# Floyd Landis: *What's Fair is Clear*

- Tour de France 2006 Champion
- No basis for positive test claims


El Tour de Tucson 2006 Presentation



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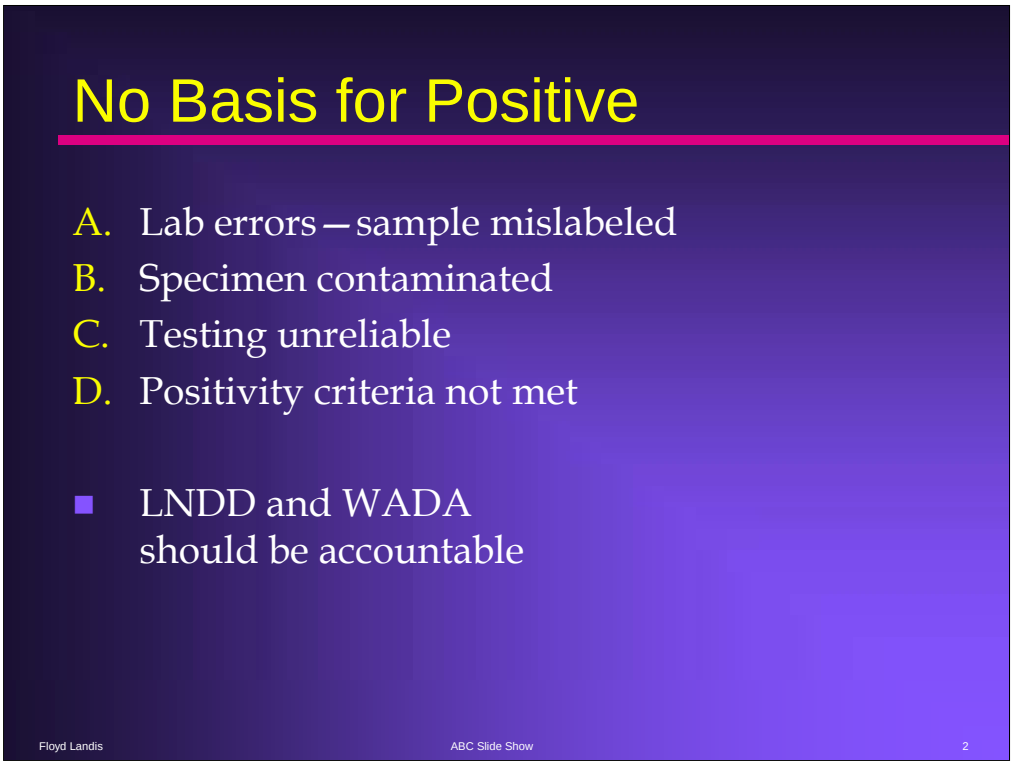
Baker has written about bicycling medicine for the lay public, International Olympic Committee, and medical community.

Arnie Baker

Digitally signed by Arnie Baker
DN: cn=Arnie Baker, c=US, email=arnie@arniebakercycling.com
Date: 2006.11.18 07:26:35 -08'00'




We have identified dozens of problems with Floyd Landis's allegedly positive doping test.

What we'll show here are some of the most important and easily understood basic problems.

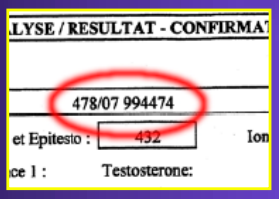
We *all* depend upon laboratories.

When medical or doping laboratories perform an analysis, they must be held to the highest standards. When the conclusion is high cholesterol, cancer, or doping… our health, our lives, may depend upon the correct diagnosis.

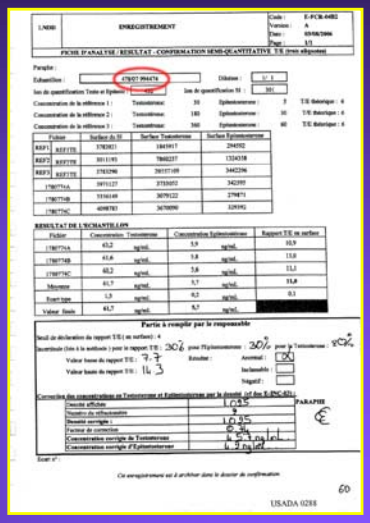
In this case, the lab (LNDD) and WADA have failed.

# Sample Not Proven to be Floyd's

- No way to clearly determine it's his
- T/E results page







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The lab made many errors in its analysis.

One of the easiest examples of lab error to see involves sample identification or labeling.

This is the page summarizing the testosterone and epitestosterone results from the A sample.

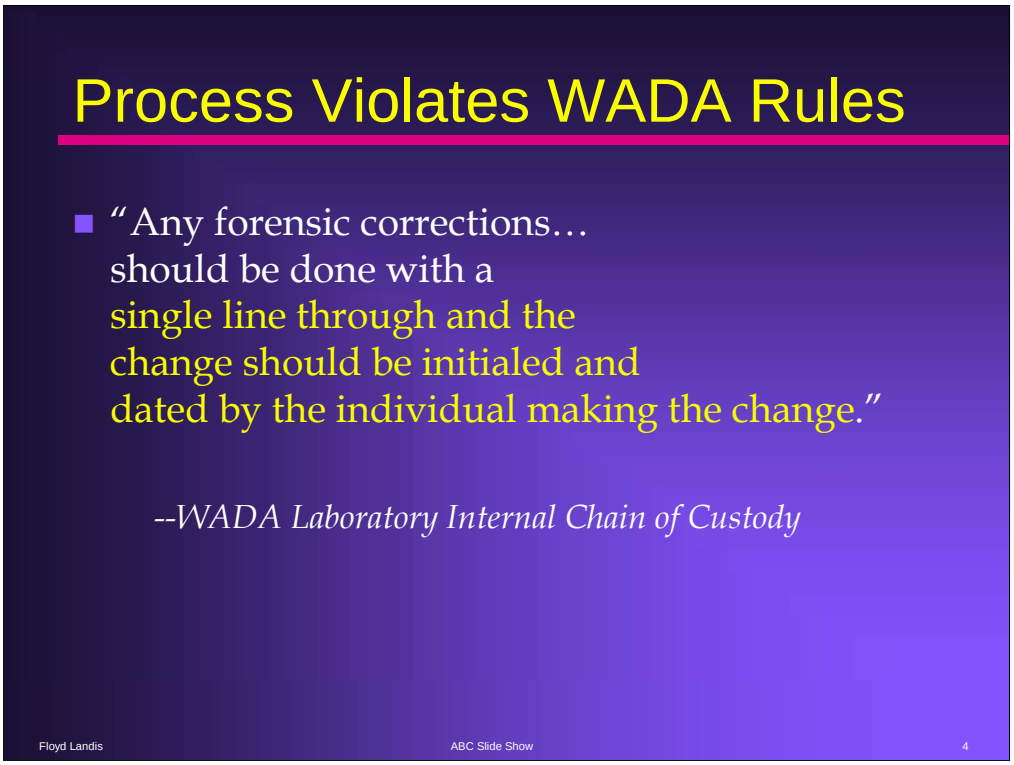
The sample number has two parts: The lab identification number and the athlete's identification number.

The lab identification number is wrong.

The lab identification number is 178/07—not 478/07.

The athlete's identification number, 994474, is not Floyd's number.

Floyd's number is the number in the barcode label taken from his attestation page. It is 995474.




World Anti-Doping Agency (WADA) Rules

"Any forensic corrections that need to be made to the comment should be done with a single line through and the change should be initialed and dated by the individual making the change. No white out or erasure that obliterates the original entry is acceptable." [1]

WADA labs are also governed by International Organization for Standardization Rules ISO 17025 [2]: "When mistakes occur in records, each mistake shall be crossed out, not erased, made illegible or deleted, and the correct value entered alongside. All such alterations to records shall be signed or initialed by the person making the correction. In the case of records stored electronically, equivalent measures shall be taken to avoid loss or change of original data."

Ignorance is not an excuse: "All personnel should have thorough knowledge of their responsibilities including the security of the Laboratory, confidentiality of results, Laboratory Internal Chain of Custody protocols, and the standard operating procedures for any method that they perform." [3]

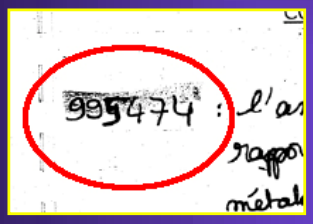
[1] WADA Laboratory Internal Chain of Custody. TD2003LCOC. (2003).

[2] International Organization for Standardization. 4.12.2.3. (2005).

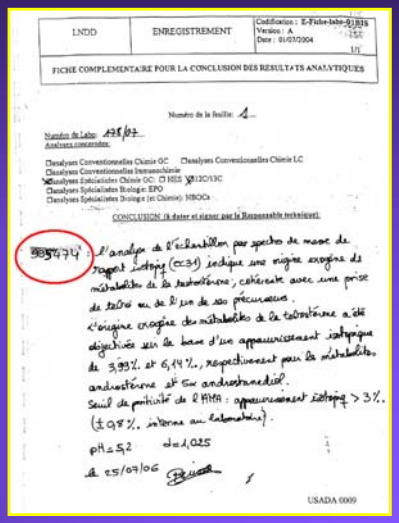
[3] WADA International Standard for Laboratories. 29, (2004),

# Clear WADA Rule Violation

- Sample number overwritten









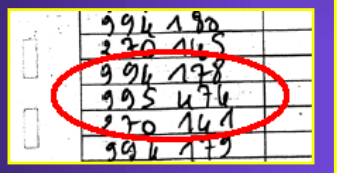

This page summarizes the results of the A sample.

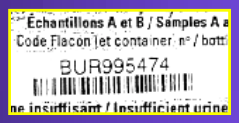
The sample identification number has been overwritten.

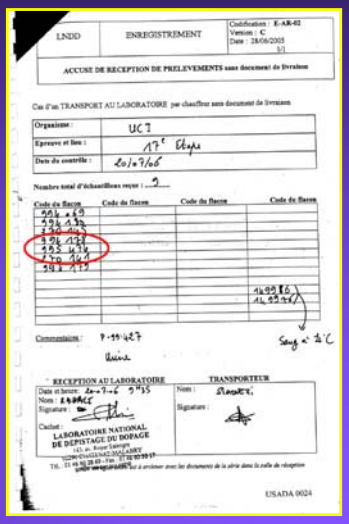
Again, Floyd's number is the number in the barcode label taken from his attestation page.

# Sample Number Questionable

- Specimen transport record
- Proves sample mismanaged
- Chain of custody issues





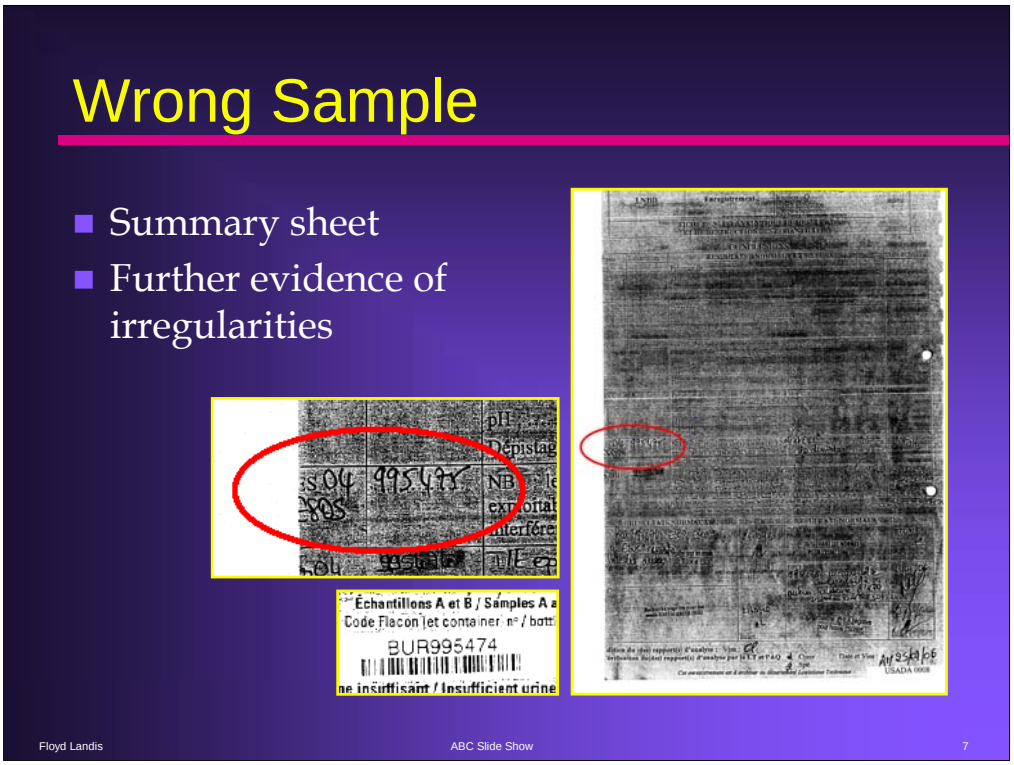



This is the chain-of-custody documentation of the transport of Floyd's sample from stage 17 to the laboratory.

Either (1) there is a number similar to Floyd's recording as having been transported, but not Floyd's, or (2) the handwriting is ambiguous.

The vast majority of people I have surveyed read the number as 995476.

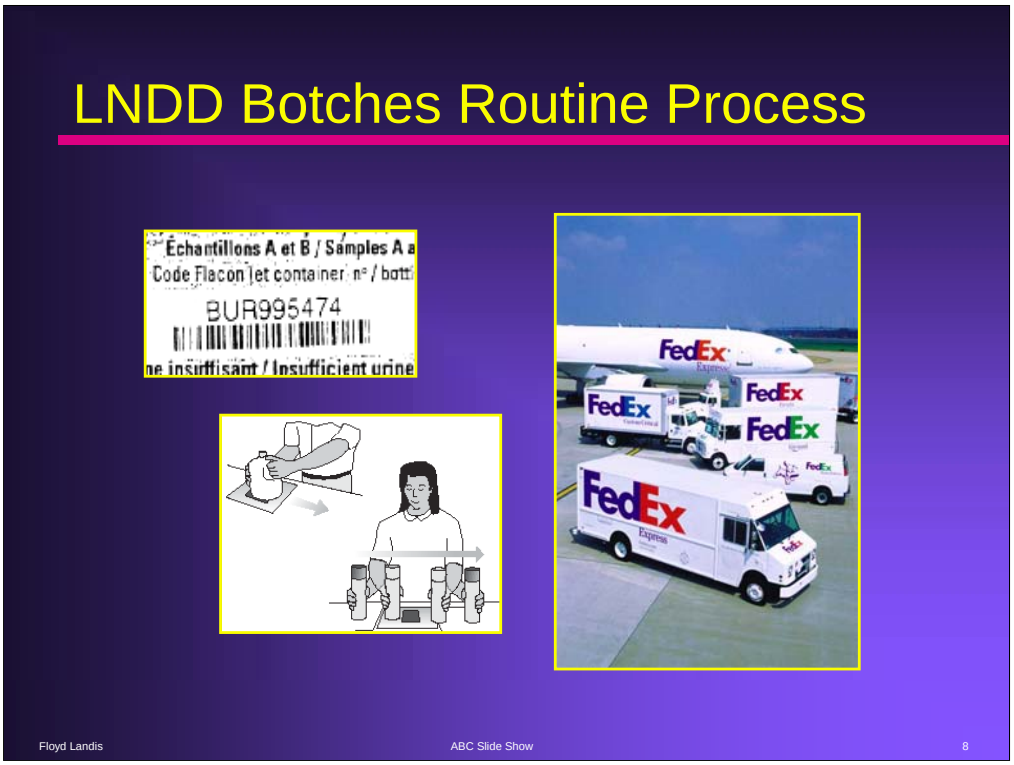
Again, Floyd's number is the number in the barcode label taken from his attestation page. It is 995474.




This is a summary page of the lab's record of the abnormalities of the three samples (three different riders tested) from stage 17.

The poor quality of the pages is how we received the document.

Again, Floyd's sample number isn't present: The handwritten number is 995475.




It's *not* complicated. One *can* keep track.

UPS. FedEx scan.

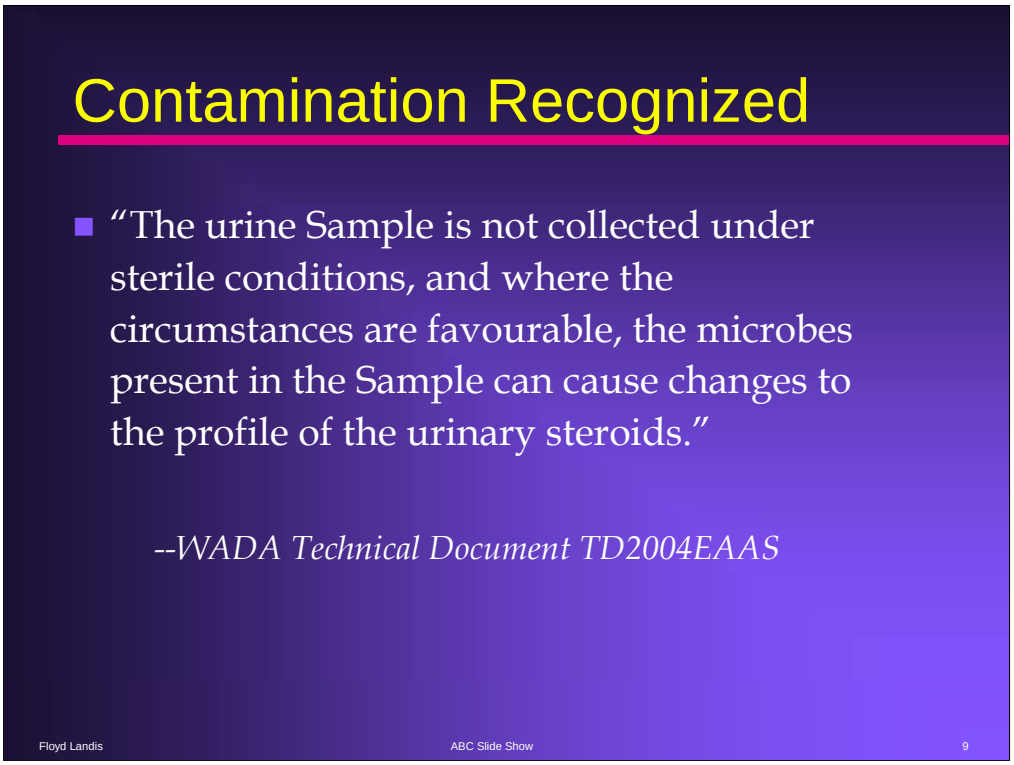
The cashier scans at store checkout.

And we're talking letters, cardboard, and groceries.

Not peoples lives.

These types of mistakes can easily be reduced.

If a lab is so obviously sloppy with keeping track of the sample and/or its number, how can we have confidence that the lab can keep track of the many analytic steps required to accurately conduct a doping test?




WADA recognizes that contaminated or degraded specimens cannot be fairly examined, and should be discarded.

Degradation can result from many factors—including bacterial contamination, improper storage, biological or other chemical contaminants (such as blood), and adulteration.

## WADA Contamination Rule Clear

- "The concentration of free testosterone and/or epitestosterone in the specimen is not to exceed 5% of the respective glucuroconjugates."

*--WADA Technical Document TD2004EAAS*



WADA rules are that if contamination or degradation levels of free testosterone or epitestosterone exceed 5%, the sample should not be analyzed.

## Specimen Clearly Contaminated

| | Epitestosterone | Reference |
|---|---|---|
| Free | 0.44 | USADA0283 |
| Conjugates | 5.7 | USADA0288 |
| Ratio | 7.7% | (> 5%) |

- No basis to proceed according to WADA rules

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Remember: More than 5% means the specimen is contaminated or degraded and should not be used.

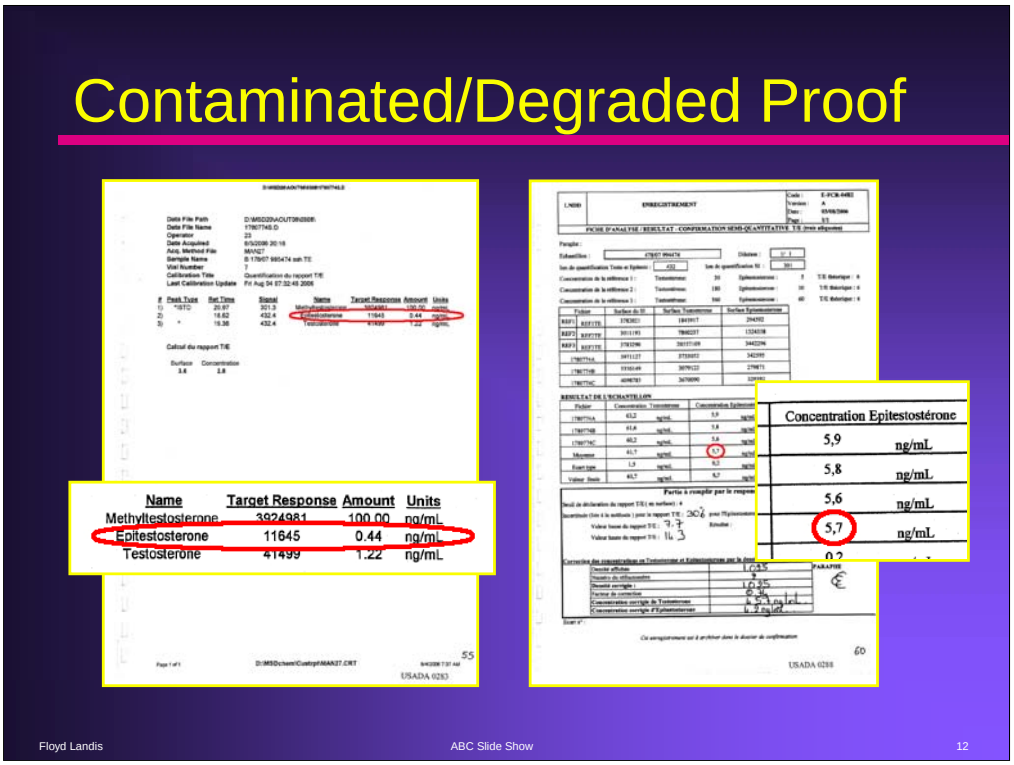
Just like food with mold or maggots, such a sample should not be used.

The table shows the math: 7.7% degraded epitestosterone.

According to WADA protocol, since the degraded epitestosterone level exceeds 5% (it is 7.7%) the specimen should not have been evaluated for an adverse analytic finding.

It should have stopped here.

The relevant screenshots are on the next page.

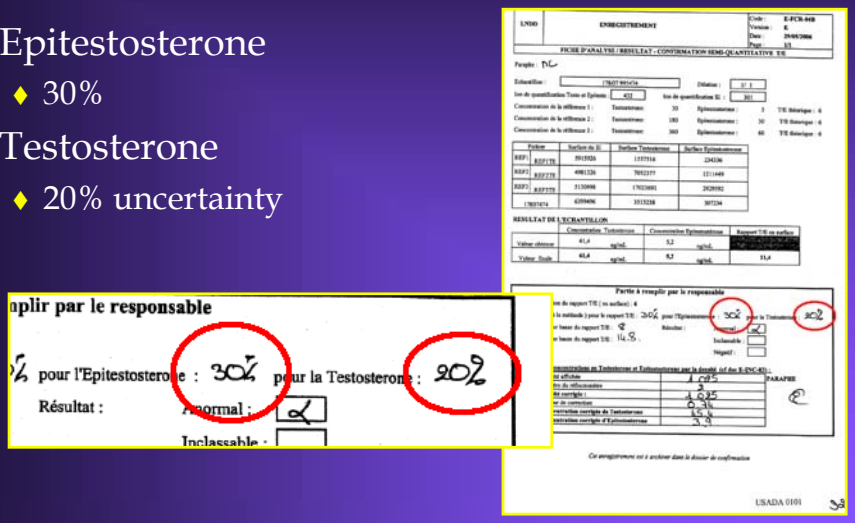



Here are the relevant screenshots used to calculate degradation from Floyd's B sample.

Again, the specimen was clearly contaminated. There was no basis to proceed, according to WADA rules.

# Violates T/E Uncertainty Standards

- Epitestosterone
  - 30%
- Testosterone
  - 20% uncertainty






By the lab's own standards, repeated sampling of testosterone levels should be within 20%, and repeated sampling of epitestosterone levels should be within 30%.

# Results Radically Inconsistent

- Same sample—radically different results!

| Testosterone | Epitestosterone | Reference |
|---|---|---|
| 61.37* | 5.2* | USADA0092 |
| 172.23 | 17.59 | USADA0212 |
| 181% error | 238% error | |

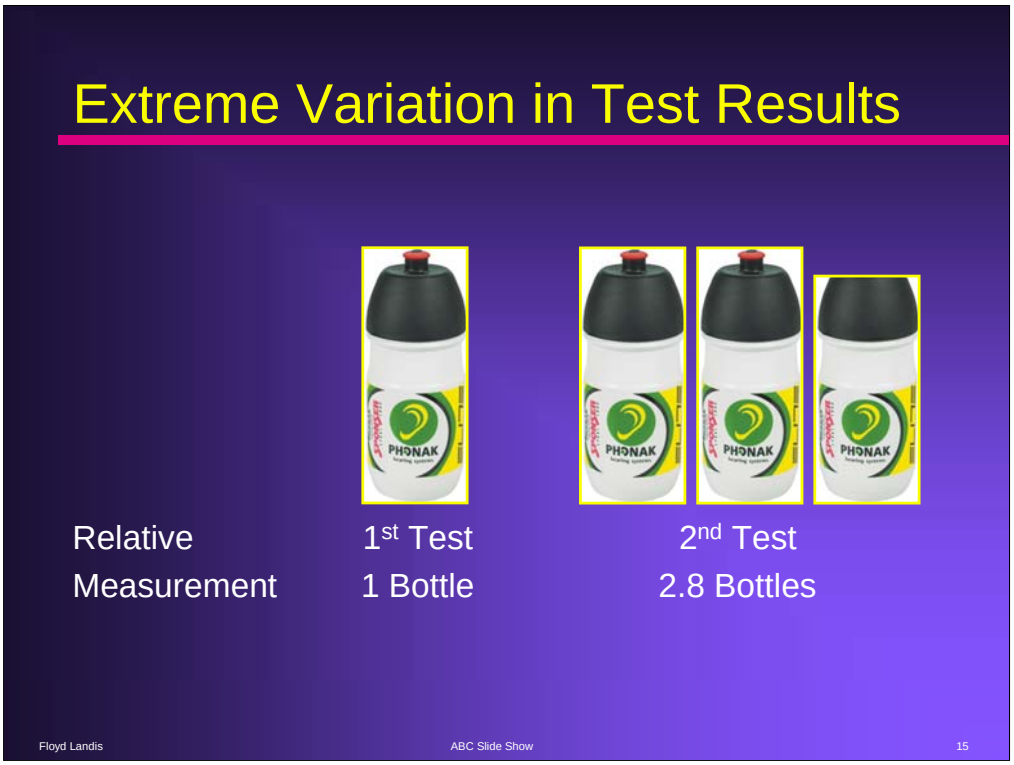


Here are two confirmation examinations of testosterone and epitestosterone, by the same method, from the A sample.

These variations cast doubt on the lab's ability to repeatably and accurately test a sample for these substances.

* Reference result. Percent error is a math term: The difference between a value and a reference value, divided by the reference value.

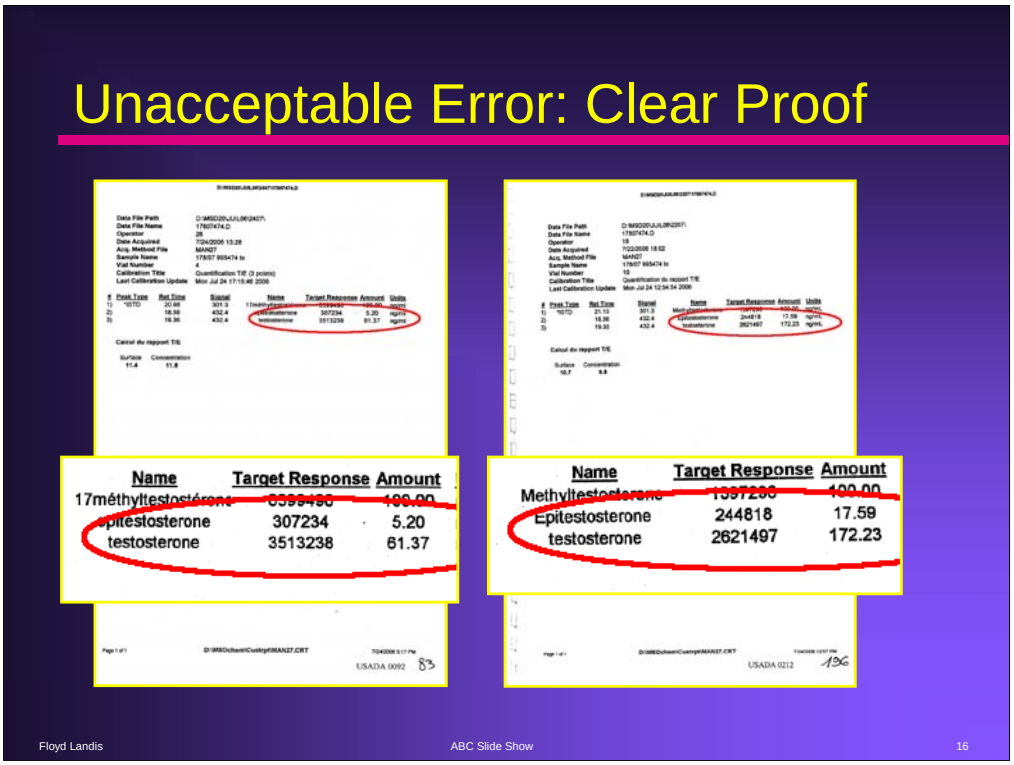
Another way to look at it: The values in the second row of numbers are about 300% greater than the numbers in the first row of numbers.




Here is another way to look at the two confirmation examinations of testosterone from the A sample.

If the amount in the first test is represented by 1 waterbottle, the amount in the second test is represented by 2.8 waterbottles.

Again, these variations cast doubt on the lab's ability to repeatably and accurately test a sample for these substances.




Here are the relevant screen shots.

By the laboratory's own standards, its testing was unacceptable.

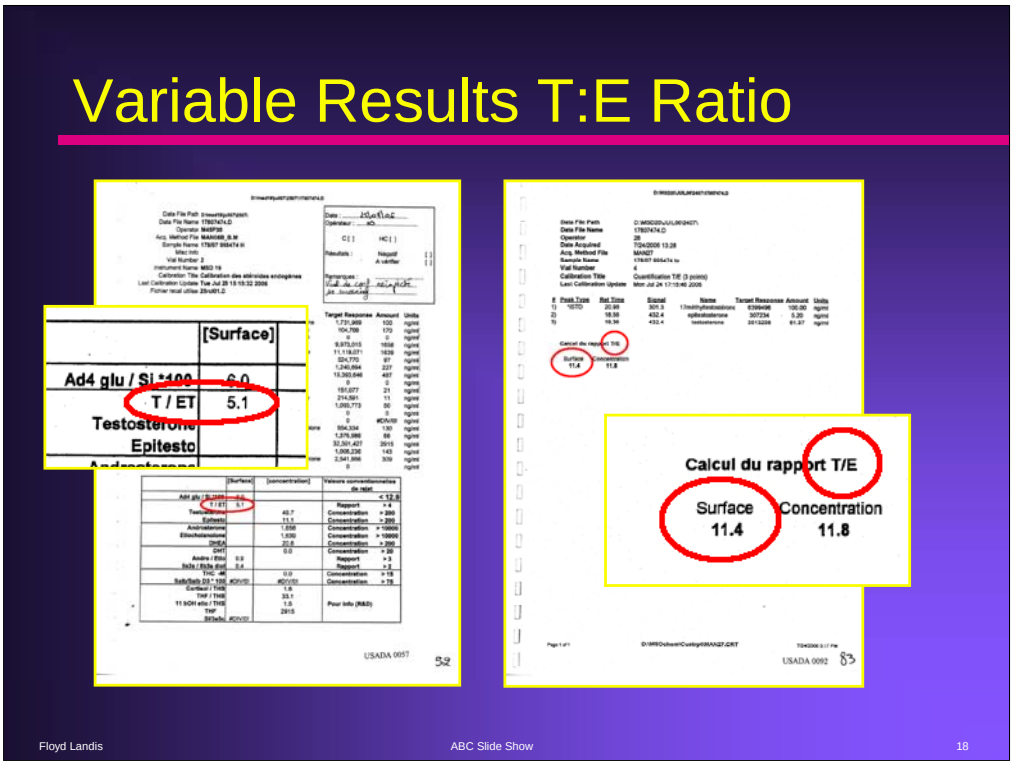
# Extreme Variation in T:E Results

- Radically inconsistent, same sample!

| T:E Ratio | Reference |
|---|---|
| 5.1 | USADA0057 |
| 11.4 | USADA0092 |



When the sample was screened for T:E ratio, the (surface) ratio was 5.1. When the sample was tested to confirm the ratio, it was 11.4.




Here are the relevant screen shots.

## Flawed T/E Screening Process

- Screening test for testosterone doping
- Since 2005, ratio > 4:1
- Floyd: 4.9

| WADA Tests 2005 | Total Tests | Not Confirmed | Confirmed |
|---|---|---|---|
| 4> T/E >6 | 955 | 952 | 3 |

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A T/E screening ratio over 4 should not create the presumption of doping.

For most results, it's just the opposite of what is the popular impression.

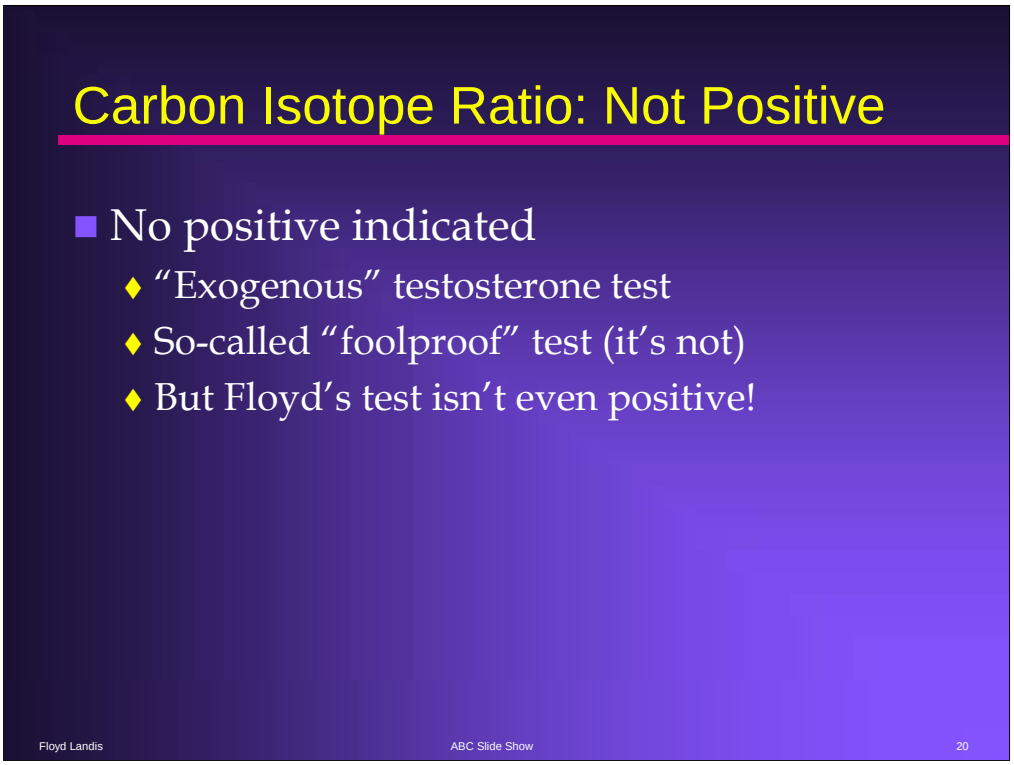
In 2005, 25 out of 33 WADA-accredited labs reported their T/E ratio test results.

A total of 955 T/E ratio tests results were between 4 and 6.

Of those, just three tests were confirmed as doping positives.

A T/E screening value between 4 and 6 could be interpreted as a 99.5+% proof of innocence.

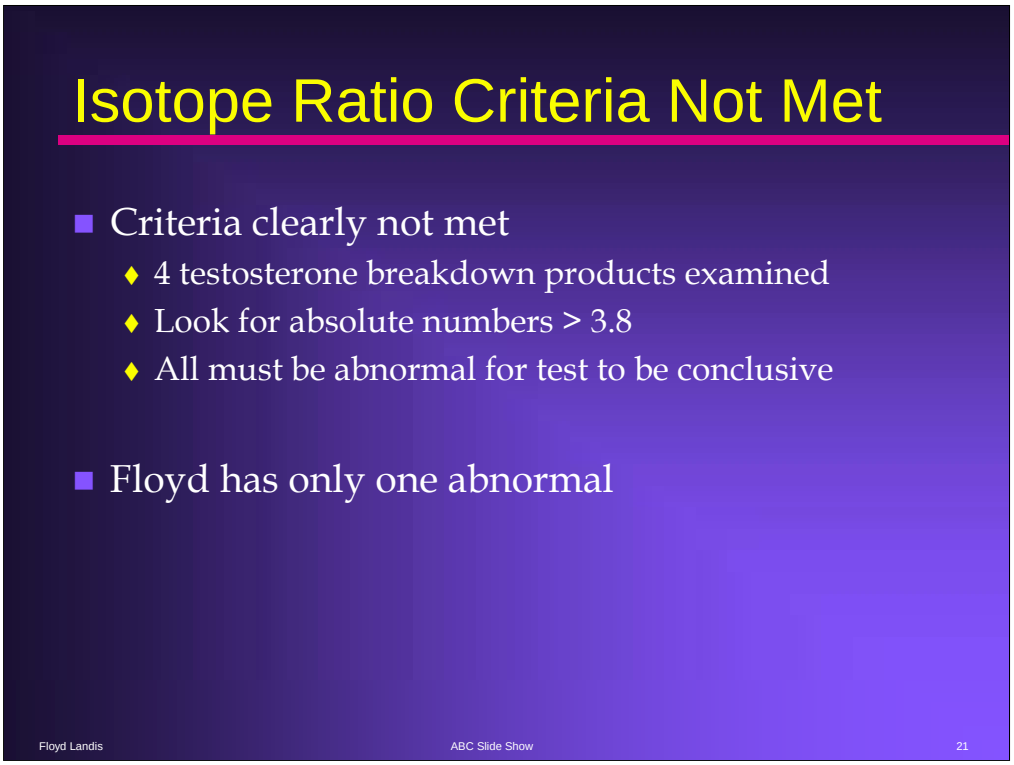
It is only when T/E ratios are above 15 that more tests than not are confirmed positive.




This is the test that has been played up in the press as the gold standard, the test that cannot be challenged: The exogenous test, or proof of synthetic testosterone.

No test is infallible, and the CIR test does have problems.

However, the test wasn't even positive, as we'll show in the next slides.




According to published studies and WADA's own protocols, the metabolites or break-down products should be abnormal.

For more details and discussion about the criteria for a positive test, see lawyer Howard Jacob's dismissal motion to the Anti-Doping Review Board.

## "All Positive" Rules Are Clear

- "Where an anabolic androgenic steroid is capable of being produced endogenously, a Sample will be deemed to contain such Prohibited Substance where the concentration of such Prohibited Substance or its ***metabolites*** or markers… in the Athlete's Sample so deviates from the range of values normally found in humans that it is unlikely to be consistent with normal endogenous production."

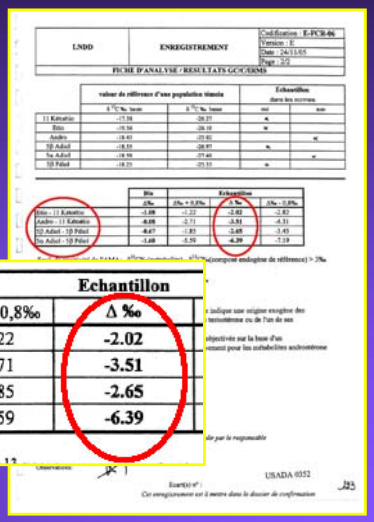
*--The 2006 World-Anti Doping Code*



The current-year rule is clear.

# Test Criteria Not Met

- Not positive



| | Blu | Echantillon | |
|---|---|---|---|
| | Δ‰ | Δ‰ + 0,8‰ | Δ ‰ |
| Etio - 11 Kétoétio | -1.08 | -1.22 | -2.02 |
| Andro - 11 Kétoétio | -0.08 | -2.71 | -3.51 |
| 5β Adiol - 5β Pdiol | -0.67 | -1.85 | -2.65 |
| 5α Adiol - 5β Pdiol | -1.60 | -5.59 | -6.39 |



Considering the criteria for positive (3.0) and stated accuracy of the lab (±0.8) isotope absolute values must be higher than 3.8. [1]

Only one of Floyd's four breakdown products examined even arguably met the criteria to determine a positive result.

Arguably—because there are many contested technical issues with the accuracy of the test, issues not discussed here.

[1] The rules for determining a positive test based on cutoffs and lab accuracy are reviewed in: Spirito, E, et al. The role of measurement uncertainty in doping analysis. Int. J Risk Assessment and Management. 5 (2/3/4), 374-386. (2005).

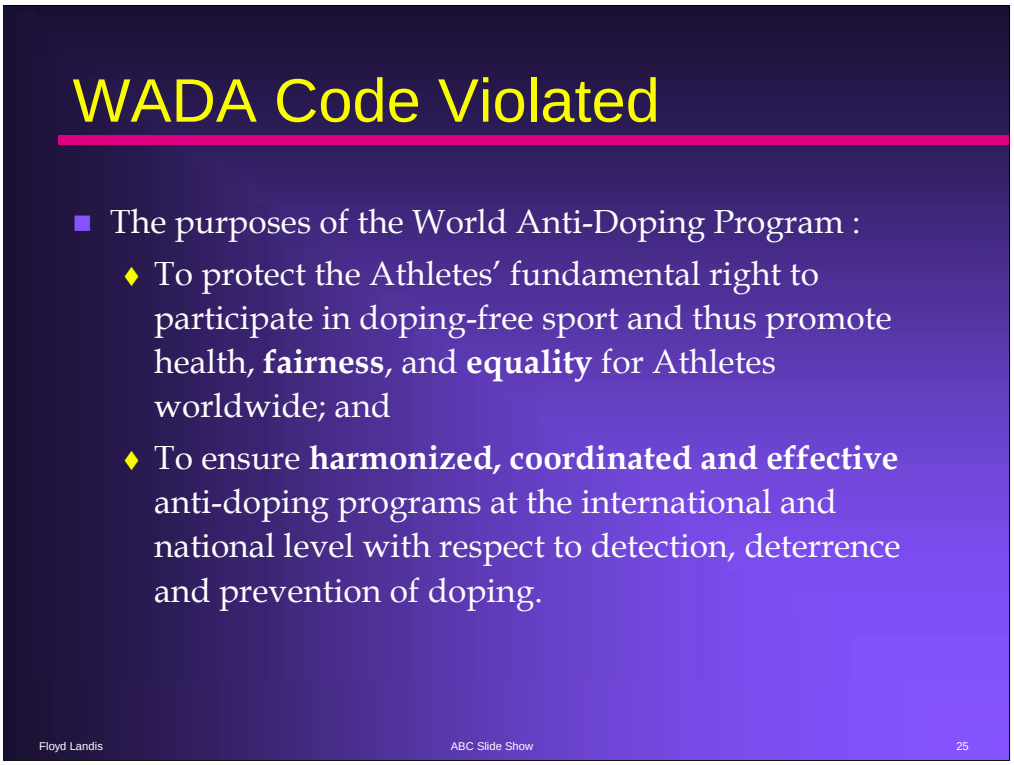
# Science Clear: *All* Metabolites

| Reference | Subjects | Metabolite 1 | Metabolite 2 | Comments | Positivity |
|---|---|---|---|---|---|
| Floyd | | Positive –(6.39) | **Negative** (-2.65) | | **One** |
| Aguilera 1996 | 8 | Positive | Positive | WADA. 5αA + 5βA | Both |
| Aguilera 1999 | 10 | Positive (-4.6) | Positive (-4.7) | WADA. 5αA + 5βA | Both |
| Aguilera 2000 | 1 | Positive | Positive | WADA. Andro + etio | Both |
| Aguilera 2001 | 2 | Positive (-7.5) | Positive (-5.4) | WADA. 5αA + 5βA | Both |
| Baume 2006 | 7 | Positive | Positive | WADA. Andro + etio | Both |
| Maitre 2004 | 1 | Positive | Positive | WADA. 5αA + 5βA | Both |
| Shackleton 1997 | 5 | Positive | Positive | 5αA + 5βA | Both |
| Shackleton 1997 | 1 | Positive | Positive | 5αA + 5βA | Both |



Why must all metabolites, rather than just one be positive?

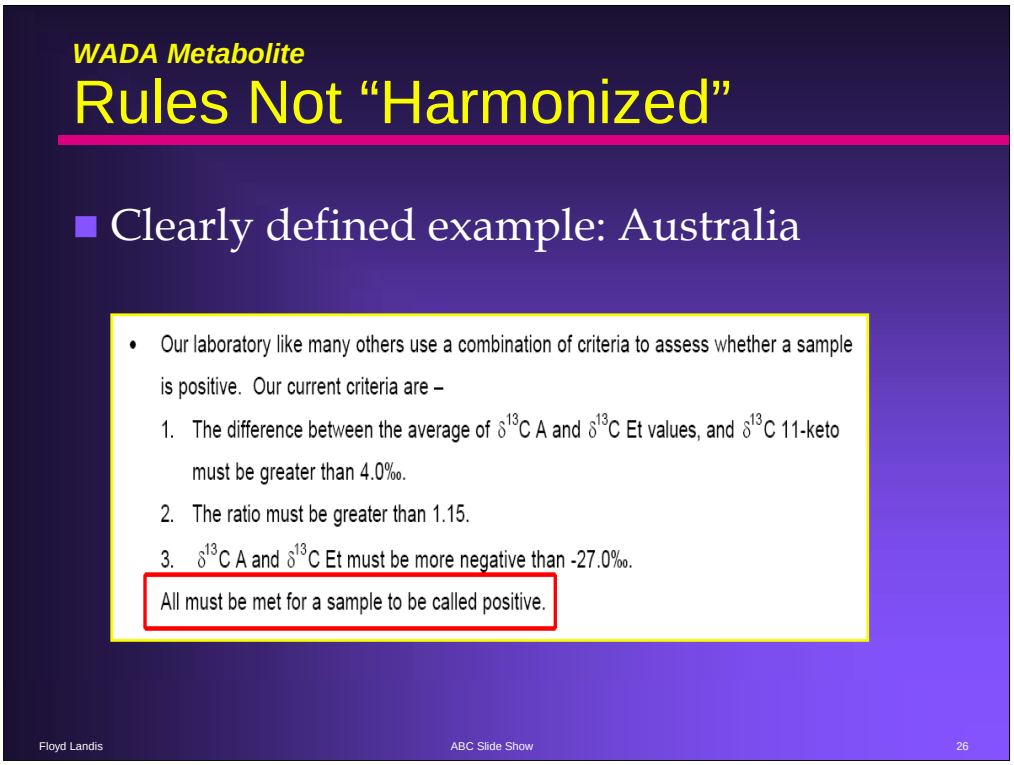
Among other reasons, because the underlying scientific studies published in the literature support that criteria.




These are the primary purposes of the World Anti-doping Program as set forth in the World Anti-Doping Code (Code). [1]

The Code is the core document that provides the framework for anti-doping policies, rules, and regulations within sport organizations and among public authorities.

[1] http://www.wada-ama.org/en/dynamic.ch2?pageCategory.id=365




Australian WADA-accredited Lab Criteria 2004. [1]

Notice that the Australian lab reduces the likelihood of a false positive result by setting their positivity criteria beyond 4.0.

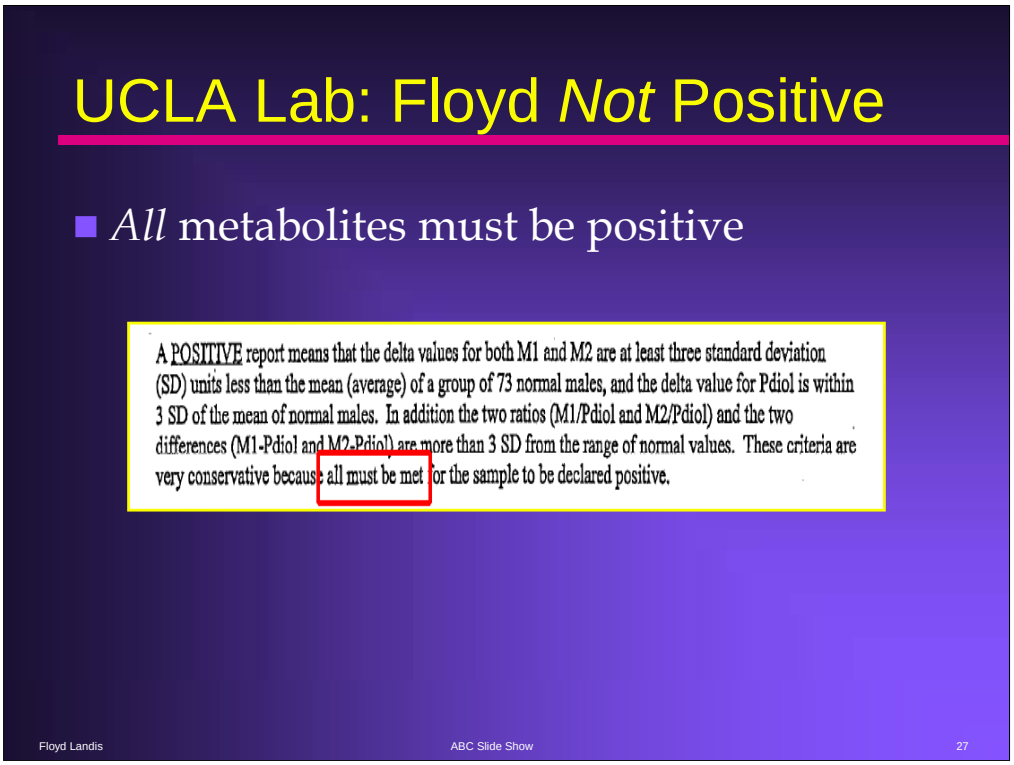
Although WADA is charged with unifying labs, examined metabolites and positivity criteria differ from lab to lab.

I view this as a failure of WADA to (1) provide fairness and equality and (2) ensure a harmonized (standardized/uniform) program.

Few labs publish their positivity criteria.

By Australia lab criteria, Floyd's test is negative.

[1] Australian rules downloaded from: http://www.aph.gov.au/SEnate/committee/economics_ctte/estimates/bud_0405/industry/addinfo/statistical_population_studies_mar04.pdf#search=%22Kazlauskas%20%22anti-doping%20research%20program%22%22.




USA WADA-accredited Lab (UCLA) Criteria 2004. [1]

We know UCLA uses these criteria because Travis Tygart, USADA's lawyer, recently quoted these criteria in an attorney letter.

Notice that US metabolite positivity values are set at 3 standard deviations, which works out to a value of 3.99 for 5-alpha-androstanediol and a value of 3.47 for 5-beta-androstanediol—whereas Australian positivity values are set at 4.00 for two different metabolites—androsterone and etiocholanone.

By both UCLA and Australia lab criteria, Floyd's test is negative.

Some WADA labs may use a 3.00 threshold, a value more likely to result in false positives. Even with a lower threshold, according to WADA's published guidelines, Floyd's test is negative because not all of his metabolites are beyond the 3.00 threshold.

Again, although WADA is charged with unifying labs, examined metabolites and positivity criteria differ from lab to lab. That the same results would be called a positive in one lab and negative in another is disquieting and a failure of WADA to achieve this purpose.

Again, I view this as a failure of WADA to (1) provide fairness and equality and (2) ensure a harmonized (standardized/uniform) program.

[1] UCLA Olympic Laboratory. Client CIR Notice. June 22, 2001.

# LNDD "Science" Clearly Absurd

- Controls would be positive in LNDD system!

| | $\delta^{13}C$, ‰ | | | Difference, ‰ | |
|---|---|---|---|---|---|
| | 5βA | 5αA[a] | 5βP[b] | 5βP − 5βA | 5βP − 5αA |
| Mean | −25.69 | −26.35 | −24.26 | 1.43 | 2.09 |
| SD | 0.92 | 0.68 | 0.70 | 0.68 | 0.63 |
| CV, % | 3.6 | 2.6 | 2.9 | | |
| Mean + 3 SD | −22.92 | −24.31 | −22.15 | 3.47 | 3.99 |
| Mean − 3 SD | −28.46 | −28.39 | −26.37 | −0.62 | 0.18 |
| Maximum | −23.90 | −24.55 | −22.92 | 3.17 | 3.72 |
| Minimum | −27.82 | −27.89 | −25.49 | −0.08 | 0.16 |
| Max − Min | 3.9 | 3.3 | 2.6 | | |

[a] Mean significantly different from 5βA.
[b] Mean significantly different from 5βA and 5αA.

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This is the seminal carbon isotope study from UCLA, by far the largest drug-testing lab in the world. [1] In this study UCLA established their positivity criteria based on 73 control ("normal") subjects. Red circles show delta maximum delta values over 3.00 for two metabolites, 5 beta androstanediol and 5 alpha androstanediol. .

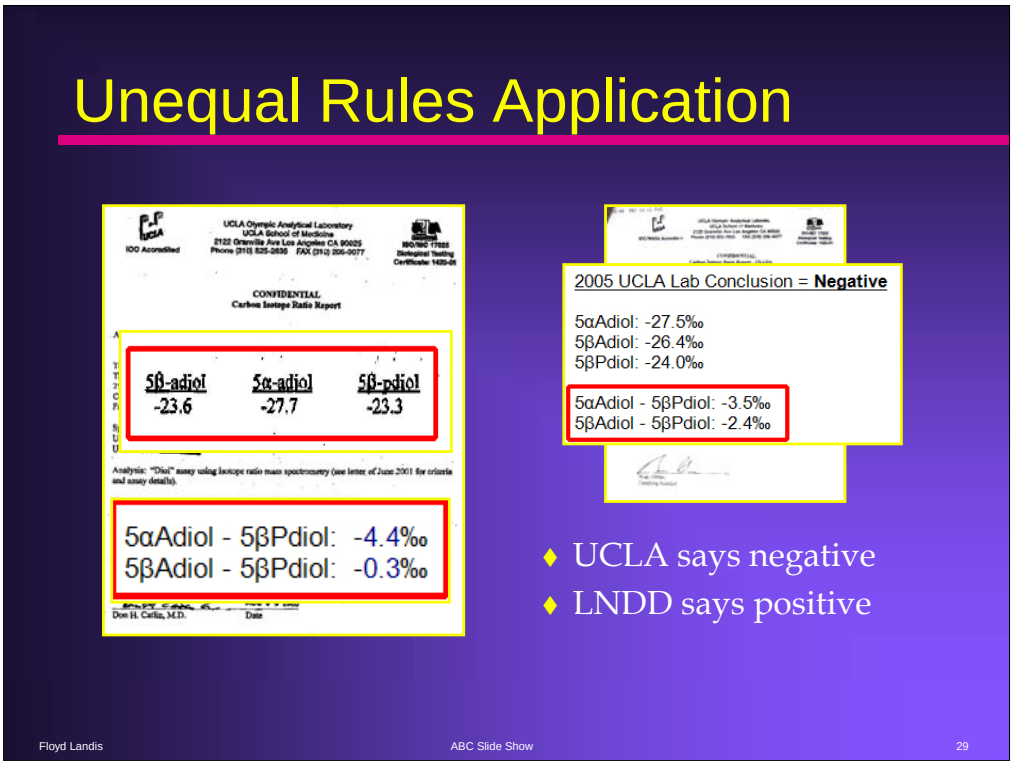
We don't know the LNDD criteria—because they haven't supplied us with their standard operating procedures. We have asked USADA to provide this information. They have refused.

Some have said that a few labs use an *any* metabolite criterion. If the LNDD standard is 3.00 for *any* metabolite, at least some of the UCLA controls would be positive.

*That is absurd*. It makes no sense for control ("negative/normal") subjects to have positive drug test results.

Again, I view this as a failure of WADA to (1) provide fairness and equality and (2) ensure a harmonized (standardized/uniform) program.

[1] Table 3 from: Aguilera, R et al. Performance Characteristics of a Carbon Isotope Ration Method for Detecting Doping with Testosterone Based on Urine Diols: Controls and Athletes with Elevated Testosterone/ Epitestosterone Ratios. Clinical Chemistry 47 (2) 292-300. (2001).




Here are two sets of data from samples analyzed at the WADA-accredited UCLA lab.

Neither data set was reported as a positive drug test.

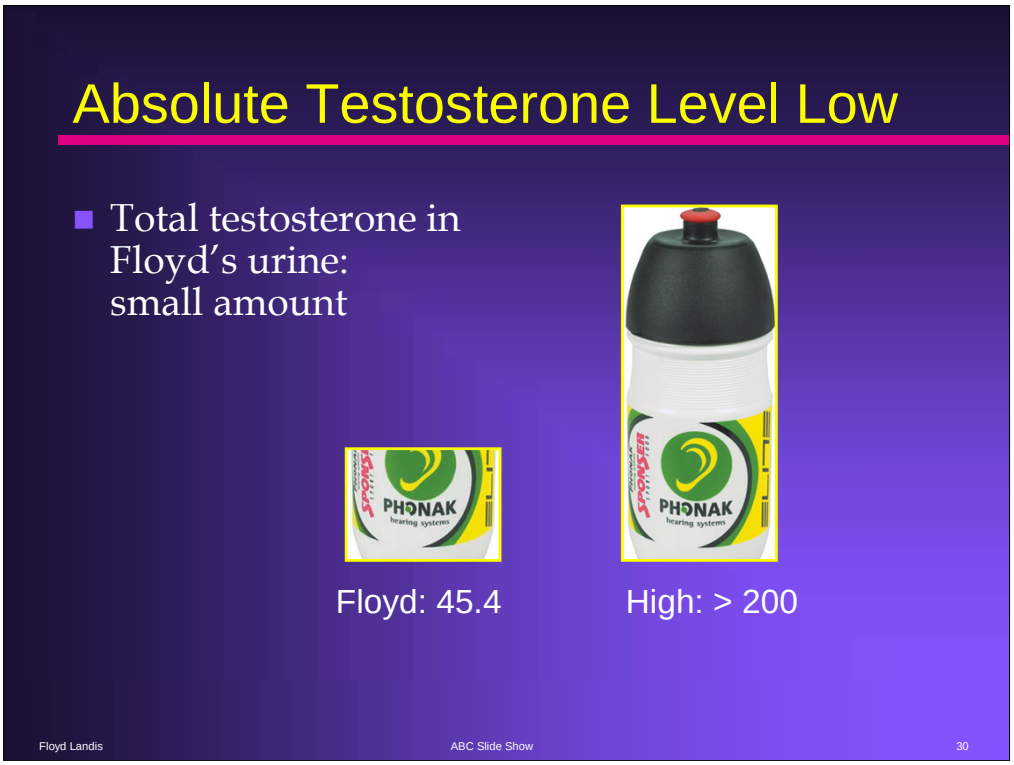
The sample reported on the left results in a 5αAdiol absolute difference of 4.4. The 5βAdiol difference is 0.3. With the *any* criteria, LNDD would call the sample positive. UCLA did not.

On the right, the 5αAdiol absolute difference of 3.5 would apparently be sufficient to call the sample positive by LNDD.

This incongruity is illogical and inequitable.

It is possible that, due to International WADA obligations, USADA is in the position of being obliged to disingenuously prosecute the different, misguided, or flawed positivity criteria of a foreign lab on an American athlete—even though if interpreted at the WADA-accredited UCLA lab the results would not be positive.

Again, I view this as a failure of WADA to (1) provide fairness and equality and (2) ensure a harmonized (standardized/uniform) program.

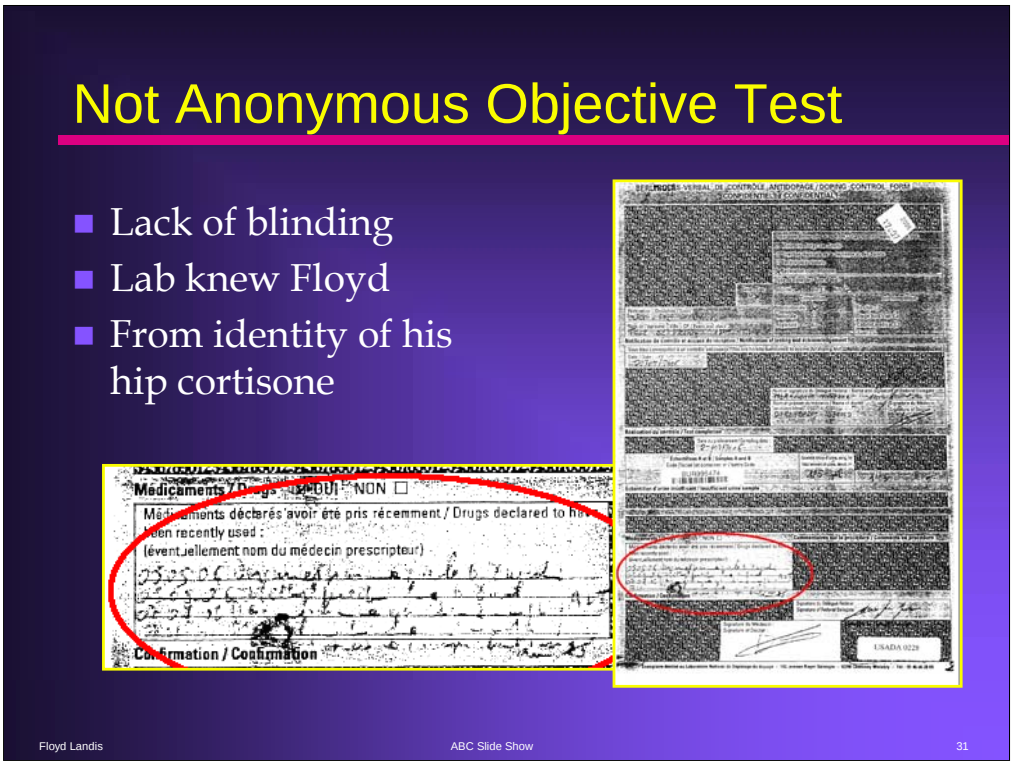



There are some other points to take into consideration:

The total amount of testosterone in Floyd's urine was calculated as 45.4 nanograms per milliliter. This is well below the value of 200 that is considered high by WADA criteria.

If a high amount is 1 waterbottle, Floyd's amount is represented by a less than ¼ of a waterbottle (23%).

In other words, there was not much testosterone in Floyd's urine.

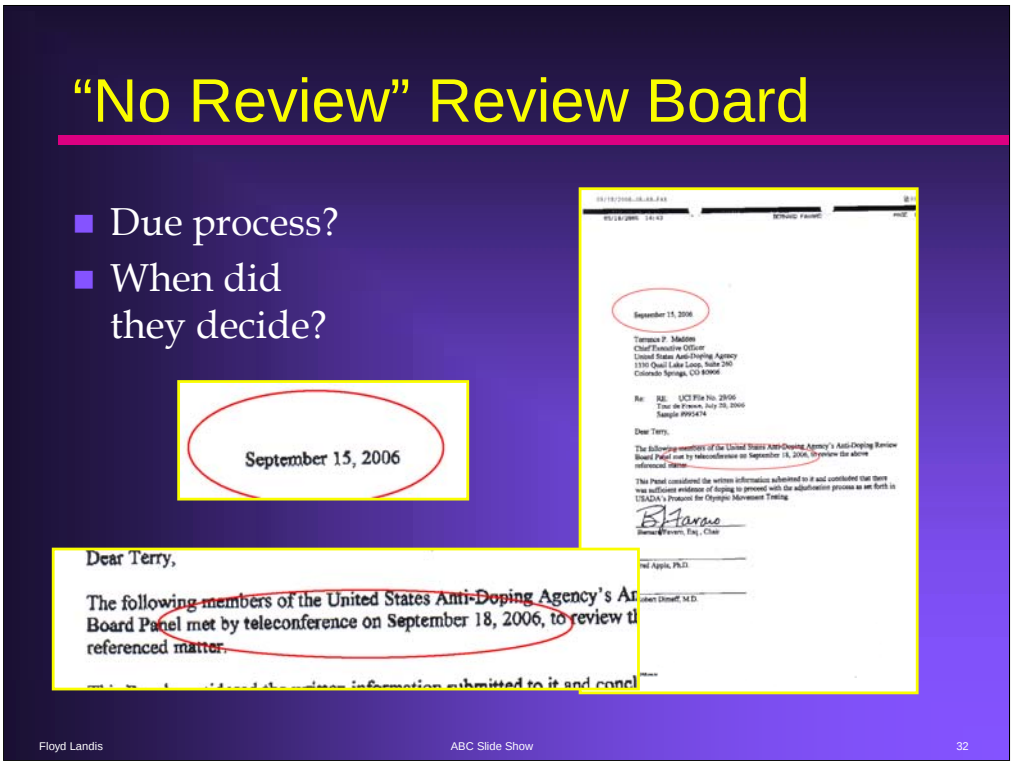



Subject identification to the lab in any study is a problem. Laboratories are supposed to conduct tests without the knowledge of whose sample they are testing.

I am not arguing that the lab was biased—I don't know that.

However, since Floyd was known to have a therapeutic use exemption for the steroids used to treat his dead hip, and since this information was not redacted from his doping control form, sample identification was a relatively simple matter.

This part of the testing process should be improved to help the credibility of the process for all.




Something about the process.

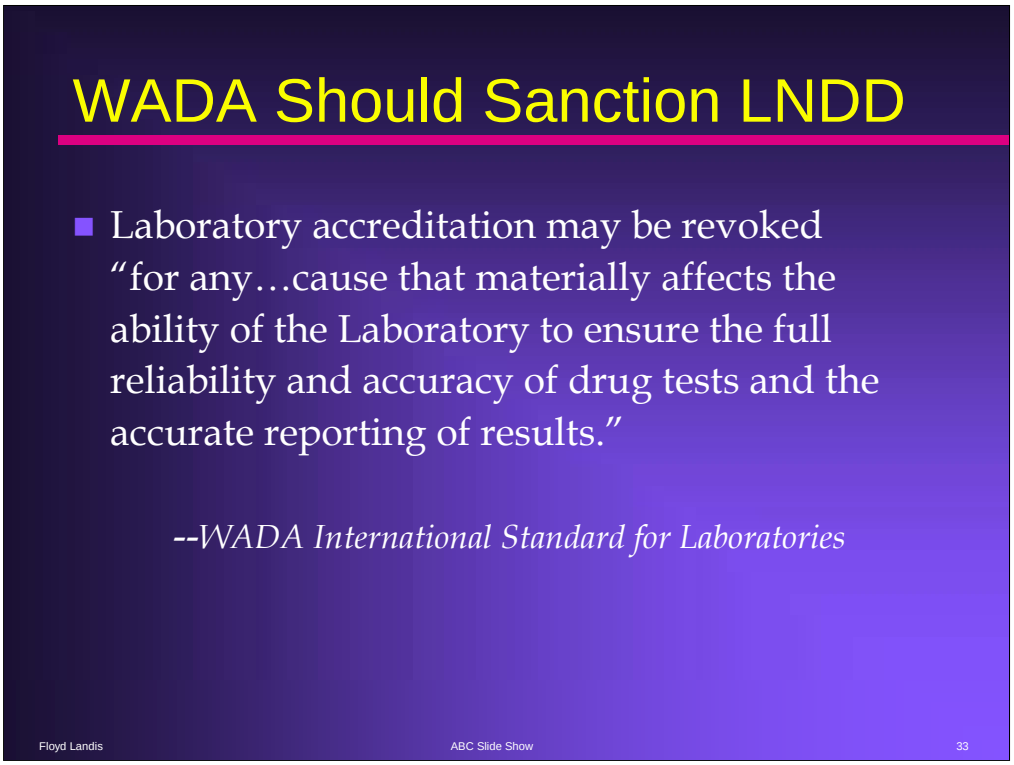
Floyd didn't accurately provide an explanation for his allegedly positive test initially—because he had not received the documentation package; he didn't know what the problems were.

After an initial two-week review of the document package, his lawyer Howard Jacobs submitted a dismissal request to the Anti-Doping Review Panel. This request was denied. The denial letter is dated three days before the meeting took place.

Typographical error? Perhaps—at least that is what USADA now claims.

Of course, any agency, board, or lab can make errors. USADA did. The French lab did.

What we have shown in the previous slides is that the whole process has been full of errors.




WADA's own rules specify that laboratories must be accountable and held to standards. [1]

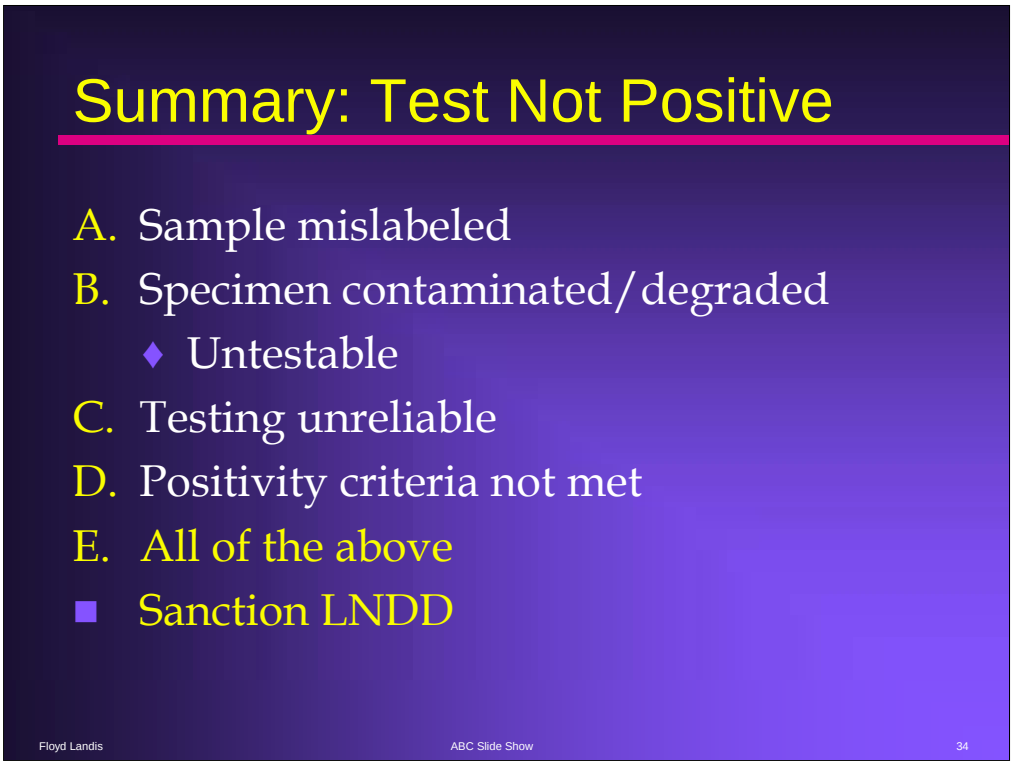
Failure to maintain reliability and accuracy of tests and the reporting of results is grounds for revocation of WADA accreditation.

Referring specifically to proficiency testing [2]:

**"No false positive drug identification is acceptable for any drug**…"

[1] International Standard for Laboratories. v4. August 2004. Section 6.4.8.3.

[2] ISL. Section 4.3.1



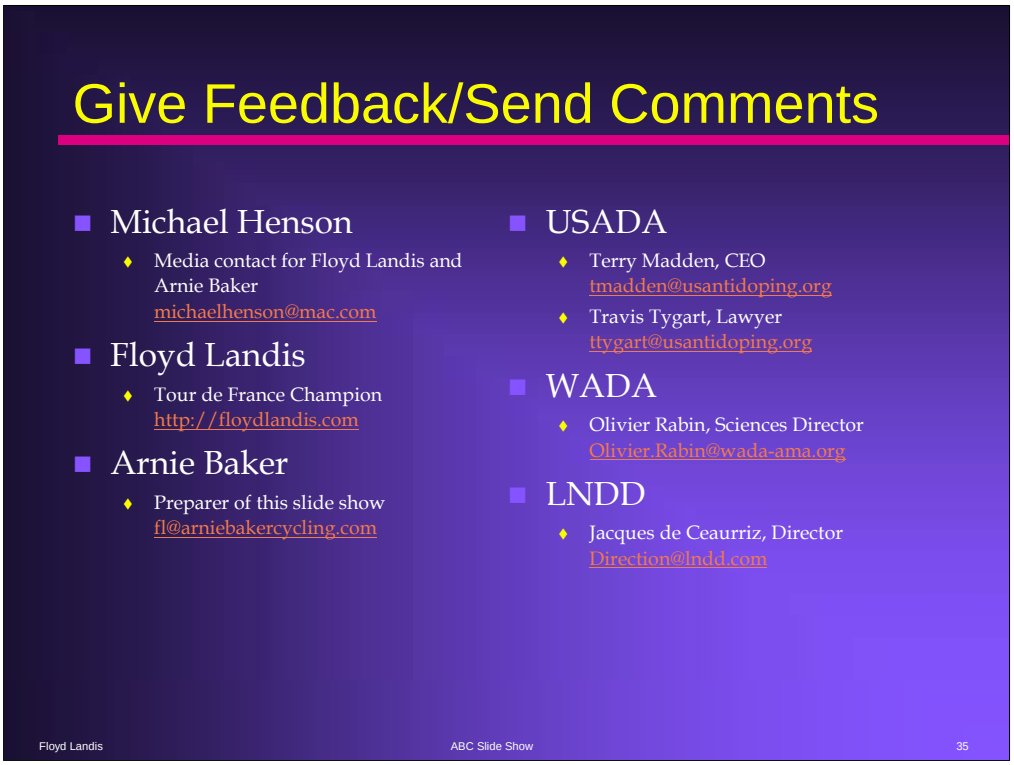

**Summary**

There are many problems and errors in the USADA documentation package.

The French lab (LNDD) has failed.

WADA has failed both of its primary purposes: (1) fairness and equality, and (2) ensuring a harmonized, coordinated, and effective anti-doping program.

Floyd Landis's doping test is *not* positive.




In this slide you'll find contact information for both parties in this dispute.

USADA: United State Anti-Doping Association
WADA: World Anti-Doping Association

Again, Floyd's drug test is negative.

By WADA's rules, the French lab (LNDD) should be sanctioned, not Floyd.

WADA has failed both of its primary purposes.

# Floyd Landis: *What's Fair is Clear*

- Tour de France 2006 Champion
- No basis for positive test claims


El Tour de Tucson 2006 Presentation

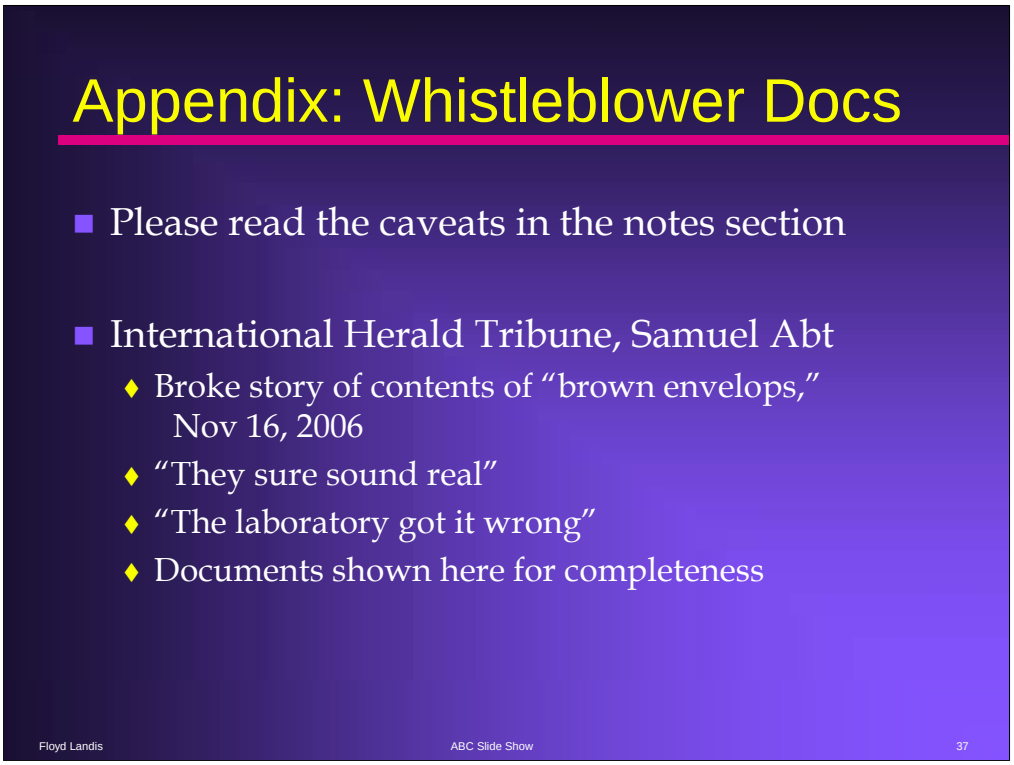


Prepared by Arnie Baker, MD.

Baker is a retired San Diego physician.

While in active medical practice, Baker had over a decade experience in medical peer review and quality assurance.

Baker has written about bicycling medicine for the lay public, International Olympic Committee, and medical community.




LNDD has a long history of problems. For an independent account of the lab's failures, see the Vrijman report. [1]

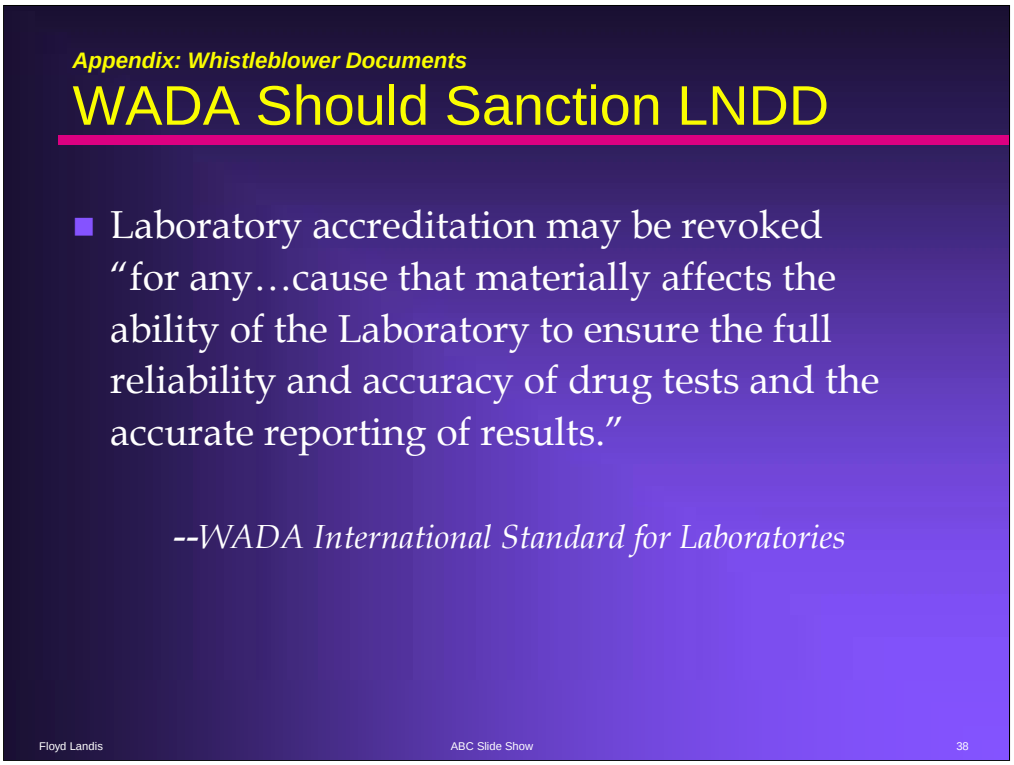
The documents in the following slides have been sent to me, multiple times, from whistleblower(s). These are documents have been in the news the last few days. On the one hand, I am suspicious of them. On the other hand, although I cannot be absolutely certain of their authenticity, they appear genuine.

I base the discussion that follows evaluating the substance of the letters. If the letters are fabricated, this discussion is moot.

Getting at the truth hasn't been easy. Please keep in mind that the "system" appears secretive to us. We haven't *even* been able to obtain Floyd's *own* test data from other stages in the Tour de France, despite repeated requests.

Not only LNDD, but the purported recipients or senders of these documents should be able to attest to their legitimacy. So far, I have not seen denials from these principals as to the substance of the contents of these documents.

[1] The Vrijman report can be accessed at:
http://www.cyclingnews.com/news/2006/jun06/vrijmanreport.pdf.

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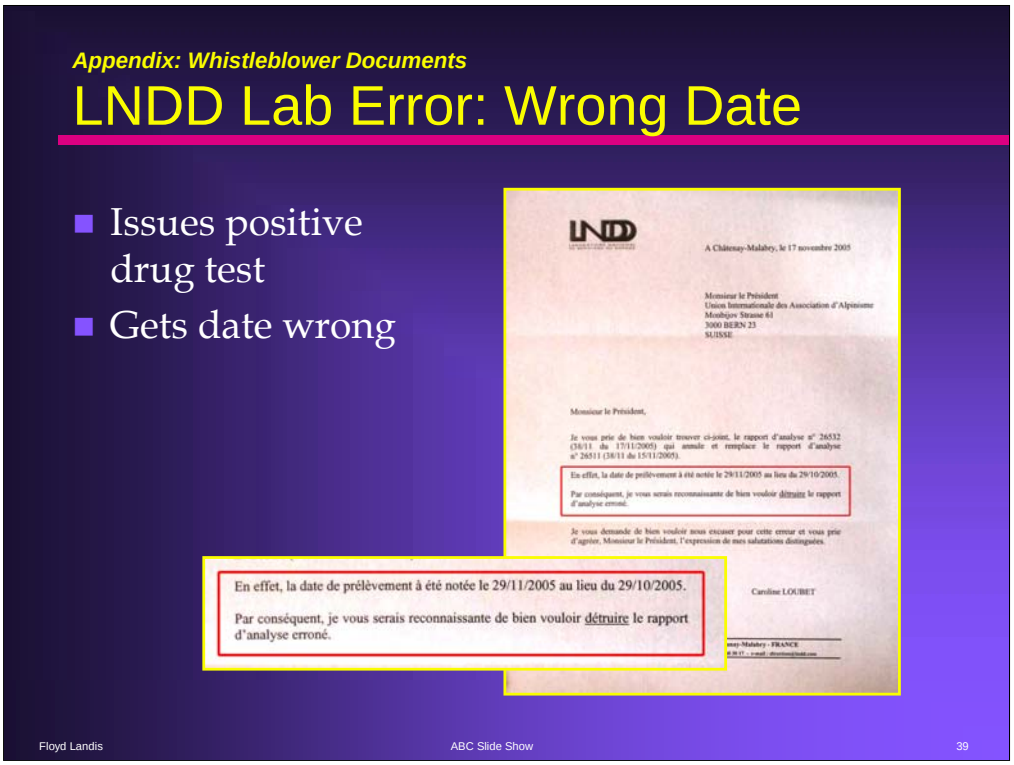


Please read the caveats at the beginning of the appendix.

In this document, the LNDD issues a retraction of an adverse analytical finding (positive doping test) to the Union Internationale des Associations d'Alpinisme (UIAA, The International Climbing and Mountaineering Organization).

LNDD reported the sample date incorrectly.

LNDD asks that the UIAA *destroy* the previous report.

If you can't match a sample and date, you can't identify a doping violation.

I read this as a failure of "the Laboratory to ensure the full reliability and accuracy of drug tests and the accurate reporting of results" and grounds for the revocation of the laboratory's accreditation.

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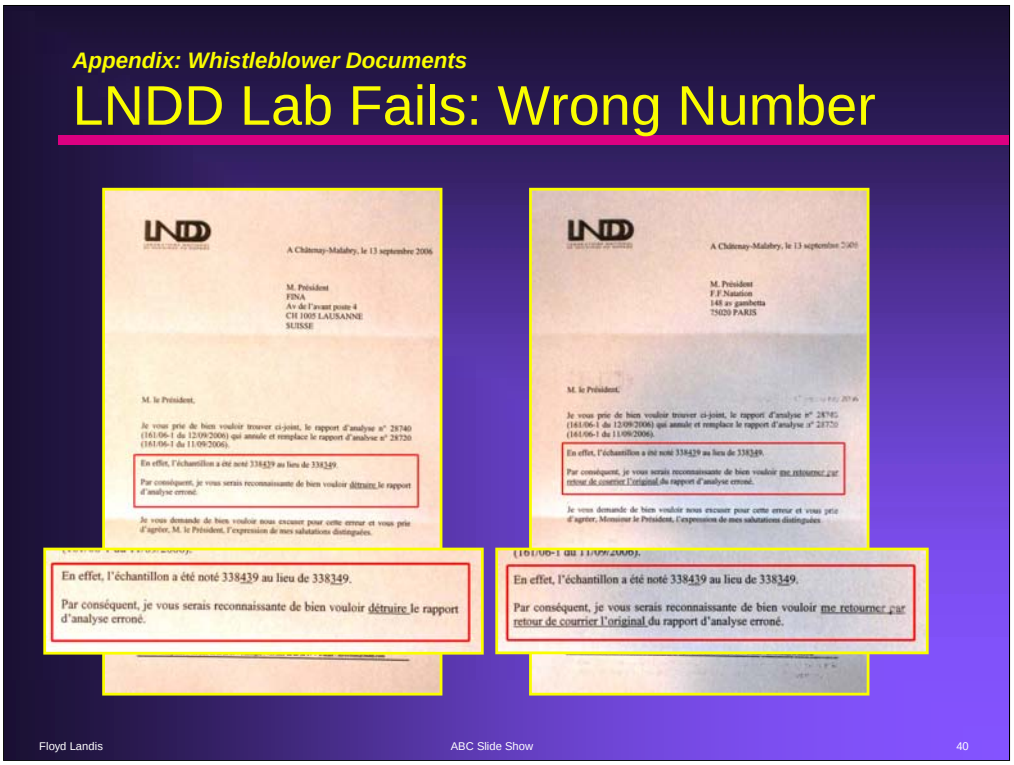
http://www.cyclingnews.com/news/2006/jun06/vrijmanreport.pdf.




Please read the caveats at the beginning of the appendix.

In these two documents, the French lab (LNDD) issues a retraction of an adverse analytical finding (positive doping test) to FINA (The International Swimming Federation) and to the F.F. Natation (the French Swimming Federation).

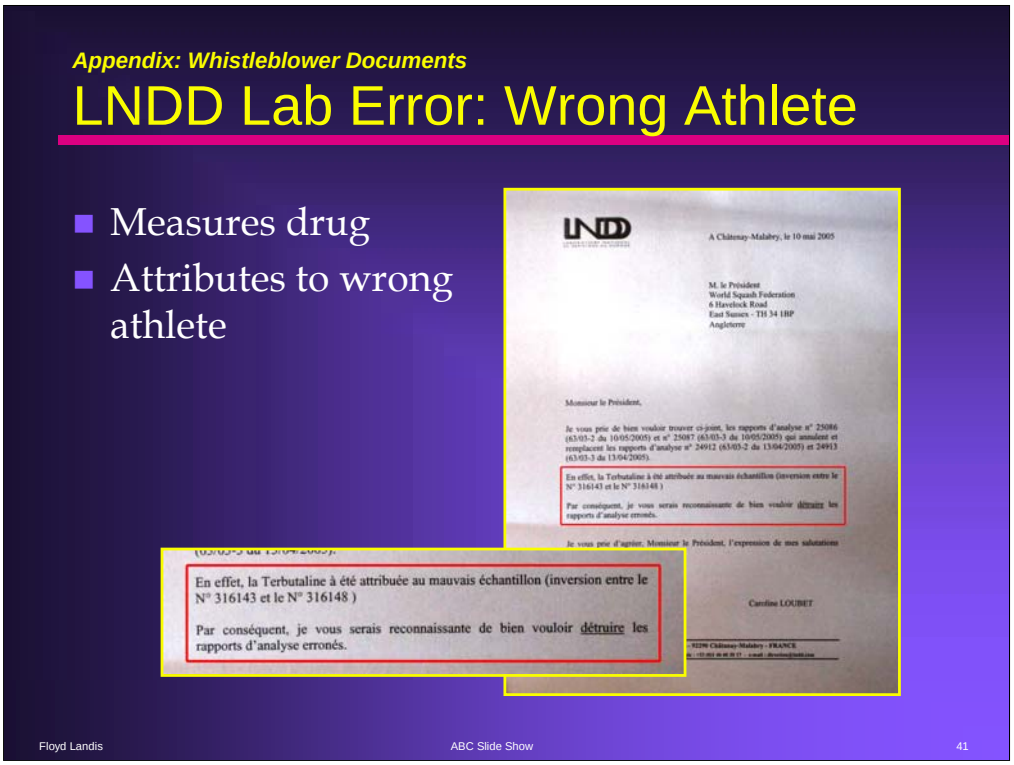
LNDD asks that that FINA *destroy* the previous report. It asks that FFN *return* the previous report.

If you identify the wrong athlete, you are accusing the innocent. If you can't match a sample identification number with an athlete, you can't identify a doping violation.

Note that this problem occurred during 2006.

As noted near the outset of this presentation, the lab made similar mistakes with Floyd's analysis.

As noted, with the caveats in the previous notes section, I read this as a failure of "the Laboratory to ensure the full reliability and accuracy of drug tests and the accurate reporting of results" and grounds for the revocation of the laboratory's accreditation.




Please read the caveats at the beginning of the appendix.

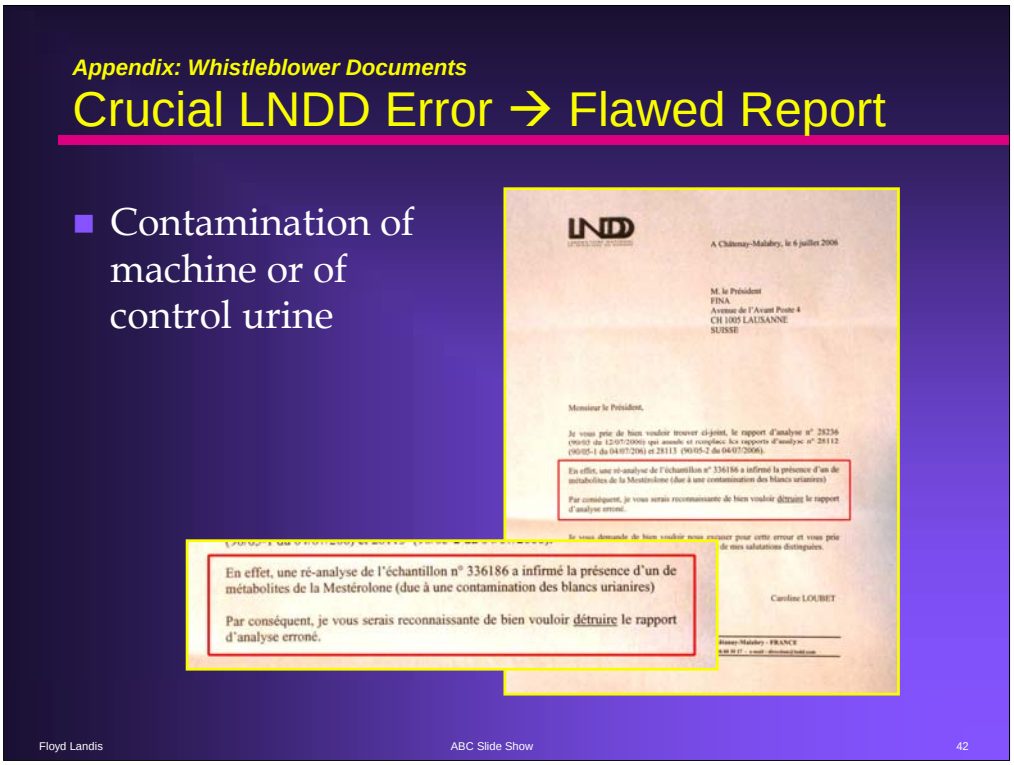
In this document, LNDD issues a retraction of an adverse analytical finding (positive doping test) to The World Squash Federation.

Upon review, the lab reported that it had attributed the finding of a banned substance (Terbutaline) to the wrong athlete.

LNDD asks that that FINA *destroy* the previous report.

This is serious. If you identify the wrong athlete, you are accusing the innocent. If you can't match a sample identification number with an athlete, you can't identify a doping violation.

I read this as a failure of "the Laboratory to ensure the full reliability and accuracy of drug tests and the accurate reporting of results" and grounds for the revocation of the laboratory's accreditation.




Please read the caveats at the beginning of the appendix.

In this document, LNDD issues a retraction of an adverse analytical finding (positive doping test) to FINA (The International Swimming Federation).

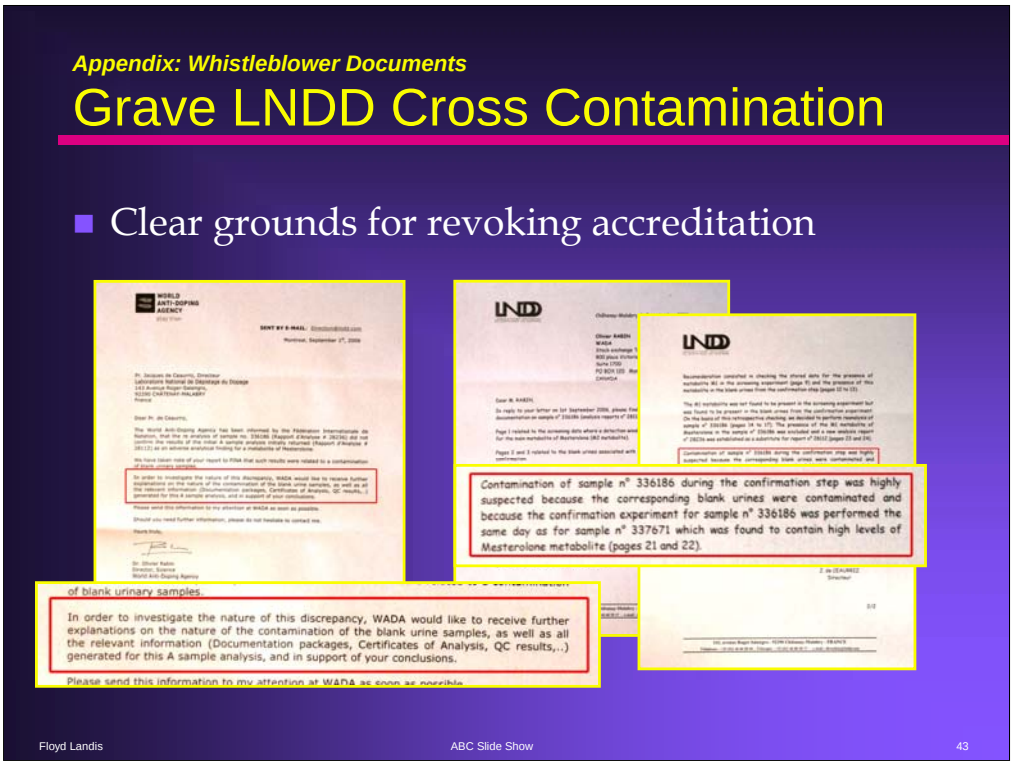
Upon review, the lab reported that it had cross-contaminated its control urine with a anabolic steroid from another athlete's sample.

LNDD asks that that FINA *destroy* the previous report.

This is an egregious error. The lab admits it falsely accused an athlete.

Note that this problem is reported for an analysis that occurred July 4, 2006—*during* the Tour de France.

I read this as a failure of "the Laboratory to ensure the full reliability and accuracy of drug tests and the accurate reporting of results" and grounds for the revocation of the laboratory's accreditation.




Please read the caveats at the beginning of the appendix.

Does WADA know about this latest, serious problem with LNDD?

Again, I have not been able to independently verify the authenticity of the documents in the last few slides, but LNDD and the purported recipients or senders of these documents should be able to attest to their legitimacy. In this example, the involved swimmer, apparently acquitted in the B sample could also come forward.

So far, I have not seen denials from these principals as to the substance of the contents of these documents.

On the left, WADA Science Director Olivier Rabin apparently wrote to LNDD, demanding to know what happened.

On the right, LNDD Director Jacques de Ceaurriz replied in this letter.

Again, note that this problem is reported for an analysis that occurred July 4, 2006—*during* the Tour de France.

Again, according to WADA standards, this is grounds for revocation of the laboratories accreditation.

Has the lab been sanctioned or otherwise penalized? I don't know.

If athletes are openly sanctioned, shouldn't the labs' status be public?

Again, Floyd's drug test is negative.

By WADA's rules, the lab should be sanctioned, not Floyd.


Prepared by Arnie Baker, MD.

Baker is a retired San Diego physician.

While in active medical practice, Baker had over a decade experience in medical peer review and quality assurance.

Baker has written about bicycling medicine for the lay public, International Olympic Committee, and medical community.