, but hopefully one which can help us in our investigation.

Maybe you are not aware of the fact that we already had one meeting in Paris with Professor De Ceaurizz, during which he was very helpful. He left us with a lot of unanswered questions, the answers to which are very important with respect to an objective and representative result.

Having had this conversation we do not understand the hesitant position you or the lab is taking. In our view it is the responsability of all parties involved to cooperate with us in order to produce a fair report, included your client.

We are sorry if we gave you the wrong impression with respect to the alleged source of the information contained in the article in L' Equipe. As the LNDD is the authority which performed the analysis, we assume that the information delivered to the reporter is likely coming from your client unless it has informed another party who gave the information to the reporter. In order to avoid such allegations in the future, it would be very helpful to get your clients full cooperation.

We would appreciate that very much, indeed.

Scholten c.s. Advocaten

Paul Scholten

Emile Vrijman

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Op al onze transacties zijn de Algemene Voorwaarden, gedeponeerd op 21 juni 2004 bij de Kamer van Koophandel Haaglanden onder nummer 26522, onverminderd van toepassing. Scholten c.s.

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Mr M.G. Suermondt

Ministère de la Jeunesse, des Sports et de la Vie Associative Le Directeur du Cabinet Mr. Jean-François Vilotte 95 Avenue de France F - 75650 PARIS cedex 13

Aussi par télécopie: 0033 - 1 - 45.82.13.70

La Haye, 2 février 2006

Ref.: 206.242.07

Re: UCI / Investigation

Cher monsieur Vilotte,

Nous avons bien reçu votre lettre dans l'affaire susmentionné, daté 27 janvier 2006.

Premièrement on veut dissiper un malentendu. Notre cabinet n'acte pas comme avocats d'UCI. Nous faisons un recherche strictement indépendant et objective concernant ce qu' a arrivé en conséquence d'un article dans le journal sportive L'Equipe en août 2005. Alors, on n'est pas votre adversaire. On espère de coopérer avec tous les intéressées pour le besoin d la cause.

Ayant compris vous bien, vous jugez un rendez-vous avec nous, comme demandé dans notre lettre daté 24 janvier 2006, d être pas nécessaire. Puisque, l'information, demandée par nous, comme les sujets, proposés par nous pour délibération plus proche avec vous et liées à cet information, vous jugez connue suffisante chez nous.

Malgré la question si cet hypothèse de votre part sera correcte ou non, en fait, elle ignore, dans tout cas, la valeur ajoutée des délibérations directes entre des intéressées en l'espèce. Le seul fait que le contenu de la politique français anti-dopage peut être réduit à le contenu de la cadre légal, lequel forme le base de cette politique française, ne signifie pas évidemment, que nous n'avons pas plus des questions concernant cette politique généralement et cet affaire particulièrement. En plus, le seul fait que le Laboratoire Nationale De Dépistage Du Dopage" (LNDD), lequel est du ressort de votre Ministère, a intéressé fortement à cet affaire, illustre le contraire. Notamment concernant le dernier sujet, on aurait bien voulu d'avoir un rendez-vous avec votre Ministère.

Un des aspects d'engagement du LNDD dans cet affaire, concerne -comme vous savez- la publication par LNDD dans son rapport de recherche de soi-disant 'information additionnelle'

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Op al onze transacties zijn de Algemene Voorwaarden, gedeponeerd op 21 juni 2004 bij de Kamer van Koophandel Haaglanden onder nummer 26522, onverminderd van toepassing. concernant des analyses des échantillons d'urine des Tours de France 1998 et 1999, accomplis par LNDD.

Concrètement, il concerne la publication explicite par LNDD des numéros de code originaux, imprimées aux les bouteilles petites de verre, lesquelles on a usées réellement à l'époque chez l'exécution des contrôles dopage en ces deux Tours de France. En conséquence, des autres avaient eu l'occasion d'évaluer des quels coureurs on a pris un échantillon d' urine. Sûrement, on a pris cet occasion en vue de la publication dans L'Equipe.

Néanmoins le fait que un laboratoire, accrédite par l'AMA, comme LNDD, est interdit formellement de publier ce genre de l'information confidentielle et, en plus, il n'existait aucun raison pour le faire, LNDD a publié 'l' information additionnelle' susmentionnée dans son rapport de recherche, puisque l'AMA l'avait le demandé formellement, à ce qu'on dit soimême.

Selon LNDD, la requête de l'AMA aura donné lieu à une discussion pour six mois entre votre Ministère à un coté et l'AMA à l'autre concernant les conditions, sous lesquelles on pourrait publier 'l' information additionnelle', demandée par 'AMA. Le LNDD a nous informé qu' il n'était pas impliqué dans cette discussion en plus.

Enfin, ces choses et d'autres auront menés à la conclusion et l'acceptation par l'AMA des deux conditions plus proche, en vertu de quoi LNDD a pensé d'avoir le permis d'informer l'AMA concernant 'l' information additionnelle' susmentionnée directement, tout au moins dans ses rapports de recherche.

Comme mentionné déjà, on a eu l'idée et le vœu d'avoir un rendez-vous avec votre Ministère, afin d'être informé par votre Ministère de votre version et de le discuter avec vous. Il le fallait se faire dans le cadre de la politique française anti-dopage généralement, de la position du LNDD là-dedans et l'engagement de votre Ministère avec l'exécution de cette politique particulièrement.

Hélas, votre lettre n' a nous donné aucune autre conclusion que ce n'est pas possible pour le moment. Si ce lettre a changé votre idée, en vertu de quoi vous êtes disposés à un rendez-vous avec nous, on aime de l'apprendre de vous par retour du courrier. Si non, on prendra votre décision dans notre rapport de recherche indépendant. Cette remarque s'adresse le LNDD aussi.

On a confié d'avoir vous informer suffisant.

Je vous prie de croire, monsieur Vilotte, à l'assurance de ma considération distinguée.

Scholten c.s. Advocaten

Paul Scholten

# august & debouzy avocats

6-8, avenue de Messine 75008 Paris - France Tél. 33 (0) 1 45 61 51 80 - Fax. 33 (0) 1 45 61 51 99 www.august-debouzy.com

February 6, 2006

Emile Vrijman Attorney-at-law Scholten c.s Advocaten Denneweg 124 2514 CL's Gravenhage Hollande

Re.: <u>Laboratoire National de Dépistage du Dopage - Request for further information and/or access to documentation</u>

Dear Sir,

We refer to your letter of January 30, 2006 and would like to make the following comments.

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

Nevertheless, we appreciate your comment on the alleged source of the information contained in the article published in *L'Equipe* newspaper, and confirm that the information provided to the reporter did not come from our client.

Yours sincerely.

Pierre-Charles Ranouil / Isabelle Vedrines

Experience of the control of the

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Châtenay-Malabry, le 15 mars 2006

# TRANSMISSION DE TELECOPIE

Expéditeur :

J. de CEAURRIZ

Directeur du Laboratoire National de

Dépistage du Dopage

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Fax: +33 (0) 1.46.60.30.17

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Destinataire :

Emile N. Vrijman

Organisme:

Scholten c.s. Advocaten

Fax: 00.31.70.345.84.29

Nombre de pages y compris celle-ci : 1

Cher Maître

Vous êtes certainement en voie de clôturer l'enquête que vous a confiée l'UCI à propos des résultats des travaux de recherche menés par le laboratoire national de lutte contre le dopage français à partir des échantillons des Tours de France 1998 et 1999 et de la diffusion par la presse des résultats de 1999.

Avant taute publication à la presse de ce rapport et, compte tenu des informations que j'ai eu l'occasion de vous fournir, je vous demande de bien Vouloir me donner communication du contenu de votre rapport qui concerne les travaux du laboratoire. Je souhaite en effet vérifier l'exactitude des faits et des informations qui y sont rapportés ainsi que la précision de la traduction qui en a été faite.

Dans l'attente de votre réponse, je vous prie de croire, Cher maître, en l'assurance de mes salutations distinguées et respectueuses.

Scholten c.s.

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Mr J.P.R. Scholten

Mr E.N. Vrijman

Mr M.G. Suermondt

J. de Ceaurriz, Directeur du Laboratoire National de Dépistage du Dopage

Par télécopie: 00 - 33 - 1 - 46.60.30.17

La Haye, 22 mars 2006 Re: Recherche UCI Dossier: 206.242.07

Cher monsieur De Ceaurizz,

Aujourd'hui on a bien reçu votre message du 16 mars 2006 dans lequel vous avez réagi à notre lettre du 15 mars 2006.

Notre traduction en français peut être critiquer, mais c'est manifeste, vous avez bien compris le contenu de notre message.

Vous n'avez pas besoin d etre peur que notre recherche sera influencé par notre connaissance de votre langue, puisque notre entretien a eu lieu en le langue anglais!

A propos notre demande pour votre documents, c' est toujours possible de les nous donner volontairement, ca veut dire, sans intervention officielle.

On n'a jamais écrit que c'était interdit de nous envoyer les documents. On a écrit que les autorités ont refusé de les nous envoyer, c'est d'autre chose.

Plus tard, vous m'avez avisé de présenter des questions officielles conforme les règles judiciaires françaises. Ayant les faits, on a refuse de coopérer chez nous.

Maintenant vous me demandez pour d'envoyer mon rapport pour vérifier ce que nous avons écrit. Ca ne serait aucune problème si vous auriez coopéré en janvier.

On a mises des questions à vous, sans réponse. Maintenant, on a mises des questions à l'AMA et onattend leurs réponses. L'AMA a nous assuré de réagir dans un bref délai.

Je vous prie de croire, cher professeur, à l'assurance de ma considération distinguée.

Scholten c.s. Advocaten

aul Scholten

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Emile Vrijnan

Op al onze transacties zijn de Algemene Voorwaarden, gedeponeerd op 21 juni 2004 bij de Kamer van Koophandel Haaglanden onder nummer 26522, onverminderd van toepassing.



# Châtenay-Malabry, le 15 septembre 2005

M. Hein Verbruggen Président UCI CH 1860 AIGLE SUISSE

Fax N° 00,41,24,468,58,54

Monsieur le Président,

En réponse à votre courrier du 9 septembre 2005, je tiens à vous apporter dans l'immédiat les précisions suivantes :

- 1°) Les reliquats des échantillons A des Tours de France 1998 et 1999 et les flacons B correspondants anonymés ont bien été utilisés par le laboratoire à l'occasion de travaux de recherche qui visaient à mettre à l'épreuve un nouveau critère de positivité à l'EPO moins restrictif que celui utilisé précédemment et mieux adapté à la détection de la prise d'EPO à des faibles doses.
- 2°) Cette recherche a été menée en collaboration avec l'AMA qui a pris en charge une partie des travaux notamment ceux qui avaient trait à l'administration d'EPO recombinante à des volontaires selon un protocole qui intégrait l'administration de fortes doses d'EPO suivies de l'administration de faibles doses.
- 3°) Le laboratoire a travaillé en toute indépendance et avec l'unique objectif d'améliorer la version initiale du standard international EPO qui sert de guide aux laboratoires antidopage.
- 4°) Le laboratoire a accepté de transmettre à l'AMA la totalité des informations dont il disposait de façon à permettre à cette Autorité de vérifier à posteriori, si elle le souhaitait, la cohérence des résultats obtenus. Il a d'ailleurs subordonné cette acceptation à l'engagement par l'AMA d'exclure toute action disciplinaire eu égard aux conditions de réalisation de ces travaux de recherche et en particulier à l'ouverture des flacons B.
- 5°) Le laboratoire a réagi à la sortie de l'article du journal l'Equipe par le communiqué de presse ci-joint.

Je vous prie de recevoir, Monsieur le Président, l'expression de mes sentiments di

J. de CHAUTETE



# MINISTÈRE DE LA JEUNESSE, DES SPORTS ET DE LA VIE ASSOCIATIVE

Paris, le 16 septembre 2005

Dominique Laurent Directrice des Sports tél: 01 40 45 94 71 fax 01 40 45 91 79 M. Hein Verbrugghen Président de l'UCI fax: 00 41244685854

mail: dominique.laurent@jeunesse-sports.gouv.fr

A l'attention personnelle et confidentielle de M. Verbrugghen, Président de l'UCI, De la part de M. Lamour, Ministre de la jeunesse, des sports et de la vie associative.

Vous trouverez ci-joint en fax le courrier que M. Lamour vous adresse parallèlement par la poste.

Secrétariat de D. Laurent

# Ministère de la Jeunesse, des Sports . et de la Vie Associative

Le Ministre

Personnelle et Confidentielle

Serio. 6 1 6 SEP. 2005

Monsieur le Président,

Après avoir pris connaissance de votre correspondance du 9 septembre dernier, il m'a semblé utile de vous faire part des informations suivantes:

1- Le Laboratoire national de dépistage du dopage français (LNDD) est un établissement public à caractère administratif (EPA) dont la spécialité statutaire est, notamment, ainsi que le précise le texte réglementaire (article R 3632-19 du code de la santé publique) relatif à ses missions « de menor des travaux de recherche en vue de l'adaptation du contrôle destiné à lutter contre le dopage au progrès technique et scientifique et d'assurer la valorisation de leurs résultats ».

L'étude conduite par le LNDD sur les échantillons prélevés lors du Tour de France en 1998 et en 1999 s'inscrit dans le cadre de cette mission de recherche. Cette recherche porte sur des produits interdits à la date du prélèvement. En 1998 et en 1999, l'EPO, même si elle ne pouvait être détectée, constituait un produit interdit.

C'est donc dans son domaine de compétence que le LNDD a agi sans qu'il n'y ait eu besoin d'une quelconque intervention ou validation de la part du Ministère français en charge des sports.

Les résultats de l'étude sur les échantillons de 1998 ont d'ailleurs fait l'objet d'une publication scientifique dans « Nature » en 2000 (n° 405 : 635 Lasne F. et de Ceaurriz J.) sans susciter d'observations particulières.

Le L.NDD continuera à exercer cette compétence dans l'avenir en tant que département des analyses de la future Agence française de lutte contre le dopage (AFLD) dont la création est prévue par le projet de loi n° 2181 relatif à la lutte contre le dopage et à la protection de la santé des sportifs, voté à l'unanimité en première lecture par l'Assemblée Nationale le 6 avril 2005. L'article le de ce projet garantit l'indépendance de l'agence qui est une « Autorité publique indépendante dotée de la personnalité morale ».

M. Hein VERBRUGGHEN
Président de l'Union Cycliste Internationale
Ch 1860 Aigle
SUISSE

95. avenue de France - 75650 Paris cedex 13 - Tel. : 01 60 45 91 18 - Fax : 01 40 45 90 47

.../ . . .

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 antidopage qui charge l'AMA d'une mission spécifique de coordination dans le domaine de la recherche.

Je ne peux que me réjouir de la contribution efficace du laboratoire français à la lutte contre le dopage au plan international, ses travaux de recherche a yant a insi permis la mise au point et l'amélioration du test de l'EPO.

2- La levée effective de l'anonymat des échantillons n'a pu être faite que par rapprochement avec les bordereaux de prélèvement qui mentionnent le numére d'échantillon et le nom du coureur.

Je m'étonne qu'un tiers ait pu se procurer le bordereau complet de prélèvement du coureur (à supposer établie l'authenticité du document publié).

En effet, à eux sculs, les résultats d'analyse des échantillons, même comportant les numéros des échantillons, n'ent pu être à l'origine de la rupture de la confidentialité des études menées par le laboratoire, rupture que je regrette comme vous.

Ni le LNDD (qui ne détient que des documents anonymés), ni le ministère chargé des sports (qui ne détient depuis 2000 que des documents anonymés et qui, pour l'année 1999, a détruit, au plus tard en 2001, les bordereaux négatifs dont il était destinataire), n'ont pu être à l'origine de ces fuites.

3- Je vous informe qu'une suite favorable et immédiate serait donnée à toute requête d'un coureur qui, connaissant son numéro d'échantillon 1998 ou 1999 et prenant la décision de le révéler, demanderait que le LNDD confie à un laboratoire d'expertise tiers, selon les voies juridiques appropriées, les produits conservés pour analyse ADN et recherche de substances dopantes interdites en 98/99 éventuellement présentes. Avant de répondre à votre lettre je me suis assuré auprès du Directeur du LNDD que, pour 1999, douze sur quinze des échantillons positifs à l'EPO sont réanalysables et, pour 1998, 24 sur 39 le sont (sur la base de 20 µl pour les retentats et de 20 ml pour les urines).

Telles sont les informations que je souhaitais vous communiquer eu égard aux compétences et prérogatives respectives de l'UCI et du ministère dont j'ai la responsabilité.

Je ne peux en conclusion que vous faire part de ma surprise quant à la nature des questions que vous avez cru bon de me poser dans le cadre de ce que vous qualifiez « d'enquête ». Vous savez la détermination du Gouvernement français à agir aux côtés du mouvement sportif et de l'AMA pour améliorer les techniques et procédures de lutte contre le dopage, et ce, sans qu'il puisse être suspecté d'agir dans le but d'attenter à l'image d'une discipline ou d'un sportif.

Sachez que je suis aussi déterminé que vous à ce que les études et recherches qui ont été conduites par le LNDD servent la lutte engagée avec le concours de l'AMA contre le recours aux procédés et produits dopants.

Je vous prie de croire, Monsieur le Président, à l'assurance de ma considération distinguée.

Jean-François LAMOUR

# Recombinant erythropoietin in urine

An artificial hormone taken to boost athletic performance can now be detected.

rythropoietin is a hormone that stimulates the production of new red blood cells (erythropoiesis). Although athletes use recombinant human erythropoietin illicitly to boost the delivery of oxygen to the tissues and enhance their performance in endurance sports, this widespread doping practice cannot be controlled in the absence of a reliable analytical procedure to monitor it. Here we describe a new technique for detecting this drug in urine following its recent administration

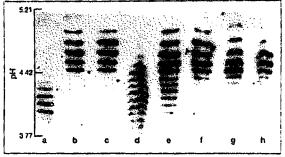
The stimulation of erythropoiesis by erythropoietin (EPO) makes this drug very attractive to sportspeople wishing to improve their aerobic power, although the International Olympic Committee banned its misuse ten years ago. Detection has been a problem—analysis of haematological or biochemical parameters indicates only that erythropoiesis has been stimulated, but cannot confirm that drug administration is to blame

To detect administered hormone directly means that exogenous, recombinant EPO must be differentiated from natural, endogenous EPO A promising electrophoretic method has proved impractical for screening by the antidoping laboratories. We have developed an analytical procedure for detecting recombinant EPO in urine and have applied it to specimens from cyclists participating in the the infamous. Tour de France 1998 competition, which was sullied by scandals about EPO doping.

Owing to microheterogeneity in their structures, natural and recombinant EPO comprise several isoforms, some of which have charge differences and can be separated by isoelectric focusing (Fig. 1). We found that the isoelectric patterns of the two recombinant EPO-α and -β forms are very similar (both have an isoelectric point, pl, in the range 4.42-5 11); although EPO-β has an extra basic band, both differ from natural, purified urinary EPO, which has more acidic bands (pl 3.92-4.42), probably due to post-translational modifications such as glycosylation, which is species- and tissuetype-dependent' Such differences in the urine analysis allowed us to ascribe excreted EPO to a natural or recombinant origin.

We developed an immunoblotting procedure to obtain a reliable image of EPO patterns in urine. Our results (Fig. 1) indicated that the patterns from control subjects consisted of about 10 bands of plantary and the purified natural urinary EPO pattern, whereas those from subjects treated with recombinant EPO contained more basic bands, reflecting

Figure 1 Autoradiograph of isoelectric patterns of exogenous and endogenous erythropolatin (EPO) images were obtained by chemiturnhescent immunodetection of blotted EPO after isoelectric focusing a, Puritled commercial human urinary natural EPO (Sigma); b, recombinant EPO-β (Neurocormon, France); c, recombinant EPO-α (Eprex, France); d, urine from a control subject; e,f, urine from two patterns (realed with



Necrecommon EPO for post-haemorrhagic anaemia; g.h, udno from two cyclists from Tour de France 1998 (samples concentrated by utrafitration). Note the imbact appearance of the pattern in e. The cathode is at the top; pH values are indicated on the left

the presence of recombinant isoforms, and sometimes acidic bands as well, depending on the presence of endogenous isoforms. The presence of exogenous hormone was always evident: any individual injected with recombinant EPO showed a striking transformation of their initial EPO urine pattern

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. Iwenty-eight of these samples had EPO levels above the normal range of 0-3.7 international units per litre (mean, 0.48 IU per litre, n = 103; 77 samples were below the minimum detectable concentration of 0.6 IU per litre). We analysed the 14 samples presenting with the highest concentrations (7-20 IU per litre): although characterization of the EPO source does not require such high levels for urine analysis, we

selected these samples for isoelectric focusing as they were more likely to contain exogenous hormone; indeed, they all gave rise to a banding pattern typical of recombinant hormone.

Our method for detecting recent exposure to recombinant EPO in athletes could be useful for in-competition controls in events of long duration (for example, cyclists have been known to use exogenous EPO continuously for 6 months at a time), but should find its principal application in out-of-competition testing

Françoise Lasne, Jacques de Ceaurriz National Anti-Doping Laboratory, 92290 Châtenay-Malabry, France

- 1 Casoni, 1. et al. Im J Sparts Med 14, 307-311 (1993)
- 2 Gareau R. et al Nature 380, 113 (1996)
- 3 Wide, L et al Mai Sci Sports Exerc 27, 1569-1576
- 4. Rademacher, T. W., Parekh, R. B. Dwek, R. A. Annu Rev. Biothem, 57, 785-838 (1988)

Phylogeny

# Parabasalian flagellates are ancient eukaryotes

iscrepancies between eukaryotic phylogenetic trees based on different gene sequences have led to the suggestion that the deepest branches of each gene tree could simply be artefacts of rapid evolution rather than indicators of an ancient divergence1-5. But if an insertion or deletion occurred in a gene sequence very early in eukaryotic evolution, the oldest eukaryotic lineages should be recognizable by their resemblance to prokaryotes lacking this character. Here we investigate the structure of the gene encoding enclase, an enzyme of the glycolytic pathway, and find that the gene from parabasalian flagellates lacks two deletions present in other eukaryotic

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enolases, indicating that Parabasalia could be the most ancient eukaryotes examined so far.

Eukaryotic enolase sequences contain several insertions and deletions compared with each other, Eubacteria and Archaebacteria, some of which have been used to link animals and fungi<sup>6</sup>. We sequenced enolase genes from three putatively ancient lineages: diplomonads, Parabasalia and kinetoplastids. Neither kinetoplastid nor diplomonad enolase genes are exceptional (nor is that of Entamocha enolase, another putatively ancient eukaryote), but parabasalian enolases lack two close, single-amino-acid deletions common to all other eukaryotic enolases (Fig. 1a, overleaf).

Given the proximity of these deletions, they may have resulted from a single event However, the surrounding alignment is reproducible, and the amino acids at these



A = Interprétation visuelle
B = % d'isoformes basiques
C= Classement mathématique SERIE LABO 127/07 126/07 122/07 93/07 34/07 33/07 29/07 **EPREUVE: Tour de France** 066 190 066 198 066 191 066 191 066 102 066 105 066 105 066 207 066 214 066 192 066 185 FLACON 066 209 066 181 066 081 066 091 066 092 066 082 066 208 066 212 066 104 066 099 066 186 066187 066 215 066 213 066 201 066 199 066 205 066 196 066 197 066 200 066 202 066 204 066 195 EPO rétentat (UI/L) 936 936 546 555 <u>수</u> 337 7 7 1861 13 g 9 **国现在**的64年 1998 Þ RESULTATS 200 Company of the Control of the Co 73,3 Œ

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A = interprétation visuelle

B = % d'isoformes basiques
C= Classement mathématique
EPREUVE : Tour de France 1998

Absence d'EPO recombinante inclassable à réanalyser

A = Interprétation visuelle
B = % d'isoformes basiques
C= Classement mathématique

EPREUVE : Tour de France 1998

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MANAGEMENT PROPERTY OF THE COMPINENTS

A m Internatation wante

Lance Armstrong zou in de Tour van 1999 Epo hebben gebruikt. Ter verdediging uitte de Amerikaan tal van beschuldigingen. Zo deugde er in zijn ogen weinig van de werkwijze van het laboratorium van Châtenay-Malabry. Directeur Jacques de Ceaurriz reageert. Door Marije Randewijk

isschien wordt het tijd, zegt Jacques de Ceaurriz, dat het tot de mensen doordringt 'De werkelijk-

heid is minder romantisch dan hij

Hij heeft de verhalen ook gelezen, over die geheimzinnige samenzweringstheorieën en -complotten. Hij heeft erom gelachen, om de verdachtmaking dat zijn laboratorium in opdracht Epo in de urine van Lance Armstrong heeft gedaan. En dat de Amerikaan daarom nu positief is bevonden.

Velen vinden het ook een ontdekking van niets. Regels zouden zijn overtreden, schorsingen niet meer uit te spreken, dus wat hebben we er eigenlijk aan gehad?

De directeur van het Franse IOC-laboratorium in Châtenay-Malabry, ten zuiden van Parijs, zegt dat hij slechts zijn werk heeft gedaan. En dat hij dat zal blijven doen, ondanks alle beschuldigingen en dreigementen. De zogenaamde Franse heksenjacht bestaat niet, dat idee zit alleen maar in het hoofd van Armstrong.

Zijn laboratorium, waar de eerste Epo-test werd ontwikkeld, heeft een naam opgebouwd in de strijd tegen doping. De laatste jaren testten succesvolle sporters als onder anderen de atletes Olga Jegorova en Kelli White, tennisser Mariano Puerta en nu dus wielren-

ner Lance Armstrong er positief. En allemaal konden ze hun resultaten teruglezen in L'Equipe.

Schouderophalend wijst De Ceaurriz de suggestie van de hand dat hij, in ruil voor informatie, een gratis abonnement op de Franse sportkrant heeft gekregen. 'Wij spelen geen informatie door, aan geen enkele krant.'

Dus ook niet aan L'Equipe?

Wij zouden dat niet eens kunnen. De stalen worden anoniem getest. Voor ons is het werkelijk onmogelijk uit te maken wat aan wie toebehoort.'

U heeft dan toch ten minste een directe link naar hun bureau? Het ligt nota bene op een steenworp afstand hier vandaan.

'Nee, werkelijk niet. L'Equipe zet de middelen in die het nodig acht. Soms te veel, wat mij betreft. Het geneert mij regelmatig dat nieuws over betrapte atleten zo snel op straat ligt. Wij zijn niet op zoek naar een scoop. We willen ons werk in alle rust kunnen doen.'

Dus de krant levert gewoon puik werken het is toeval dat uw laboratorium er telkens bij betrokken is? "Zo is het. Tot de Tour van 1998 had L'Equipe de naam dat het doNu hebben ze vier onderzoeksjournalisten die in doping zijn gespecialiseerd. En ze hebben ook een goed correspondenten-netwerk. Hoe weet je anders dat Puerta positief heeft getest? Dat is niet mijn fout, dat nieuws komt uit Argentinië.'

Dus u was ook verrast toen u op 23 augustus de krant las?

'Zoals iedereen was ik verbaasd en ontgoocheld. Tegelijkertijd was ik ook gerustgesteld. Dat zes positieve stalen van Lance Armstrong afkomstig blijken te zijn, wijst op een zekere consistentie. Ik had me minder comfortabel gevoeld als slechts één staal aan hem had toebehoord.'

#### Waarom zijn jullie de urinestalen uit de Tour van 1999 gaan onderzoeken?

'Het WADA, het internationale anti-doping bureau, wilde in 2004 weten of sporters hun methoden de laatste jaren hebben veranderd. Ze vermoedt dat atleten, tijdens de competitie slechts heel lichte doses Epo gebruiken. Buiten competitie zouden ze dan wel veel hogere doses gebruiken. Dat maakt het veel moeilijker om ze te betrappen.

'We hebben dankzij onderzoeken met nierpatiënten een nieuw

Jacques de Ceaurriz

FOTO AFP

Controleur De Ceuarriz hoopte op een klacht van Armstrong om gerechtelijk onderzoek ta forceren

mathematisch analyse-model ontwikkeld dat gevoelig blijkt voor zowel hoge als lage doses. En met dat nieuwe model hoeft niemand meer te twijfelen.'

Hoe wist u dat u positieve stalen in uw opslagruimte had waarop die nieuwe test kon worden uitgeprobeerd?

Tussen 1999 en 2001 hadden we al een nieuwe analyse gedaan van urinestalen uit de Tour van '98. Die diende om de toenmalige Epo-test te verfijnen. Toen het WADA ons vroeg om die tweede Epo-test verder te ontwikkelen, hebben we op nieuw stalen van '98 gebruikt, er die van '99 erbij genomen.'

# Hoeveel stalen hebt u onder-zocht?

'Uit de Tour van '98 hadden we nog negentig stalen over. Daarvat hebben we er zestig onderzoch: En veertig waren positief. Uit de Tour van '99 hebben we er negentig onderzocht. Daarvan hebber zo'n vijftien stalen positief ge

(3.)

# Het woord is aan Emile Vrijman

'De leugen van Armstrong' titelde de Franse sportkrant L'Equipe op 23 augustus van dit jaar in blokletters op de voorpagina. De zevenvoudige Tourwinnaar, in juli afgezwaaid als wielrenner, zou bij zijn eerste overwinning in 1999 Epo hebben gebruikt. Het werd in zes van zijn urinestalen aangetroffen. De sportwereld reageerde geschokt. Armstrong verdedigde zich. 'Er is gerommeld met mijn urine. Wat hebben ze erin gedaan? Wie is er bij die test geweest. Toen ik in dat flesje plaste, zat er geen Epo in. No way.' Wekenlang wezen betrokken instanties elkaar met beschuldigende vinger, Want wie lekte de informatie waarmee de krant de naam van Armstrong op

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de positieve test kon plakken? Moest het laboratorium van Châtenay-Malabry, dat zonder toestemming oude urinestalen van sporters gebruikte voor wetenschappelijk onderzoek ook niet worden geschorst? En wat is de zin van retrospectief testen zonder goede regalgeving? **Emile Vrijman zal snel** antwoord moeten geven op die vragen. De Nederlandse advocaat is door de internationale wielerunie gevraagd orde in de chaos te scheppen. Hoewel de UCI zijn rekeningen betaalt, verwacht Vrijman geen bemoeienis. 'Ze kunnen het onderzoek niet beinvloeden of ons rapport inzien voor publicatie. Ik heb de vrije hand gekregen.' Daarom verwacht hij

ook volledige medewerking van alle partijen, ook van het wereldantidopingagentschap. (WADA), dat een eigen reconstructie maakt van de zaak-Armstrong: Jacques Rogge, voorzitter van het internationaal olympisch comité (IOC), heeft al opgeroepen tot een onafhankeliik onderzoek als de conclusies van beide Instanties te zeer uiteenlopen. Vrijman vreest daar niet voor, 'lk denk dat het in het belang van alle sporten is dat de kwestie van retrospectief onderzoek wordt bestudeerd..We moeten er zeker van zijn dat het binnen de regelgeving plaatsvindt. Onze conclusies moeten een leidraad zijn voor hoe we in de toekomst met zo'n zaak dienen om te gaan.

De UCI laat Emile Vrijman nu een onderzoek doen. Wat verwacht u daarvan?

'Ik ken die man niet, ik heb hem nooit gesproken. Heeft hij verstand van deze materie? Ik zie het allemaal wel. Iedereen voert nu zijn onafhankelijke onderzoek, liever had ik een gerechtelijk onderzoek. Dat is voor mij de enige onafhankelijke instantie, niet de UCI of het WADA.'

Dus het geheim van Châtenay-Malabry wordt niet onthuld? Jullie vinden wel opvallend veel meer in de urine van grote sporters dan andere laboratoria.

'Wacht even. Ik vind de andere Europese laboratoria ook goed werk leveren.'

Maar bij jullie komt het eerst in de krant. Het lijkt erop dat jullie geen vertrouwen hebben in de bestaande instanties die de dopingzaken moeten afhandelen. voor de dopingstrijd. Als er iets is dat deze zaak heeft aangetoond, is het wel dat de huidige dopingcontroles niets uithalen, omdat de sporters nu volgens een beperkt juridisch kader kunnen worden vervolgd.

We hebben niet alleen punctuele straffen nodig, maar straffen die werkelijk afschrikken. Daar moeten UCI en WADA zich mee bezighouden. Vandaag kun je zelfs niet zeggen aan wie de urinestalen toebehoren en wie het recht heeft ze te analyseren. Horen ze nog altijd de atleten toe, of de federatie, het laboratorium misschien?

IOC-voorzitter Jacques Rogge heeft WADA-voorzitter Dick Pound gevraagd zo'n handleiding op te stellen. Wat moet daar volgens u instaan?

Het moet het sportieve domein overschrijden. Ze moeten de ruimte laten voor een gerechtelijk gebruik van de testresultaten. Be-



U twijfelt niet aan de resultaten van uw onderzoek?

'Al onze testresultaten klasseren we onder zwart, wit of grijs: positief, negatief of twijfelachtig. Positief is positief, dan moet er niet worden getwijfeld.'

Ook niet een klein beetie?

De testresultaten zijn wat ze zijn. Toevallig blijken ze op de Tourwinnaar van '99 te slaan. Ze hadden ook kunnen toebehoren aan iemand die de Tour niet won. Overigens hebben we ook in negen andere stalen Epo gevonden. Dat die de krant niet halen, wordt ons aangerekend terwijl wij daar helemaal niets mee te maken hebben.'

Volgens Armstrong heeft iemand hier op het laboratorium die Epo in zijn urine gedaan.

'Het eerste wat sportlui doen om zich te verdedigen, is het laboratorium aanvallen dat de tests heeft gedaan. Zo gaat het altijd. We hebben al erger meegemaakt.

'We hebben ook geen advocaten ingeschakeld, dat doen we alleen bij moeilijke gevallen. Dit is een klare zaak met duidelijke feiten.'

Uw naam wordt desondanks door het slijk gehaald. Ook door de internationale wielerunie. 'Ach, dat weet ik niet. Om het bewijs te leveren voor onze onschuld, hebben wij baat bij een gerechtelijk onderzoek. Ik hoopte daarom op een klacht van Lance Armstrong, opdat het gerecht de resten van de gebruikte stalen in beslag zou nemen. Ik wacht er nog op. Maar helaas zal die klacht er niet komen. Dus laten we alles maar over ons heen komen.

Ondertussen willen heel veel mensen dat u uw IOC-accreditatie wordt ontnomen omdat u het vertrouwen van de sporters hebt geschonden.

Dat is een probleem voor het WA-DA; zij accrediteren de laboratoria. Nogmaals, ik heb ergere kritiek meegemaakt. Ik kan u wel vertellen dat de oorlog volop woedt binnen het IOC. Dat zijn bastions tegenover elkaar, daar wordt om bevoegdheden gestreden. Wij zijn maar een laboratorium. In de strijd tegen doping vind ik dit hele debat betreurenswaardig.'

De aandacht wordt afgeleid van waar het om gaat? 'Ja, zeker.'

Heeft het WADA u om uitleg gevraagd?

'Men heeft me vragen gesteld. En ik heb geantwoord.'

Lanca mucica amangeren.

'Dat zou je kunnen beweren als wij iets te maken hebben met die publicaties en dat is niet zo. Ik kan wel zeggen dat de UCI en het IAAF een grote bijdrage hebben geleverd aan de strijd tegen doping. Alleen is de strijd tegen doping meer dan het ontwikkelen van nieuwe onderzoeksmethoden. Er moeten ook strategieën worden uitgedacht, hoe de controles worden uitgewoerd.

den uitgevoerd.

'Wat dat betreft levert de IAAF beter werk dan de UCI. Vaak lijkt de UCI meer op een praatclubje. Dat geldt ook voor het WADA. De coördinatie van federaties en overheden die elk hun eigen anti-dopingstrategie hebben, zal haar beslist niet gemakkelijk vallen. Het WADA heeft ook een oude anti-dopingcode geërfd. Het wordt hoog tijd dat die code wordt vernieuwd.'

De vraag is of zij de noodzaak zien. Het is toch ophef om niets? U gebruikte alleen de B-stalen, dus Armstrong kan zich niet verdedigen en gaat sowieso vrijuit.

'Dat is volgens de sportieve regelgeving wel zo; het gerechtelijke apparaat werkt anders. Daar moeten ze zelfs met lijken werken. Die wek je ook niet eerst opnieuw tot leven. De sportieve regelgeving zoals die nu is, werkt verlammend bruik van de testresultaten. Belangrijke informatie mag niet begraven worden onder medische ethiek die op sportlui ook niet van toepassing is. Dat zijn namelijk geen zieken. In naam van de bescherming van alle sporters worden vooral degenen beschermed die de kluit belazeren. De nieuwe code moet sporters beschermen die niet frauderen.'

Bent u een voorstander van retrospectieve analyses? "Zeer zeker. Alleen moeten dan

'Zeer zeker. Alleen moeten dan oplossingen worden gevonden voor de B-staal die wordt gebruikt bij zo'n analyse en voor de contraexpertise. Desnoods moet er een deurwaarder bijkomen, wanneer de stalen worden geopend en weer ingevroren. En er moeten oplossingen gevonden worden voor het bewaren van urinestalen. Daarin moeten keuzes worden gemaakt.'

Als u eerlijk bent, wie is voor u de winnaar van de Tour van 1999?

Wat moet ik daarop antwoorden? Het is niet aan mij de winnaar van een Tour de France aan te wijzen. Wij hebben gewoon ons werk gedaan. Het is aan anderen om te zien wat ze daarmee doen en hoe de regelgeving moet worden veranderd. Dit nieuws was namelijk nog het allerergste voor het systeem van de dopingbestrijding.



8 = % d'iso	A = interpretation visuelle B = % d'isoformes basiques	les					Absence d'EPO recombinante	combinante
C= Classen	C= Classement mathématique	tique					à réanalyser	
	EPREUVE : Tour	Tour de France	nce 1999					
SERIE	FLACON	EPO rétentat		RESULTATS	G,	Remarques	Volume d'urine	Volume de retentat
LABO		(UNL)	Α	8	C		résiduel (ml)	résiduel (μί)
05/07	157:371	<125		955		Intensité faible	ô	40+20
	160 294	828		6.66			20	
-	160 297	600					0	10+5
,	160 300	534		67.11			0	
06/07	157 372	210		89 7			25	5
	185 553	603			+		45	
,	185 558	732		- 6119			40	
•	185 559	531					45	
•	185 560	<125	<b>新型工作</b>				35	
13/07.	186 581	434		3115			30	
,	186-582	457		50			40	5
	186.585	259		81,3			45	
	186.586	133		69,1			35	
·	186 587	442	-		+		46	
40/07	160.292	1526					20	10
,	160.295	<125		Indétectable			30	
	186 588	<125		Indétectable			40	
,	186 590	441		40.7			45	
53/07	186-075	<125					30	
	186-076	1092					0	
	186 077	576		IN SHIET			0	
,	186-079	<125					40	
55/07	186 071	312		36/1, 38			0	
	186 072	<125		Indéfectable			0	
-	186 073	1826		212.5 mg			0	
	186 074	131		Indétectable			0	
59/07	157 373	2452		901			30	10
ŀ	157 378	<125					45	
	157 380	653					50	15
60/07	160-296	<125		1888			45	
	157 070	1444		10 0 0 0 W			30	זל



A = interprétation visuelle
B = % d'isoformes basiques
C= Classement mathématique SERIE LABO 104/07 61/07 106/07 83/07 82/07 63/07 103/07 **EPREUVE**: Tour de France FLACON 185 473 185 478 185 895 185 471 186 392 185 472 185 474 185 474 185 894 186 395 186 395 186 396 186 398 185 479 186 393 186 393 186 393 186 393 185 556 186 584 185 557 185 891 185 892 185 898 185 480 185 554 186 080 186 078 160 291 EPO rétentat (UI/L) 4125 1439 125 Hautoradio Þ 1999 RESULTATS W n Remarques Intensité faible manquant manquant Absence d'EPO recombinante inclassable Volume d'urine résiduel (ml) 888 00433333335 288886 0 8 8888888 0 Volume de retentat résiduel (µI) 88 20 8 8 ĊTI 10



A = interprétation visuelle
B = % d'isoformes basiques
C = Classement mathématique SERIE LABO 154/07 153/07 144/07 106/07 145/07 152/07 **EPREUVE**: Tour de France 1999 185 803 186 237 186 353 185 802 185 884 185 888 185 900 186 358 186 352 FLACON 186 **58**3 185 108 186 239 186 240 186 357 186 238 185 551 185 887 186 232 186 351 185 896 185 899 186 397 185 **4**77 186 234 EPO rétentat 1772 349 <125 RESULTATS indétectable Indélectable Indélectable 78,2 Œ Remarques manquant manquant Présence d'EPO recombinante

Absence d'EPO recombinante

inclassable

Illill à réanalyser Volume d'urine résiduel (ml) 008 0 Volume de retentat résiduel (µI) 8 ð Ċ 5 5 즁

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Date:	October 15,2004	Required for analyses performed after:	January 15, 2005

HARMONIZATION OF THE METHOD FOR THE IDENTIFICATION OF EPOETIN ALFA AND BETA (EPO) AND DARBEPOETIN ALFA (NESP) BY IEF-DOUBLE BLOTTING AND CHEMILUMINESCENT DETECTION.

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 <u>Laboratories</u> are required to apply these criteria in the routine performance of the urine EPO test.

In this document, erythropoietin and its analogues are specified as follows:

rEPO: recombinant erythropoietin, also referred to as epoietin, including epoietin  $\alpha$  and  $\beta$ .

uEPO: endogenous erythropoietin, found in the urine.

Endogenous: secreted naturally, by the athlete's own tissues.

**NESP:** the erythropoietin analogue, darbepoietin  $\alpha$ .

The original method was described by F. Lasne et al. in *Analytical Biochemistry* 311 (2002) 119-126.

## Description of the method

The EPO urinary test must be performed according to the following method:

#### 1) Sample preparation:

Sample preparation consists of a partially selective pre-concentration technique based on centrifugal ultrafiltration and buffer washing. Preventing degradation of the EPO during this concentration process is essential.

Note: Although other more selective concentration techniques may potentially be used, any change to Sample preparation may affect the isoform distribution and consequently would require an appropriate validation by the laboratory.

#### 2) Isoelectric Focusing (IEF):

Isoelectric focusing is performed in a pH range compatible with the isoelectric point (pl) of both the natural urinary EPO and its recombinant analogues (e.g. routinely in the pH range of 2 to 6). The pH gradient is constructed using carrier ampholytes and IEF is performed under denaturing conditions (approximately 7M urea).

#### 3) Double blotting:

After IEF separation, a double blotting procedure is followed. In the *first blot*, proteins in the gel are transferred to a *first* PVDF membrane. After that, a monoclonal antibody (mAb)(clone AE7A5, recommended supplier: R&D Systems of Minneapolis, USA) is applied to recognise EPO. In a *second blot*, the interaction between EPO and mAb is disrupted at an acidic pH and the mAb is transferred to a *second* PVDF membrane.

Note: The method relies on the particular specificity of the monoclonal antibody with which it was developed (clone AE7A5). This antibody is considered a <u>critical reagent</u> and shall not be changed. Because the method relies on an isoelectric focusing separation prior to the antibody

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based detection, the use of a unique primary antibody is deemed scientifically acceptable. Consequently, clauses 5.2.4.3 ( $2^{nd}$  sentence) and 5.2.4.3.1.3 of the WADC International Standard for Laboratories do not apply for this specific test.

#### 4) Chemiluminescent detection:

The position of the mAb on the membrane is revealed by adding a sequence of reagents terminating in a peroxidase. This peroxidase generates light in the presence of the appropriate chemiluminescent substrate, allowing the generation of an image that maps the original position and quantity of EPO in the gel after IEF separation. Typically, this sequence of reagents is made up of:

primary mouse anti-human EPO mAb - biotinylated anti-mouse secondary antibody - streptavidin- horseradish peroxidase complex - chemiluminescent substrate for horseradish peroxidase.

#### **Testing**

In compliance with the WADA International Standard for <u>Laboratories</u> (clause 5.2.4.3.1.1), a presumptive Adverse Analytical Finding in the <u>Screening Procedure</u> should be confirmed using a second aliquot taken from the original "A" Sample.

## **Evaluation and Interpretation of Results**

Results need to fulfil the quality, identification and stability criteria described herein. Figure 1 shows an example of a test result with the definition of basic, endogenous and acidic areas. Bands of the reference substances are identified by numbers and letters.

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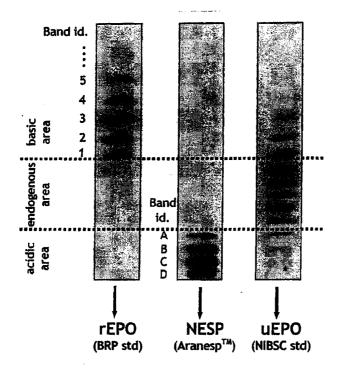


Figure 1. Image of three lanes obtained by the chemiluminescence acquisition system, and corresponding to the analysis of rEPO, NESP and uEPO.

Basic and acidic areas are defined, as described, by the position of the bands corresponding to rEPO (Biological Reference Preparation, BRP, of the European Pharmacopeia) NESP (aranesp™, Amgen) and by exclusion, the endogenous area is defined in between. In the figure it is exemplified by uEPO (International Reference Preparation, IRP, from the National Institute for Biological Standards and Control, NIBSC, of UK). The bands in the basic and acidic areas are identified by numbers and letters as shown.

The evaluation of the image obtained is based on the consecutive application of:

- acceptance criteria
- identification criteria
- stability criteria

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#### Acceptance criteria.

The acceptance criteria define the requisites that the image has to fulfil to allow the application of the identification criteria in order to ascertain the presence of rEPO or NESP.

- 1.- Spots, smears, areas of excessive background or absent signal in a lane that significantly interferes with the application of the identification criteria shall invalidate the lane.
- 2.-Comparison to reference samples shall allow assignment of band numbers in the athlete's sample.

#### Identification criteria.

When the EPO urinary method was initially developed, the proposed method of detection quantified the relative amount of basic band areas. Several CAS cases have referred to the "80% basic bands" rule in making decisions. Further research and experience has indicated that the identification criteria below are more discriminating than the "80% basic bands" rule and therefore the "80% basic bands" criterion should not longer be used.

The following identification criteria define the requisites that the image has to fulfil to consider that an adverse analytical finding corresponding to the presence of rEPO or NESP has occurred.

#### <u>rEPO</u>

- 1.-in the basic area there must be at least 3 acceptable, consecutive bands assigned as 1, 2, 3 or 4 in the corresponding reference preparation.
- 2.- the 2 most intense bands either measured by densitometry or assessed visually in the basic area must be consecutive and the most intense band must be 1, 2 or 3.
- 3.-the two most intense bands in the basic area must be more intense than any other band in the endogenous area either measured by densitometry or assessed visually.

#### **NESP**

- 1.-in the acidic area there must be 3 acceptable, consecutive bands assigned as B,C and D in the corresponding reference preparation.
- 2.-The most intense bands either measured by densitometry or assessed visually must be C or D.
- 3.-the most intense band (C or D) must be more intense than any other band in the endogenous area either measured by densitometry or assessed visually.

Methyl red may be used in the electropherogram to facilitate positioning and numbering of bands on the gel.

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Stability Criteria

When, after applying the above identification criteria, a urine sample is suspected of an *Adverse Analytical Finding* for rEPO or NESP, the confirmation phase shall also establish the stability of the profile found. Since it cannot be discounted that some rare factors may interfere with the stability of a urine *Sample* and may affect the interpretation of an *Adverse Analytical Finding* for EPO, a stability test must be performed before reporting an *Adverse Analytical Finding* for EPO in urine.

While it is recognized that other specific reagents may be developed and validated by the laboratory, an acceptable procedure for the stability test is as follows:

#### Reagents:

Pepstatin A: 1mg/mL in methanol Complete<sup>TM</sup> (Roche): 1 tablet /2 mL of water Microcon® YM-30 (Millipore), MWCO, 30,000 Da 50 mM sodium acetate buffer pH-5 Tween-80 BRP and NESP

#### Method:

Centrifuge 0.6 mL of urine 10 min, 2700 RCF, 20°C and put 0.5 mL of supernatant in a test tube Add 20  $\mu$ L of Pepstatin A and 5  $\mu$ L of Complete<sup>TM</sup> Concentrate to approximately 30  $\mu$ L using the Microcon® Add 200  $\mu$ L of acetate buffer into the sample reservoir and mix by vortexing before the invert recovery spin Adjust the volume of the recovered sample to 0.5 mL with acetate buffer Add 20  $\mu$ L of Pepstatin A and 5  $\mu$ L of Complete<sup>TM</sup> Incubate 15± 2 min at room temperature Add a mixture of BRP and NESP to a final concentration 1.5 x conc. used in references lanes of IEF Incubate overnight at 37°C Take 20  $\mu$ L. Heat 80°C for 3 min Add Tween-80 Apply to IEF gel

#### The stability criteria are:

- 1. The method described above does not result in a substantial shift in the position of the bands in the stability test lane compared to the reference standard lane.
- 2. The distribution of the most intense bands in the A screen, A confirmation and B confirmation results is similar.

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#### **Documentation and Reporting**

The following information is considered the minimum acceptable as "screening and confirmation test data" in compliance with the WADA International Standard for Laboratories-Technical Document TD2003LDOC, for this particular method:

#### Screening Assay Data:

- Image acquired from the detection system, corresponding to the lanes representing:
  - Sample (screening aliquot)
  - o Positive control sample or standard of the suspected or equivalent substance (i.e rEPO or NESP)
  - Negative control sample or standard of urinary EPO (uEPO).
- Processed images, such as densitometry profiles and/or contoured renditions of the signal density in the original image. These should show annotations demonstrating the application of the criteria to the isoform distribution of the Sample.
- Description of the result based upon application of all the criteria described in this Technical Document.

#### Confirmation Assay Data:

- Image acquired from the detection system, corresponding to the lanes representing:
  - o Sample (confirmation aliquot)
  - o stability test
  - Positive control sample and standard of the suspected or equivalent substance (i.e rEPO or NESP)
  - o Negative control sample and standard of urinary EPO (uEPO).
- Processed images, such as densitometry profiles and/or contoured renditions of the signal density in the original image. These should show annotations demonstrating the application of the criteria to the isoform distribution of the Sample.
- Description of the result based upon the application of the different criteria described in this Technical Document.

#### Opinions:

Any comment(s) from the <u>Laboratory</u> deemed necessary in support of the analytical finding.



October 5, 2005

By e-mail:

Mr. Lance Armstrong

Dear Mr. Armstrong:

Subsequent to the publication of the story in the issue of L'Equipe dated August 23, 2005 of possible positive samples for EPO during the 1998 and 1999 Tours de France, there have been requests from WADA stakeholders and others for an investigation into the facts as alleged.

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 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 analyzed by the laboratory in France.

WADA has therefore 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.

Please provide your written response by October 17, 2005.

Very truly yours,

David Howman Director General

Enclosure

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### **Questions for Lance Armstrong**

- 1. Can you confirm that as part of the doping control regulations applicable to the 1999 Tour de France, you provided urine samples for analysis?
- 2. Can you recall whether EPO was a prohibited substance for purposes of compliance with the then applicable anti-doping rules for the Tour de France?
- 3. Can you recall how many such samples you provided in respect of the 1999 Tour de France?
- 4. Have you kept your copies of the doping control forms that you would have signed on the occasion of providing each urine sample during the 1999 Tour de France?
- 5. Would you agree that, even if you have not kept copies of such forms, one would have been signed by you on each occasion a sample was provided?
- 6. Are there any other doping control forms, such as Therapeutic Use Exemption forms, that might be relevant to this matter?
- 7. Can you confirm that during the summer of 2005, you authorized the UCI to disclose the doping control forms signed by you, in the possession of the UCI, to a reporter from L'Equipe?
- 8. To whom did you communicate such authorization?
- 9. Was such authorization in writing?
- 10. Were there any written or other limitations placed by you on the use of the doping control forms signed by you that were disclosed to the reporter from L'Equipe?
- 11. Were there any written or other instructions from you to the UCI requiring that the code number in respect of each doping control form be deleted or covered so that no link could ever be made with a particular sample?
- 12. Have you taken cognizance of the copies of the doping control forms purportedly signed by you that were published by L'Equipe on August 23, 2005?
- 13. Can you confirm whether the copies of such doping control forms that were published have or have not been altered? If they have been altered, please provide us with the details of any such alterations.
- 14. Has the UCI provided you with a copy of the laboratory analyses? If not, would you care to receive a copy?



- 15. Do you have any grounds for belief that there has been:
  - a. any failure at the laboratory in the chain of custody of the 1999 samples;
  - b. any technical shortcoming in the analysis of such samples;
  - c. any alteration of such samples; or
  - d. any manipulation of such samples?

If so, please provide us with details, to enable us to follow up on your concerns.

- 16. Have you contacted the laboratory to request any additional information or explanations regarding the analyses?
- 17. Have you requested any re-analysis of samples by the laboratory?
- 18. Would you be willing to provide a DNA sample for purposes of establishing that the samples apparently linked to the code numbers on the doping control forms are not your samples? [This is not a suggestion that you are in a position of having to prove anything, but simply a thought for you to consider as a means of putting an end, for once and for all, to any uncertainty.]
- 19. Are there any other facts in your possession that might be helpful in identifying all of the relevant facts relating to this matter?
- 20. Are there any questions that you believe it may be helpful for WADA to direct to other parties for purposes of identifying all of the relevant facts relating to this matter?

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#### Clarification About the EPO Detection Method

Following misleading information in the public domain concerning the detection method for EPO and recent cases, WADA wishes to clarify the following:

- 1. EPO is a performance-enhancing substance that is abused by some athletes to increase their oxygen-carrying capacity. EPO has been banned since the early 1990s. A detection method for EPO in urine was introduced in 2000.
- 2. The detection method for EPO is valid and reliable. It has undergone an extensive scientific validation process and has been used successfully for many years by many anti-doping laboratories around the world. It is a well-established procedure widely accepted by the scientific community, as demonstrated by publication in a number of international scientific journals. Further, in all its decisions relating to EPO, the Court of Arbitration for Sport (CAS) has supported the validity of the EPO detection method. At is meeting of September 26-27, 2005, the WADA Laboratory Committee reiterated its strong support to the method when properly applied.
- 3. The conservative approach used in the initial phase of implementation of the method has however allowed a large number of EPO abusers to escape detection. Consistent with the advancing science in anti-doping, work is done on an ongoing basis on all detection methods to refine the method and interpretation of results. In the case of this led, based on expert consensus, to the introduction by WADA of new interpretation criteria for a more discriminant reading of EPO results, in January 2005. At the same time, laboratories were advised to have their adverse EPO results confirmed by another laboratory with extensive experience of the method.

#### Why have recent cases questioned the validity of the EPO detection method?

A new phenomenon, currently under investigation, has been reported by a few anti-doping laboratories in some rare cases. In rare circumstances, it appears that normally endogenous EPO may shift into the recombinant EPO area. This phenomenon can be clearly identified by laboratories, and is distinguished from profiles revealing EPO due to doping (exogenous EPO). When such a profile is identified, it is not reported as an adverse result.

#### Is this phenomenon recent?

It was not an issue prior to the introduction of new interpretation criteria in January 2005 because the former interpretation criteria were not as discriminant and these profiles would never have been reported as adverse results. WADA was fully informed of this phenomenon by a few accredited laboratories in the spring of 2005.

#### What is WADA doing about it?

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 in their interpretation. Laboratories have also been advised that a second independent opinion is now mandatory before reporting any adverse result. Therefore, there is still no risk of false positives. All accredited laboratories are in a position to distinguish between this profile and exogenous EPO.

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 conclusion of the research project soon.

Could there have been false positives between January 2005 (when WADA introduced new interpretation criteria of EPO results) and July 2005 (when WADA contacted all accredited laboratories performing EPO analysis to inform them of the phenomenon)?

When WADA contacted the laboratories in July 2005, the Agency asked laboratory directors whether they had previously noticed similar profiles.

Several laboratories were aware of this phenomenon and had already incorporated it in their routine procedure for the reading of EPO results. Others undertook to review cases they may have had in the past six months. This therefore gives the Agency full confidence that there have been no sanctions of athletes due to such profile.

#### Is WADA going to change its interpretation criteria of EPO results?

Based on the ongoing research project on this phenomenon, the precautions that WADA has asked the accredited laboratories to take may be formalized in the document explaining the interpretation criteria of EPO results.