

UNITED STATES OF AMERICA
DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

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CLINICAL CHEMISTRY AND CLINICAL
TOXICOLOGY DEVICES PANEL

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MEETING

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TUESDAY,

NOVEMBER 14, 2000

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The Panel met at 9:00 a.m. in Salons C and D of the Gaithersburg Hilton, 620 Perry Parkway, Gaithersburg, Maryland, Dr. Martin H. Kroll, Chairperson, presiding.

PANEL MEMBERS PRESENT:

- MARTIN M. KROLL, M.D., Chairperson
- DONNA M. BUSH, Ph.D., D-ABFT, Guest/Federal Liaison
- JAMES EVERETT, M.D., Ph.D., Member
- CASSANDRA E. HENDERSON, M.D., Member
- THOMAS L. KURT, M.D., M.P.H., Consultant
- FRED D. LASKY, Ph.D., Industry Representative
- SHERWOOD C. LEWIS, Ph.D., Consultant
- BARBARA R. MANNO, Ph.D., Member
- STANLEY M. REYNOLDS, Consumer Representative
- ARLAN L. ROSENBLOOM, M.D., Member
- DIANA G. WILKINS, Ph.D., Consultant
- VERONICA J. CALVIN, M.A., Executive Secretary

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FDA REPRESENTATIVES:

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Reviewer Clinical Chemistry and Clinical
Toxicology Branch

STEVEN I. GUTMAN, M.D., M.B.A., Division
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JEAN M. COOPER, M.S., D.V.M., Branch Chief

CLARA SLIVA, M.P.A., Acting CLIA Coordinator

LINDA R. MANLEY, Secretary

PUBLIC SPEAKERS:

DAVID BRILL, M.D., M.A., M.P.H

ROBERT DUPONT, M.D. (MRO),

DUPONT ASSOCIATES, P.A.

THOMAS CAIRNS, PH.D., D.SC., Senior
Scientist, Psychomedics

CARL SELAVKA, PH.D., Director,
Massachusetts State Crime Lab

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WILLIAM THISTLE, ESQ., Vice President
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P-R-O-C-E-E-D-I-N-G-S

1

2

9:12 a.m.

3

DR. KROLL: I am Martin Kroll, and I am a
4 Chairperson for this session. I'd like to call the
5 meeting to order.

6

And first we have some opening remarks
7 from our Executive Secretary, Veronica Calvin.

8

MS. CALVIN: Good morning and welcome to
9 this meeting. Today the Committee will discuss and
10 make recommendations on a pre-market notification 510K
11 for a first of a kind prescription use screening
12 device in human hair.

13

When yesterday the Committee discussed
14 prescription use and OTC use guidance documents for
15 drugs of abuse, and information where you can obtain
16 transcripts or summaries from the meeting is on a
17 salmon colored sheet outside on the table, and that
18 also goes for today.

19

Also, we had indicated persons may submit
20 comments in writing. And where you can send that is
21 on a green sheet outside on the table.

22

At this time, I would like to ask the

1 panel members to introduce themselves starting with
2 Dr. Lasky.

3 DR. LASKY: Fred Lasky, Director of
4 Regulatory Affairs, Ortho Clinical Diagnostics. I'm
5 the Industry Representative.

6 DR. REYNOLDS: Stanley Reynolds,
7 Supervisor at the Immunology and Virology Pennsylvania
8 Public Health Laboratory. I'm the Consumer
9 Representative.

10 DR. EVERETT: James Everett. I'm the
11 Director at Madison Memorial Health Care and member of
12 the panel.

13 DR. WILKINS: Diana Wilkins, Assistant
14 Director of the Center for Human Toxicology and
15 Research Associate Professor of Pharmacology and
16 Toxicology at the University of Utah.

17 DR. KURT: Tom Kurt, Medical Toxicologist
18 and MRO, who is a founder at the Certified North Texas
19 Poison Center at Parker Memorial Hospital in Dallas,
20 and a Clinical Professor of Internal Medicine at that
21 Institution.

22 DR. KROLL: Martin Kroll. I am the

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1 Director of Clinical Chemistry at the Dallas VA
2 Medical Center, and I'm an Associate Professor of
3 Pathology at the University of Texas Southwestern
4 Medical Center in Dallas.

5 DR. MANNO: I'm Barbara Manno. I'm a
6 Professor of Psychiatry at the Louisiana State
7 University Health Sciences Center in Shreveport,
8 Louisiana.

9 DR. LEWIS: I'm Sherwood Louis, Director
10 of Toxicology at the Office of the Chief Medical
11 Examiner in the state of Connecticut, and faculty
12 member in the Department of Laboratory Medicine at the
13 University of Connecticut Health Center, consultant to
14 the Committee.

15 DR. CLEMENT: Steve Clement, Associate
16 Professor in Washington, D.C. at Georgetown University
17 and practicing Endocrinologist.

18 DR. ROSENBLOOM: Arlan Rosenbloom,
19 Distinguished Service Professor of Emeritus at the
20 University of Florida of Pediatrics, and Director of
21 Children's Medical Services in Gainesville. I'm a
22 regular voting member of the panel.

1 DR. GUTMAN: I'm Steve Gutman. I'm
2 Director of the Division.

3 MS. CALVIN: I will now read the conflict
4 of interest statement. The following announcement
5 addresses conflict of interest issues associated with
6 this meeting and is made part of the record to
7 preclude even an appearance of an impropriety.

8 To determine if any conflict existed, the
9 Agency reviewed the submitted agenda and all financial
10 interests reported by the Committee participants. The
11 conflict of interest statutes prohibit special
12 government employees from participating in matters
13 that could affect their or their employer's financial
14 interest.

15 However, the Agency may determine that
16 participation of certain members and consultants, the
17 need for whose services outweighs the potential
18 conflict of interest involved, is in the best interest
19 of the government. We would like to note for the
20 record that the Agency took into consideration certain
21 matters regarding Drs. Martin Kroll, Arlan Rosenbloom,
22 and Diana Wilkins.

1 Drs. Kroll and Rosenbloom reported
2 unrelated interests with firms at issue. Since the
3 interests are unrelated to the issue before the panel,
4 the Agency has determined that they may participate
5 fully in today's deliberations.

6 Dr. Wilkins reported an imputed interest
7 with a firm at issue. Since the interest is imputed
8 through her employer, and is not her personal direct
9 interest, the Agency has determined that she may
10 participate fully in today's deliberations.

11 In the event that the discussions involve
12 any other products or firms not already on the agenda
13 for which an FDA participant has a financial interest,
14 the participant should excuse him or herself from such
15 involvement, and exclusion will be noted for the
16 record.

17 With respect to all other participants, we
18 ask in the interest of fairness that all persons
19 making statements or presentations disclose any
20 current or previous financial involvement with any
21 firm whose products they may wish to comment upon.

22 Thank you, and I'll turn the meeting back

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1 over to Dr. Kroll.

2 DR. KROLL: All right. Thank you.

3 At this part of the meeting, we have our
4 open public hearing. And as you can see in the
5 agenda, public attendees who have contacted the
6 Executive Secretary prior to the meeting, will address
7 the panel and for that information relevant to the
8 agenda.

9 I'm urging the speakers to state their
10 name, where they're from, and whether or not they have
11 any financial involvement with the manufacturer of the
12 product being discussed, or with their competitors.

13 The first speaker we have on the agenda is
14 David Brill.

15 DR. BRILL: Good morning. I'm Dr. David
16 Brill. I'm Boarded in Internal Medicine and
17 Occupational and Environmental Medicine. Until June,
18 I was the Corporate Medical Director at Michelin of
19 North America. That's the tire company without the
20 recall.

21 And I was also a representative on the
22 hair testing work group for Donna Bush, who I see

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1 isn't here today, which was evaluating hair drug
2 testing for the Drug Testing Advisory Board, SAMSHA.
3 I represent an industry interest in that group.

4 I have a conflict of interest. I do have
5 shares of diagnostic laboratory companies. I do not
6 have any interest whatsoever in the laboratory here
7 today.

8 What I want to tell you today is that hair
9 is critical -- absolutely critical component of the
10 employer's tool box. And I'll share a couple of
11 anecdotes as to why.

12 So that you understand, hair testing for
13 drugs tests long term use. When you clip a hair from
14 the head, an inch an a half tests about three months
15 worth of drug use. It cannot test acute use. It
16 takes time for the blood, or any involvement of drug
17 with hair, to come into the hair.

18 It simply cannot test for acuteness. It
19 can only test for chronic use. Obviously, it can also
20 not test for immediate impairment. Again, because it
21 takes days to move from the blood to the hair.

22 However, for employers who want to use

1 effective tools in the workplace, hair is critical
2 because of its effectiveness and especially its
3 transparenence. And what do I mean by transparenence?
4 You'll see in a few minutes.

5 My past to this position right here in
6 front of you today began shortly after I began at my
7 former employer. We used urine testing, and I've been
8 taught that you don't use hair testing in MRO training
9 because it's a new technology which is not method
10 tests and so on.

11 Shortly after I came, we had a 26 year old
12 young man who passed his screening urine test. He was
13 a contractor. Again, he passed his scheduled
14 screening urine test. He passed his scheduled
15 screening urine test, and then two days later, died on
16 the floor of a cocaine overdose in the plant.

17 I repeated that three times. After we put
18 in hair testing for new hires, after investigating it
19 thoroughly, both on scientific, legal, and other
20 basis. After we put in hair testing, suddenly our
21 positive rates with no other changes in the program
22 tripled the same number of times that I just repeated

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1 that statement.

2 Every time that we were doing the urine
3 test, two other -- and finding one positive -- two
4 other people who were using drugs were entering the
5 company routinely.

6 Two years after that, we had implemented
7 a random hair testing program where we had the CEO of
8 the company giving the first sample with a video tape
9 of that event distributed to all employees, and
10 required to be viewed by all employees so that they
11 could see that everybody was in this together.

12 And it starts with the top, with the CEO
13 actually giving the sample with one of my nurses
14 taking the collection. Try that with urine. In fact,
15 at the time in Oklahoma, we had a plant where we
16 couldn't use drug testing.

17 The Oklahoma Board of Health has now
18 changed that. We can use hair testing in Oklahoma.
19 But at the time, we had to put in a urine random
20 testing program. And there the plant manager, when
21 coming to the same moment, had to discreetly turn
22 around and walk away toward the lab where he would

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1 give his urine collection.

2 But you get the point. Hair testing
3 doesn't involve genitals. It also can't be
4 adulterated. It also can't be substituted because
5 it's a witness collection.

6 In urine testing, the person is alone with
7 the sample 95 percent of the time. And of course, you
8 know what wonderful creative things are on the
9 Internet. Many of you may or may not, but for
10 instance, 30 miles away from where our headquarters
11 were, there was a creative young gentleman who was
12 marketing his own urine on the internet.

13 And further, he had developed a device
14 which would strap the urine to the leg, warm it to
15 body temperature so that it could pass SAMHSA
16 temperature requirements. And then move along the
17 genitals, so that even if it were a witness
18 collection, you couldn't see the tube.

19 I was asked to comment on this. And
20 frankly, I said it's essentially irrelevant to us
21 because we've used a hair testing program.

22 Now, let me help you understand workplace

1 drug testing if you're not familiar with it already.
2 There are essentially two critters here. Scheduled
3 tests and unscheduled tests.

4 The unscheduled tests tend to be reactive.
5 That's if there's an accident in the workplace and you
6 have a trigger for a drug test after that accident.
7 That's catching -- or perhaps catching something after
8 the damage has been done.

9 And 40 percent of the time, that's
10 involving harm to someone not using the drugs. It's
11 not the person who's driving the forklift who gets
12 hurt.

13 Reasonable suspicion testing is another
14 one. If someone is tottering in the plant, and you
15 have a drug test, that's a reactive.

16 Now, the scheduled tests are proactive, or
17 can be viewed as proactive. That would be an
18 applicant drug test, and let me again repeat, as an
19 applicant drug test, that's not a new hire drug test.

20 Because Congress expressed its will very
21 clearly in the Americans With Disabilities Act saying
22 that a drug test is not a medical test. In fact, they

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1 went so far as to say that it can be done before an
2 offer is made. Whereas, every medical test has to be
3 done after the offer is made to the applicant.

4 So you say applicant drug testing, not new
5 hire drug testing, because you can do the drug testing
6 before as per the will of Congress.

7 The second scheduled type of test is
8 random or periodic testing where an employer either
9 periodically says, "We'll test at such and such a
10 time," or, "We will have random testing."

11 Let me describe to you what the difference
12 is for an employer between random urine testing and
13 random hair testing. I ran five random urine testing
14 programs under the DOT airline -- you know, aircraft
15 pilots -- everybody who puts a tire or who makes a
16 tire for an airplane is covered. Anyone who puts a
17 tire on a bus is covered, and so on.

18 If I'm an employer, or if I'm the Medical
19 Director of the company, and I'm running a random
20 urine testing program, I am immediately going to be a
21 secret son of a gun. I'm playing the keystone cops,
22 because I have to keep that darn list secret.

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1 Because if anybody knows that they are
2 going to be either giving a random urine test, they
3 can tip the person off. Or, if they're going to be
4 receiving the random urine test, obviously they have
5 a thousand and one ways to adulterate and substitute
6 and so on.

7 So, we have to be secret, which is a pain.
8 You don't want to be secret with your employees and
9 your staff. So, the list has to be really, really
10 secret.

11 Second, everything has to be incredibly
12 abrupt. Once it goes down to the nurse that there is
13 going to be a urine test, they have to go out on the
14 floor, grab the person off the floor.

15 Usually there's two people off the floor.
16 The person whose coming off of the job, and another
17 person to accompany them back to the laboratory and
18 make sure they don't stop at their locker, don't stop
19 at the drinking fountain, da da da da da.

20 So, you have two people off the floor and
21 the Supervisor, who is a little PO'd that he suddenly
22 lost somebody and he has to scramble to get somebody

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1 to get on that machine. It's very abrupt. It's
2 really not fun. A lot of workplace disruption.

3 So, you've got these two people off the
4 floor. They come back. You have to have it in a
5 place with a laboratory because genitals are involved.
6 You have to have security in the laboratory as
7 witnessed every time, except for the moment when the
8 person is alone with the sample, of course.

9 And then the sample is put in a Fed Ex box
10 or whatever -- three samples typically, and you send
11 the biohazards through the mail. If it happens to be
12 the CEO on the other hand, if you want to have a fair
13 program, and the CEO is just about to fly off to
14 General Motors to clinch that contract and his number
15 or her number comes up, you have to say, "I'm sorry.
16 You really can't fly on that plane right now. You
17 really in all fairness to all the other employees, you
18 have to give the sample now just like anybody else.
19 Oh, you just peed? Well, here's eight ounces. Drink
20 this and we'll wait. We'll just keep the pilots
21 waiting."

22 That's urine testing in a random person.

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1 That's the reality. Now, look ahead. I don't have to
2 keep it a secret. If anybody gets that list, three
3 weeks in advance, I don't care. We just took the
4 list, put it on an Excel spreadsheet, send it out,
5 anybody can know who's on that list a couple weeks in
6 advance.

7 In fact, there's some preferences to do
8 that because then they can schedule their vacations or
9 whatever else is going on. If somebody comes back,
10 the Supervisors have no trouble with people off the
11 floor.

12 They schedule it in advance. You don't
13 need two people off the floor at any time. You don't
14 need a laboratory. You don't send biohazards through
15 the mail.

16 And if somebody says, "Oh, I'm on vacation
17 that day." Or the CEO is heading off to Detroit, just
18 say, "Sure. Schedule it to come back at your
19 convenience any time in the next couple of weeks." No
20 big deal.

21 You can't substitute the sample. You
22 can't adulterate the sample, and it's a long window of

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1 testing. So, it's wonderfully transparent. It's
2 beautiful for an employer, because you can be really
3 up front with employees.

4 That's what I wanted to tell you. Along
5 with short window tests, which are wonderful. For
6 instance, saliva, urine, breath for unscheduled tests,
7 reactive tests. Hair is great for scheduled tests.

8 In fact, if you do have a scheduled test,
9 everybody knows how to beat it with urine. If you're
10 going to have a scheduled test, really employers have
11 very little choice but to use something like hair.

12 In fact, hair is the only choice
13 available. The long range winners in the new media
14 will probably be hair, saliva, followed by urine -- or
15 breath, urine, and blood. Each one with a descending
16 level of ability to substitute the sample or
17 difficulty in attaining the sample.

18 So, what I wanted to tell you today is
19 that hair is a critical component of an employer's
20 tool box. Again, it has wonderful uses. It's
21 effective as opposed to the others. And it's
22 transparent. It lets you be a human being with your

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1 employees.

2 Thank you very much.

3 DR. KROLL: Thank you.

4 The next speaker is Dr. Robert Dupont.

5 DR. DUPONT: Thank you, Mr. Chairman. I
6 apologize for the voice. I got all prepared except
7 for one problem for this, and that was I got
8 laryngitis last night, so I apologize for any
9 difficulty you have hearing. And please put up a hand
10 and I will say it again. It's distressing but not
11 painful, so I'm happy to mostly to listen.

12 Let me say about the conflict of interest
13 issue that came up that I do own stock in the
14 Psychomedics Company and many other companies, and I
15 also serve as the Scientific Chairman of the
16 Scientific Advisory Board for the Psychomedics
17 Company.

18 I have been a strong advocate for drug
19 testing in general, including hair testing. And I'm
20 also active in supporting all the other companies that
21 promote or develop hair testing. And I don't think of
22 myself as an employee or an advocate particularly for

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1 Psychomedics, but for drug testing generally. And not
2 even just hair testing.

3 Now, my background -- I began in this
4 field more than 30 years ago working for the District
5 of Columbia government, and drug testing was central
6 to what we did. We did a study in D.C. jail using
7 urine testing that identified heroin use as a major
8 factor in the crime problem in the District at that
9 time.

10 That was published in the New England
11 Journal of Medicine, and was one of the central pieces
12 of evidence in the identification of the heroin
13 epidemic in the early 1970's and the late 1960's in
14 this country.

15 And I have been active in the drug testing
16 field generally since that time. I was the first
17 Director of the National Institute on Drug Abuse, the
18 second White House drug czar, then called the Special
19 Action Office for Drug Abuse Prevention.

20 And since 1982, I've been Vice President
21 of Benzinger Dupont and Associates, a national
22 consulting firm advising workplace programs dealing

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1 with drug and alcohol abuse. And in that role, I've
2 been a Medical Review Officer, and have been active as
3 a Medical Review Officer not only supervising other
4 physicians, but also doing medical reviews myself.

5 And I speak primarily as a Medical Review
6 Officer to you today. I came to the Psychomedics
7 Company into hair testing from working in my own
8 practice with my own patients who were addicted. And
9 to send off samples of their hair to be tested when I
10 knew what their drug use was, including sending
11 samples of people who I knew were not users.

12 And I was impressed by the fact that the
13 hair testing got the information right. As Dr. Brill
14 said, the phenomena of a long surveillance window of
15 90 days as opposed to three days -- one to three days
16 for urine testing -- was very attractive from a
17 clinical point of view in my work.

18 But also the resistance to cheating. I
19 want to emphasize that that also is a very important
20 factor. And it was on the basis of that personal
21 experience as a physician with my patients that I
22 contacted the Psychomedics Company and asked them what

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1 I could do to help encourage wider use of hair testing
2 in this country.

3 Now, I wanted to say two things by way of
4 background with respect to the opiate testing, which
5 is our subject today.

6 First of all, drug testing is extremely
7 important to demand reduction in this country. It is
8 absolutely central to the national effort to reduce
9 the demand for drugs. This is the most important part
10 because a central element of the drug experience is
11 dishonesty -- is lying about it.

12 And the .8 million current illegal drug
13 users in the country are spending 63 billion dollars,
14 a year on drugs. And the central technique for being
15 able to reduce that demand is drug testing linked to
16 consequences in all areas of our life including
17 workplace, which is what we're talking about primarily
18 today. But the criminal justice system is another
19 very important area.

20 The second point of background that is
21 going to come up in a moment that may not be obvious
22 is that heroin is a relatively new product. It was

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1 introduced in 1898 by the Bayer Company, by the simple
2 manipulation of adding two acetyl groups to morphine.

3 And the addition of those acetyl groups
4 was very important in terms of what we're going to
5 talk about in terms of the identification of heroin
6 use through hair testing because of the identification
7 of 6-MAM in that.

8 That was introduced by the Bayer Company
9 at the same time they added one acetyl group to
10 salicylic acid to create aspirin. And that's why the
11 two names heroin and aspirin are so similar. Because
12 they were introduced at the same time by the Bayer
13 Company.

14 With respect to the opiate testing, as an
15 MRO, the practical matter is -- and practical reality
16 is that all opiate positive are reversed on MRO review
17 of the opiate positive. The only exceptions are if a
18 heroin user admits use freely. I have never had that
19 happen as an MRO.

20 And the other possibility is that you
21 identify 6-MAM in the urine result. I have rarely
22 seen that happen. Almost all opiate testing using

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1 urine is reversed by the Medical Review Officer which
2 means urine testing is almost completely ineffective
3 at identifying heroin use in workplace drug testing.

4 That's very important to understand that
5 that is the reality that is faced today by anyone
6 who's using urine testing to identify heroin in
7 workplace or other testing.

8 And that is because of the poppy seed
9 problem. Poppy seeds contain morphine. And they will
10 trigger a positive test on a urine test. And because
11 of the way the testing is done, if there is any
12 possibility that the testing could be innocent, even
13 if the person does not claim to have eaten poppy seeds
14 in the prior three days, the MRO is duty bound to
15 declare that test a negative test.

16 Now, hair testing is very different in two
17 regards with respect to this problem with the poppy
18 seeds. First of all, poppy seeds do not produce a
19 positive hair test even when large amounts of poppy
20 seeds are consumed. They do not produce a positive
21 test at the cut off levels that are traditionally
22 used.

1 And sencon, 6-MAM rather than being rarely
2 identified, is routinely identified on hair testing.
3 That means that hair testing can identify heroin use
4 very efficiently. And urine testing cannot identify.
5 That is very important in terms of this particular
6 application of this technology.

7 Now, I want to mention three areas of --
8 let me call it concern about hair testing. The first
9 has to do with the concern about external
10 contamination as an explanation for a positive result.

11 And in thinking about this, I call your
12 attention to the fact that heroin is not a common
13 contaminant in the environment. It is not easy to get
14 heroin on your hair or anywhere else. So, that's
15 probably the most important point.

16 Second of all, should one get heroin on
17 his or her hair, the wash techniques that are used by
18 Psychomedics of a minimum of three hours and 45
19 minutes of wash are sufficient to exclude external
20 contamination as a source of a positive test.

21 I think that that's very important about
22 the external contamination -- that the wash is very

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1 important to exclude that rare possibility. An
2 example being a police officer working in a narcotics
3 unit where heroin is an environmental contamination.
4 That is important as a protection. So, the external
5 contamination issue is dealt with by the washing.

6 The second issue has to do with bias with
7 respect to hair color. This is very important that
8 you understand this. First of all, there is no
9 possibility of a person who does not use having a
10 positive test as a result of hair color, or race, or
11 any other factor.

12 So, non-use is zero for everyone. The
13 only argument exists about if a person has used the
14 drug heroin, is the concentration in the hair the same
15 or different depending on the hair color. So, this
16 only relates to people who have used heroin. And I
17 want to emphasize that point.

18 Now, with respect to the question of
19 whether there is a "bias" based on hair color, I call
20 your attention to other drug testing, which is very
21 extensive including the most striking example to me,
22 is alcohol testing.

1 In alcohol testing, we make no effort to
2 level the playing field in the sense that each alcohol
3 drinker can drink the same amount to get the same
4 blood level. We know that gender is a major factor in
5 the relationship between blood level of alcohol and
6 alcohol consumption.

7 But we also know that weight is a major
8 factor. And there are dozens of other factors. And
9 there is no attempt to normalize or equal the amount
10 of alcohol consumed in terms of declaring a positive
11 test.

12 The same thing is true with urine testing.
13 The biggest determinant of whether a person is going
14 to reach that cut off, or at a close call which is
15 only what we're talking about by the way for hair
16 either -- at a close call, near the cut off level, is
17 how much fluid the person has consumed.

18 We don't make any attempt at urine testing
19 to normalize for fluid consumption. The cut off is
20 the cut off regardless of how much you've consumed.
21 And the other determinant for urine testing is how
22 many hours it's been since you've used.

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1 We don't make any attempt to try to
2 normalize that, to say a person who has used six hours
3 ago is going to be judged equal for someone who used
4 one hour ago. None of that is done as we use a per se
5 standard for both urine testing for all drugs, and for
6 breath testing and blood testing for alcohol.

7 No attempt is made to level that playing
8 field based on the amount that the person has
9 consumed. And that's very important because I think
10 this whole argument is without precedent in the drug
11 field, and throws a curve ball into the equation that
12 is very harmful to the process, and bears no
13 relationship to some sense of equity.

14 Now, in addition to that, the -- and you
15 will hear more about this -- the tests that have been
16 done looking at hair tests around the question of
17 racial bias that is now among the people who have used
18 the drugs, is there a difference in positive rates
19 between urine self report and hair have shown that
20 there is not.

21 Whatever the laboratories studies show,
22 this is the result of a real world study. And it

1 shows no difference in the ratio between hair, and
2 urine, and self report. That's very important data to
3 take into consideration about this.

4 Now, my third concern has to do with
5 cheating. And that is -- I think those of you who are
6 not expert in the drug testing area -- Dr. Brill did
7 a wonderful job of explaining the fact that most drug
8 testing in the workplace is pre-employment testing, as
9 he called it applicant testing.

10 That is a scheduled test. That is more a
11 test of intelligence than it is a test of drug use.
12 The window for a urine test is one to three days.
13 That's very important.

14 That means that the major testing that is
15 done in the workplace is ineffective in a scheduled
16 test with a one to three day window. All the user has
17 to do is not use for one to three days, and the test
18 is negative.

19 It is also very easy on a scheduled test
20 to consume extra fluids. Never mind the complicated
21 kinds of problems as he was talking about a sample
22 substitution. The problem of cheating in urine

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1 testing is an enormous problem.

2 And it is particularly a problem for the
3 most serious drug users. The ones who are most
4 important to identify are least identified by urine
5 testing because of the ease of cheating on the test.

6 Hair testing cannot be cheated on as you
7 heard. There is no possibility of sample
8 substitution. No issue of additional hydration, for
9 example, or using an adulterant. These are not
10 relevant matters. This is extremely important in
11 terms of the integrity of the test and the
12 effectiveness of the test in being able to identify
13 drug use.

14 Now, for these reasons, I believe that
15 hair testing deserves a place along with urine testing
16 and other testing. Because I think saliva testing is
17 particularly important in an application like highway
18 testing, which as you may or may not know, there is no
19 testing now for drugs in the highway which is a
20 terrible national problem right now. And saliva is
21 the obvious means of doing that.

22 But hair testing does belong in there with

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1 urine testing. And of the hair testing, the opiate
2 test is particularly important for the identification
3 of use. In fact, I think that one of the things that
4 would be a very practical thing for somebody who has
5 a positive opiate urine test where there is any
6 concern whatsoever, is to require a hair test.

7 Because as Dr. Brill said, you've got 90
8 days. And the fact that you get a positive urine test
9 makes it fairly easy because you can't substitute
10 anything. You've got 90 days to look at it.

11 So, I think hair testing does add
12 substantially to the ability to detect drug use. And
13 it should be approved in the national interest to be
14 able to reduce the demand for drugs. And it is in
15 that spirit that I address you.

16 Thank you very much.

17 DR. KROLL: Thank you.

18 Now we proceed to the sponsor presentation
19 from Psychomedics Corporation. The first speaker is
20 Dr. Thomas Cairns.

21 MR. THISTLE: Actually, the first speaker
22 will be me. I'm Bill Thistle. I'm Vice President and

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1 General Counsel for Psychomedics.

2 And before we start the presentation, I'd
3 actually like to go through and introduce the people
4 that we have that will not necessarily be presenting.
5 You should have a list of presenters there. But we
6 brought people who are available to answer questions,
7 and I'll just go over them briefly so you know who is
8 here.

9 And the people here, just acknowledge who
10 you are. We'll get that out of the way first.

11 We have Werner Baumgartner, who is a
12 Scientific Director of Psychomedics Corporation. He
13 is a founder of Psychomedics and a pioneered hair
14 analysis for illicit drugs over 20 years ago.
15 Additionally, along with working with Psychomedics, he
16 has served until recently for the last 24 years as
17 Director of the Clinical Radioimmunoassay lab in Los
18 Angeles for the VA Medical Center.

19 We have Thomas Cairns, Senior Scientist at
20 Psychomedics, an adjunct Professor at Pharmaceutical
21 Sciences at USC. He served 20 years with the FDA.
22 Part of that time was as Director of the FDA National

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1 Center for Toxicological Research. He continues to be
2 a Senior Science Advisor to the FDA, and he was at one
3 point the recipient of the FDA Office of Regulatory
4 Affairs Regulatory Scientist of the Year Award.

5 We have Michael Schaffer, Vice President
6 of Lab Operations at Psychomedics. He's a licensed
7 NIDA Inspector. He was formerly Director of
8 Toxicology at the Smith Klein Lab, and formerly Chief
9 Toxicologist for the Office of the Medical Examiner in
10 Cook County, Illinois, where he made the determination
11 several years ago that the Tylenol scare we had of
12 tampering occurred post manufacturer.

13 We have John Irving, Deputy Director of
14 Laboratory Operations at Psychomedics. Again, a
15 licensed NIDA Inspector. John Irving was a member of
16 the first drug testing Advisory Board for NIDA, now
17 SAMHSA. He participated in drafting the initial
18 federal drug testing guidelines and he was formerly
19 Director of several Navy drug testing laboratories.

20 We have Virginia Hill, a Research
21 Scientist with Psychomedics Corporation who worked
22 directly with Werner Baumgartner on hair analysis at

1 the VA Medical Center.

2 We have Carl Selavka, who's not with
3 Psychomedics, but is Director of Massachusetts State
4 Crime Lab. He is co-chair of a hair testing working
5 group created by the drug testing Advisory Board to
6 advise SAMHSA on inclusion of hair testing. He has
7 published one of the seminal studies on poppy seed
8 ingestion and the issues that that creates, and to
9 serve as a consultant in that regard to HHS.

10 He was formerly Director of Forensic
11 Services for New York's 25 public forensic science
12 labs. Formerly Operations Officer for the U.S. Army
13 Toxicology Drug Testing Lab in Hawaii. And has
14 testified as an expert witness in over a dozen
15 military cases involving hair analysis.

16 We also have Richard Newel. He's a
17 Professor of Statistics Research and Methodology in
18 Forensics at the University of South Florida. Along
19 with Dr. Mieczkowski, Mr. Newel has amassed one of the
20 largest databases of its kind regarding race, drug
21 testing, and drug prevalence.

22 We have Jonathan Ma, Manager of

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1 Biostatistics at Engine X Pharmaceutical Sciences,
2 formerly a Mathematical Statistician with the FDA.

3 And myself, I'm General Counsel with
4 Psychomedics.

5 We -- is there technical difficulties with
6 this? Is that why it keeps flipping?

7 As we approached this, we found it
8 difficult to condense two decades of research and over
9 a decade of use into a one hour presentation. We tend
10 to provide a background on hair analysis as done by
11 Psychomedics, and then get into the submission
12 specifics.

13 And already we're out of sequence here.
14 But our Corporation -- is that legible at all?

15 Our Corporation was founded in 1987 to
16 analyze specifically drugs of abuse in hair following
17 years of research by Dr. Baumgartner. We test for the
18 NIDA five drugs, opiates, cocaine, methamphetamine,
19 including MDMA, ecstasy, which should be part of the
20 covered guidelines in the future, just for marijuana
21 and PCP.

22 We are licensed as a -- you should have

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1 this incidentally in front of you, so follow along as
2 we go through this. The audience can pretend they're
3 watching this.

4 I think it would work better if we could
5 get somebody clicking up there. Is there a problem
6 with the length of the cable? Why don't we do that?
7 Why don't we have someone clicking up there. We're
8 going to take a couple minute break and just set it
9 up.

10 (Whereupon, the foregoing matter went off
11 the record at 10:52 a.m. and went back on
12 the record at 10:56 a.m.)

13 MR. THISTLE: We are a licensed high
14 complexity clinical lab under federal CLIA standards.
15 We are CAP certified with the limited urine testing
16 that we do. We are licensed and certified by numerous
17 states, including states that have specific criteria
18 for hair analysis labs, Florida, Maryland, New York,
19 Oklahoma.

20 We have three U.S. patents on aspects of
21 the methodology unique to Psychemedics. We have
22 European, Japanese, and Canadian patents as well. And

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1 we have over 1,800 corporate accounts from a wide
2 variety and cross section of U.S. businesses.

3 And by corporate accounts, I'm not talking
4 about doing one or two tests. For instance, for
5 General Motors, we do all their pre-employment at a
6 104 North American plants, all the North American
7 operations.

8 We do Anheuser Busch, testing for Anheuser
9 Busch, FIC, Rubbermaid, Toyota, BMW, Michelin,
10 Goodyear, Whirlpool, Gillette, Steelcase, U.S. Steel,
11 Federal Reserve Banks. In addition to the major
12 corporations, we also -- I know you thought it was
13 going to be all 1,800, but in addition to those major
14 corporations, we're also utilized by law enforcement
15 agencies, including some of the nation's largest,
16 NYPD, Chicago PD, Boston PD.

17 We're used in prisons in several states.
18 We're utilized by court systems in diversionary and
19 first offender and probationary programs. These are
20 programs designed to keep people out of jail through
21 hair testing.

22 We're utilized by state use and family

1 service agencies, in child custody issues, chemically
2 abused children. We're utilized by schools. We have
3 over 100 schools in 26 states utilizing hair testing.

4 We've been upheld in federal courts. This
5 is a June 2000 decision. The court agreed there was
6 no scientific support for the claim that the plaintiff
7 could have tested positive due to her race.

8 Over ten years ago, we were upheld in
9 federal court where the court recognized that RA hair
10 testing -- they're recognized through liability and
11 acceptance in the field of forensic toxicology when
12 used to determine cocaine use.

13 We've been upheld in state courts. We
14 have a number of police officer cases where there's a
15 tremendous impact on society. These are people
16 involved in drugs and protecting the public.

17 We've been upheld in state appellate
18 courts, where the courts have found that the
19 radioimmunoassay analysis of human hair to determine
20 cocaine use is generally accepted in the scientific
21 community.

22 We've been upheld by state supreme courts.

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1 This Nevada case concluded that hair testing,
2 especially when coupled with a confirmatory GC/MS test
3 was an acceptable and reliable scientific methodology
4 for detecting illicit drug use.

5 We've been upheld by administrative
6 agencies, unemployment boards, unemployment appellate
7 boards. We've been upheld in union arbitration
8 decisions, including Teamsters, United Steel Workers,
9 Operating Engineers, fairly tough unions.

10 Every issue that can be brought regarding
11 a hair test has been brought and is brought, and we
12 get decisions similar to this where they find
13 Psychomedics' wash procedures are effective in
14 removing environmental contamination.

15 The cut off level for cocaine is
16 appropriate in the field studies. There was no bias
17 here on the basis of race or hair color. The chain of
18 custody was unbroken.

19 Many of these companies use hair analysis
20 because of the advantages. The hair analysis -- and
21 you've heard some of them earlier today. There's a
22 wider window of detection.

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1 Approximately three months for morphine,
2 and six for acetylmorphine in hair. Urine is 24 to 72
3 hours for morphine, several hours for 6
4 acetylmorphine. Six acetylmorphine, or other clinical
5 evidence of use is necessary to confirm heroin use.

6 We have significantly increased detection
7 rates, because you're looking at several hours.
8 You're comparing several hours to several months. In
9 real life, the purpose of testing is for a third party
10 to determine the likelihood of future use based on
11 approximate past behavior.

12 It's certainly more effective and safer to
13 the general public to make that decision based on a
14 long period of time as opposed to a shorter period of
15 time.

16 There are many reasons to use tests with
17 a shorter period of time, but certainly in pre-
18 employment, there's a reason to use a test with a
19 longer period of time. Many of our clients have done
20 side by side hair and urine tests, and have found
21 tremendous differences in the detection rates.

22 We are also a less intrusive collection.

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1 It's a small snip of hair, the thickness of a shoelace
2 tip. People regularly will get their hair cut in
3 public, at least with a barber present. Sometimes in
4 front of a plate glass window at the mall. It is not
5 likely you'll find people urinating in front of the
6 plate glass windows at the mall.

7 In fact, the U.S. Supreme Court has long
8 held that the collection of urine was a search, and
9 found that there are few activities in our society
10 more personal or private than the passing of urine.

11 In contrast, again the U.S. Circuit Court
12 of Appeals Federal Court, concluded that the
13 collection of hair in 1982 was akin to obtaining
14 fingerprints and did not rise to the level of a
15 search. We are also, as mentioned earlier, an
16 observed collection.

17 One of the biggest threats to urine
18 testing is adulteration and substitution. That can't
19 be done at the collection site. And these are just
20 two companies off of hundreds that we've pulled off
21 the internet.

22 The one on the left is the gentleman that

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1 provides the clean urine and heater pack. And the
2 tubing guarantees 100 percent satisfaction, because
3 obviously a lab cannot tell the difference between if
4 you submit clean human urine that's of the proper
5 temperature when it's collected. A lab cannot
6 identify that.

7 The second on the right is an adulterant,
8 Spectrum Laboratories. The gentleman that runs
9 Spectrum Laboratories has been interviewed on
10 television, and he says, "I get the same publications
11 as the urine labs. Obviously when they begin to test
12 for my products, I change my products."

13 We have the ability to repeat the
14 collection. And this is a huge, huge advantage for
15 the employee or the donor. You can collect a wholly
16 new sample that can encompass the original time frame
17 after the original result is known.

18 This eliminates concerns over sample error
19 or lab error, or sample mix up. It's not possible
20 with liquid matrices as the original window of
21 detection has passed by the time the result is
22 obtained.

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1 Getting a second urine sample four days
2 later, or five days later, or three days later -- even
3 two days later -- is worthless in terms of seeing what
4 happened during that original time frame.

5 This provides unprecedented fairness to
6 the donor. We have repeatability with a new sample,
7 with a new collection, with the union representative
8 present. Unprecedented fairness to the donor.

9 We identify 6 acetylmorphine, establishing
10 heroin use. Hair testing eliminates the poppy seed
11 issue. Our studies that have been submitted with this
12 submission have shown that even massive ingestion of
13 poppy seed products will not cause a positive hair
14 result.

15 In contrast, in '95, HHS reported that 87
16 percent of confirmed urine opiate positive were
17 overturned largely due to the inability to distinguish
18 that use from poppy seed use. That was at the cut off
19 level of 300, which does not, as it turns out, protect
20 the individual because it could be a poppy seed
21 positive.

22 The level has been raised to 2000, which

1 at this point may not protect the public, because now
2 you've raised it to the point where you may be
3 eliminating heroin users.

4 We also have ease of shipping and storage.
5 It's not a biohazard. They have much more safety --
6 increased safety in shipping and handling the
7 specimen.

8 There are several unique aspects to our
9 submission. It may be somewhat different than what
10 you're used to seeing. For one, it's been used in
11 millions of tests over 13 years. We have a track
12 record of safety and effectiveness.

13 It is an in house assay, a home brew.
14 It's not sold to other labs. And this is a test where
15 the donor knows the results before taking the test.
16 The donor knows clearer than everybody what the
17 results should be.

18 You're not advising the donor that they
19 have cancer. You're letting them know that they
20 engage in activities that they know certainly well
21 that they engaged in.

22 It's a forensic test that provides a third

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1 party with information on past illegal activity.
2 Heroin is a Schedule one drug. This test does not
3 show intoxication, under the influence, or addiction.
4 It's a forensic test.

5 At this point, I'm going to turn it over
6 to Dr. Cairns who will get into more of the laboratory
7 operations and the science.

8 Thank you.

9 DR. CAIRNS: Good morning, Mr. Chairman,
10 members of the panel. I welcome this opportunity to
11 do a presentation before you, not only on an overview
12 of our hair test procedures, but also on the seven
13 important questions that have been posed by the panel.

14 I need to go open my own presentation.
15 Apologize. We used to get along so better with these
16 slides in the old days, and I wonder whether
17 technology should take a back seat and go back to
18 slides.

19 However, what I wanted to do for you just
20 for a few moments is to place into a proper
21 perspective setting where the RA assay for morphine
22 sits in our strategy of hair testing.

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1 Now, the next slide will show basically
2 that there are three major platforms here. The first
3 platform is in fact the primary stringing via RA to
4 identify presumptive positive based on morphine.

5 If at that point, the assay -- the screen
6 is negative, the sample is reported negative. If
7 however, that primary screen -- and by the way, that
8 primary screen involves only eight milligrams of hair
9 digested or liquified for the analysis.

10 And that's a five drug analysis panel,
11 similar to NIDA. The next step, if a presumptive
12 positive is triggered by the screening assay, then we
13 go into a second sample weighing from the original
14 envelope that contains the hair and the chain of
15 custody.

16 Except in this case, this second weight of
17 hair is in fact extensively washed, washed to remove
18 external contamination. Once the hair is washed --
19 and I'll be going into the exact details of the wash
20 later -- that hair is then liquified, it's digested,
21 and sent on for structural confirmation.

22 Now Psychemedics has developed mass

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1 spectrometry that goes back to in fact just the simple
2 gas chromatography mass spectrometry, but more
3 recently has elevated the specificity by looking at
4 these compounds, meaning morphine, 6-MAM, and codeine,
5 by a liquid chromatography mass spectrometry, mass
6 spectrometry.

7 So, what are we looking for? We're
8 looking for morphine and the heroin metabolite. And
9 in that process, we're looking at the analysis of the
10 last wash in our review of the data before we release
11 a positive.

12 Now, let me just go over the criteria for
13 properly conducted hair testing. We want the sample
14 under chain of custody. We want the digestion
15 procedure, that is the process of dissolving the hair
16 to release the drugs from the matrix to allow the
17 screening.

18 But it's important to stress at this
19 point, that you must use rigorous forensic standards
20 that is both quality control and quality assurance.
21 Now, by that I mean that in the RA assay, we have in
22 fact the standard at the cut off.

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1 We have a high control at 25 percent
2 above. We have a low control at 25 percent below.
3 We have a negative and several blind samples in each
4 batch. Now if in fact that is then satisfied, the
5 next step is the re-weigh and the washing procedure.

6 And that is an extensive wash lasting
7 three and three quarter hours plus an analytical
8 extrapolation to have five additional hours. Then we
9 move into structural confirmation.

10 Depending on the result, we will review
11 the wash criteria. And then the final review by a
12 certifying scientist before the issuance of a positive
13 result.

14 Looking at all of the QA/QC blanks and
15 blinds that go into the batches, whether it's the RA
16 batch or whether it's the GCMS batch.

17 Now, let me give you just one last slide
18 on our overview. We accessioned the hair. That's the
19 process of weighing the hair, giving it a bar code.
20 At that point, the paperwork is checked for valids and
21 invalids, and fatals. Maybe that the seal -- the
22 integrity seal was not initialized by the donor.

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1 Weigh the eight milligrams, liquify the
2 hair, go to radioimmunoassay. Five panel drug,
3 marijuana, cocaine group, amphetamine group, opiates,
4 and PCP.

5 The negatives are released, the
6 presumptive positive move forward by a new sample
7 being re-weighed and washed, then digested, and moving
8 into structural confirmation by mass spectrometry,
9 whether it is GCMS, or the more sophisticated tandem
10 mass spectrometry associated with either gas
11 chromatography or liquid chromatography.

12 Once that data is forwarded, the wash data
13 is also reviewed in conjunction with the mass
14 spectrometry result, and the certifying scientist
15 reviews the positive before release.

16 Now, with that little background, let me
17 move into the next part of the presentation. And this
18 is to focus basically on the issue before us today.
19 That is regarding the safety and effectiveness of an
20 RA screening assay for morphine using a cut off of two
21 nanograms or ten milligrams of hair.

22 Now, question one revolved around clinical

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1 studies. If you were to use the traditional
2 perspective clinical controlled study, there would be
3 two major impediments, and one is an ethical problem.
4 That is, can you ethically administer multiple and or
5 chronic doses of heroin for a period of 30 to 90 days
6 to mimic drug abuse?

7 The second one is an analytical problem
8 involved in the time frames between urine and hair.
9 And we've heard that's a few days, and the hair is 90
10 days. The administration of a single low dose would
11 not challenge the cut off of the sensitivity of the
12 assay.

13 Therefore, the design of the clinical
14 trials in Volume 3, which is a response to FDA, was
15 that the study hypothesis was to demonstrate
16 substantial equivalence to a urine predicate device.

17 Number two. The positive clinical gold
18 standard was a positive urine and a positive self
19 report. A negative clinical gold standard is a
20 negative history of hair analysis and a negative
21 urine.

22 And the inclusion exclusion criteria were

1 the same for all the studies we submitted in this area
2 of the application. Now, from the statistical point
3 of view, the standard error of clinical sensitivity
4 and specificity has been determined and submitted.

5 The next slide will show you the five
6 independent studies that were submitted to support the
7 performance of the assay. These are five heroin user
8 field studies, and they are involving Study A involves
9 22 individuals, Study B, 93, Study C, 94, Study D, 20,
10 and Study E, 16.

11 Now, I'd like to go through each of these
12 in turn to explain perhaps a few more details on each
13 of these clinical studies. The first one was
14 published in Journal of Forensic Science in 1989. The
15 hair testing cut off was two nanograms per ten
16 milligrams.

17 Again, 22 subjects. The use by self
18 report was somewhere between 6.4 and 288 milligrams
19 per day. The morphine range found in hair was from
20 the two nanogram level to 130 nanograms per ten
21 milligrams of hair.

22 This permitted a mean detectable heroin

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1 dose use resulting in the value of 173 milligrams of
2 heroin per month. And the clinical sensitivity
3 derived from the data using 17 true positive, and five
4 false negatives, with 77.2 percent.

5 Study B, from the National Development and
6 Research Institute to Mount Sinai Hospital and various
7 clinics surrounding the New York area, once again, 93
8 subjects self report heroin.

9 The morphine levels found in hair by RA
10 assay ranged from zero all the way up to 605 nanograms
11 per ten milligrams of hair. Cutting through the
12 calculations, the clinical sensitivity reported with
13 90.3 percent.

14 Study C, a NIDA Research Monograph
15 Publication in 1997 from the Center for Substance
16 Abuse. Here again, 94 subjects. The clinical
17 sensitivity calculated from the study is 90.4.

18 Study D, published in the International
19 Journal of Addictions. The study conducted at the Van
20 Etten Hospital Drug Treatment Program in the New York
21 area. Only 20 subjects, a sizable number, morphine
22 range two nanograms to 98 nanograms per ten milligrams

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1 of hair. Again, the clinical sensitivity calculated
2 from the study results, 80.0 percent.

3 Study E, by Baer et al U.S. Probation in
4 Santa Ana Southern California, in conjunction with the
5 Veterans Administration Hospital in Los Angeles,
6 California. Sixteen subjects in the study. The
7 morphine range found in here, two nanograms to 130
8 nanograms per ten. The clinical sensitivity
9 calculated 75 percent.

10 Now, taking all five studies as submitted
11 in the application, and doing a combined approach to
12 the calculation of clinical sensitivity from such five
13 independent sources resulted in a clinical sensitivity
14 calculation of 87 percent.

15 However, that clinical sensitivity really
16 does not in fact address the issue of the
17 effectiveness of using hair versus urine. In
18 Attachment 22 in our submission, we list the following
19 data.

20 We looked at two matrices, urine and hair,
21 and the number of tests performed within a large
22 population. Seventeen hundred and eighty-three urine

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1 tests performed, eleven positive were identified
2 yielding a positive rate for morphine and for heroin
3 use of 0.6 percent.

4 In the cases of hair samples taken from
5 the same population, only 187 hair samples were taken.
6 But the number of positive were 15, a dramatic shift.
7 Looking at the hair results, hair is more effective
8 than urine in this environment.

9 Next slide.

10 Now, looking at analytical sensitivity and
11 specificity for the assay admitted most of the data.
12 The detailed data is in our Volume 3 response, but
13 essentially, analytical specificity is 96.6 and the
14 analytical sensitivity is 100 percent.

15 Now, the negative portion of the clinical
16 study, we used a group of Psychomedics' employees, 81
17 employees. And the clinical specificity is 100
18 percent.

19 Now, the questions the panel had regarding
20 the clinical sensitivity and specificity was in the
21 inclusion criteria. And the cross question was
22 negative urine plus negative self report.

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1 Psychemedics did not simply use those two
2 criteria. We did not simply use a negative urine and
3 a negative self report. We used an employee group
4 with a history of negative hair tests and a
5 contemporary negative urine test.

6 So, the features of our negative
7 controlled study where yes, they were volunteer
8 employees. They were required before entering
9 employment to have a negative hair test for
10 Psychemedics. And the company policy is that we
11 conduct randomly monitored hair tests.

12 The urine samples were also monitored for
13 any immunoassay response as compared to the negative
14 control. We did not apply a cut off there. If the
15 drug was present, even below cut off, it was pursued
16 by mass spectrometry for identification.

17 The next question asked, "Was positive
18 urine not always confirmed plus a positive self
19 report?" And here again, we also went beyond those
20 two criteria by looking at clinical evidence of drug
21 use. Hence, heroin treatment programs basically for
22 the controlled studies.

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1 There is a limited ability in urine to
2 confirm the heroin metabolite, 6-monoacetyl morphine,
3 or 6-MAM for short. And this tends to make the urine
4 test the weakest piece of information.

5 Hair, on the other hand, does provide for
6 storage of 6-monoacetyl morphine, which can define
7 heroin use. Therefore, in urine, 6-MAM will clear in
8 less than eight hours.

9 Now, if we look at the recent history with
10 morphine at the old cut off of urine of 300 nanograms,
11 it took 24 to 72 hours to clear. When we moved to the
12 higher cut off of 2,000 nanograms, 24 hours to clear.
13 And 6-MAM, that unique descriptor of heroin use, less
14 than eight hours to clear.

15 Now, the minimum dose issues. The
16 estimated mean minimal detectable heroin dose from the
17 field studies, that is A through E as outlined to you,
18 results in a value of 173 milligrams per month. And
19 that's in Volume 3.

20 This translates to a choice for use of a
21 cut off of two nanograms of morphine. Heroin addicts,
22 in a paper by Kintz, used 900 to 24,000 milligrams per

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1 month. So, you can see already that the average
2 heroin addict is way above the mean minimal detectable
3 heroin dose, and i.e., well above the cut off.

4 Now, the poppy seed controversy.
5 Psychedics has presented data on the poppy seed
6 issue. And by feeding 150 grams of poppy seed, the
7 morphine level in hair was only 0.17 nanograms per
8 ten, well below the cut off of two nanograms. And of
9 course, no 6-monoacetyl morphine.

10 Pharmacokinetic considerations. Again, I
11 go back to the impediment to controlled clinical
12 trials is that it is not ethical to conduct single,
13 multiple, or chronic dose levels studies with heroin.
14 The minimal detectable dose information is all that
15 should be really necessary due to the proven
16 accumulation and stability of both morphine and 6-
17 monoacetyl morphine in hair.

18 That is, the ability for hair to act as a
19 trapping device, not only for the metabolite directly
20 from heroin, but also for morphine. The RA assay
21 using hair can detect heroin use via the mass
22 spectrometry confirmation of any presumptive positive

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1 above the two nanogram level by detecting the
2 metabolite, 6-MAM.

3 So clearly, the combination of morphine
4 and 6-MAM is found in the hair of heroin users. The
5 combination of morphine and 6-MAM is not found in the
6 hair of non-users.

7 The bias issues. I'm merely going to
8 summarize some of the bias issues. We have submitted
9 a hair color and curvature study, meaning curly hair
10 versus straight hair, in Volume 3.

11 The large multiple statistical studies,
12 that is those studies involving large populations and
13 a statistical analysis, are not significant. In other
14 words, no bias.

15 And these studies are the Pinellas County
16 Probation Study, the Pinellas Cleveland Juvenile
17 Study, the New Orleans Diversion Data, the National
18 Institute of Justice Study, the Pinella County Drug
19 Use Forecast Emulation.

20 Eighteen hundred participated. And
21 finally, a large metropolitan police department.
22 Again, very large study of 1,800.

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1 Methodological differences within research
2 reports can create variances in results that appear to
3 be color related, but are not. By that I mean that
4 the study protocol may have used inefficient
5 extraction procedures, failure to remove melanin and
6 sweat, ineffectual wash procedures. These are all
7 part and parcel of methodological differences.

8 The bias studies have previously not been
9 required for submitted applications with immunoassay
10 applications for urine to correct for either diet,
11 gender, muscle mass, creatinine level, body weight.

12 And finally, individual biochemical
13 variability. That issue of the bioavailability within
14 the individual within any population can create large
15 variances.

16 Now, at this point I'd like to introduce
17 Professor Newel to discuss in detail the statistical
18 evaluation of these large populations as well as the
19 small.

20 Professor Newel has the largest database
21 on hair to look at statistical profiles with color
22 versus hair.

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1 Professor Newell.

2 MR. NEWELL: Thank you and good morning.

3 I do not have any conflict of interest or
4 financial ties to the Psychomedics Corporation, nor
5 any other laboratory.

6 May I have the next slide.

7 I work at the University of South Florida.
8 I've been doing research involved in hair testing with
9 funds primarily from the Department of Justice,
10 National Institute of Justice for about ten years.
11 So, I appreciate the opportunity of being able to come
12 before you and share with you some of the work that
13 we've done.

14 First I'm going to start with a kind of
15 conceptual transition slide. The question that was
16 posed by the panel regarded racial bias. Originally,
17 racial bias evolved from some initial concerns that
18 there were associations between type of hair and its
19 ability to record exposure to drugs.

20 People wondered if racial bias would be
21 part of that problem. And I think, probably first
22 that was because there was an erroneous perception on

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1 the basis of the general public that there are
2 biochemical racial differences.

3 In fact, I think over time this has
4 evolved further, and that now racial bias issues are
5 handled primarily as issues in the type of hair, that
6 is color of hair, or curvature of hair, other
7 descriptors of the hair itself.

8 Also, there have been some ethical
9 limitations. Research has generally relied on an
10 epidemiological approach to this issue. That
11 typically has involved taking hair analysis results
12 and comparing them to self report drug use and
13 urinalysis results.

14 For studies that have proceeded that way,
15 no such race effects have been confirmed for either of
16 these drugs, cocaine or heroin. And more recently,
17 this issue has been addressed I would say more
18 scientifically than calling it racial bias, by calling
19 it differences due to hair color or hair type.

20 Can I have the next slide?

21 I want to share with you very briefly a
22 secondary analysis, a statistical analysis, that was

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1 conducted on five data sets that have appeared in the
2 literature. All five of these were characterized with
3 small-n.

4 Could we have the next slide? Thank you.

5 Small-n is just basically the number of
6 people that participated in the study. The basic
7 question is, is there a statistical relationship
8 between hair color and assay concentration value?

9 In these five small-n studies, we had
10 anywhere from nine to 20 subjects. Analysis is done
11 for studies recording analyte concentration along with
12 color. Now, that's important.

13 A lot of studies may have reported only
14 the analyte concentration, and we can't analyze for
15 color unless the authors either initially reported it
16 or we were able to recover that data from the authors
17 subsequent to a paper's publication.

18 There are three methods of analysis that
19 we used. These are statistical techniques that we
20 used through the analysis. I'll go through these in
21 a minute. But they include things like analysis of
22 variance, when we had two comparison groups and two

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1 piece procedures when we had three or more.

2 And a linear regression, we had
3 independent and dependent variables are both
4 continuous in a racial level data.

5 Next slide, please.

6 This is a one slide summary of these five
7 small-n studies. You see they've started in the early
8 90's and up through the Kronstrand study at the
9 bottom, published recently in 1999. The n's refer to
10 the number of subjects, 20, ten, 15, nine subjects.

11 And the analytes refer to the kinds of
12 drugs that were being examined in the hair by these
13 respective authors. What we did is a secondary data
14 analysis, taking those original articles and those
15 original data points, and subjecting them to
16 additional tests to see if there were any associations
17 in those early works with hair color and with drug
18 concentrations.

19 Those statistical tests included analysis
20 of variance, Tukey's HSD, and some linear regression.
21 Significant question mark as the column total there
22 refers to after the test, did we find any significant

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1 effect?

2 And you see for four of the five, we did
3 not. The fifth one, the Kronstrand study actually
4 does show a strong significant effect. The
5 significance ranges are on there. We use an a priori
6 alpha of .05. Most of those are nowhere close. The
7 Kronstrand study is a departure from that.

8 Can we have the next slide, please.

9 This is just the summary of basically what
10 I just said, four of the five reviewed small-n studies
11 do not show a statistically significant effect
12 associated with color for either cocaine or heroin.

13 Now, why is this a likely result? Why
14 would we expect to see this? Well, we have small-n
15 studies, very small-n studies. And initially, I think
16 the authors, when they reported their studies, looked
17 at mean values and just reported, "Well, the mean is
18 bigger here than it is here."

19 The use of mean values is typically a very
20 poor measure of central tendencies since these scores
21 are very sensitive to extreme scores. High values for
22 dispersion mitigate all the systematic mean

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1 differences, especially in these small-n studies.

2 And of course, not all influencing
3 variables can be controlled or even enumerated in a
4 laboratory design study, and hence the need for
5 epidemiological research.

6 The Kronstrand's study has significant
7 results may indeed be due to unique features of
8 codeine. We don't know yet. Tommy, just a moment
9 ago, suggested some alternatives that included some
10 important analytical differences of what the lab does
11 that may account entirely for this particular effect.

12 May I have the next slide, please.

13 I'm going to spend just a few minutes
14 reviewing what are characterized as large-n studies.
15 We have five data sets here, each of which has 70 or
16 more cases.

17 Next slide.

18 These studies contain approximately 2,900
19 data points. Currently, we have about 100,000 cases
20 right now in our database, and I don't have all of
21 that analyzed. But we have substantially more than
22 the small-n studies.

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1 The advantage of this is that generally
2 larger-n studies provide a more stable database, and
3 they reduce the likelihood of a beta error. Large-n
4 studies are also more likely to find significant
5 effects. They have higher statistical power, and they
6 allow a measurement of their strength.

7 Here's basically a list of the five
8 studies. One from Glasgow on MDMA and analogs. One
9 from Pinellas County, Florida on cocaine. One from
10 Las Vegas, Nevada, cocaine and cocaethylene
11 amphetamine. Another from Los Angeles, cocaine and so
12 on. University of South Florida, morphine study that
13 we recently concluded and I'll report on last.

14 All of these statistical analysis utilized
15 analysis of variance into these procedures.

16 The first study, the Glasgow study,
17 collected hair samples from volunteers who attended
18 rave parties. Hair samples were analyzed for the
19 presence of amphetamine, methamphetamine, and so on.
20 There were 232 subjects who donated the hair samples.
21 And the specimens were analyzed at two laboratories,
22 139 at the University of Glasgow and 93 at Tricho-Tech

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1 in London.

2 However, and unfortunately, hair color was
3 only recorded for the 139 specimens that were tested
4 at the University of Glasgow. Nevertheless, there
5 were no statistically significant relationships
6 between hair color and drug concentration.

7 The Pinellas County, Florida study. We
8 had specimens collected from adult probationers who
9 were asked to voluntarily participate in a six month
10 project. For each volunteer, at least monthly urine
11 and hair specimens were collected. Psychomedics
12 Corporation did do the hair analysis with RA, GC/MS,
13 and tandem MS confirmation.

14 We had a total of 589 hair samples, but
15 only about 95 were testing positive for cocaine. Hair
16 -- brown hair was the most prevalent color. And when
17 we looked at these 95 cases again, we found no
18 significant associations relating color to cocaine
19 concentration.

20 The data from 500 randomly selected
21 cocaine positive, and 500 amphetamine positive
22 subjects were collected and analyzed by the same

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1 techniques. Hair assays were performed for the parent
2 cocaine, and cocaethylene, and amphetamine by hair
3 color.

4 Hair color was arrayed over seven
5 categories, red, grey, blonde, light brown, medium
6 brown, dark brown, black. When you have this many
7 people involved, basically you have enough people in
8 each one of those categories for a sufficient
9 statistical power.

10 The hair specimens at extracts were
11 screened by radioimmunoassay, cocaine metabolites,
12 hair specimen extracts were confirmed by GC/MS. And
13 again, there were no significant relationships
14 uncovered for these analyzed drugs.

15 Out of these 998 people from the
16 Psychomedics Laboratory -- again analysis was done by
17 RA, confirmed with GC/MS, or GC/MS/MS. Samples were
18 taken as a consequence of employment, those people who
19 were applicants to employment.

20 Because this is an applicant test, only 72
21 tested drug positive. That's typical for pre-
22 employment screening procedures. Among these 72

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1 people, we had no statistically significant
2 associations between color and concentrations.

3 And finally, the last study -- one we just
4 concluded -- random study of 95 morphine positive
5 clients. Hair color was arrayed in five dimensions,
6 and curvature in two, curly and straight.

7 Statistical associations were tested by my
8 colleague, Tom Mieczkowski. He has an article in the
9 present Journal of Analytical Toxicology, and myself
10 presented here using a variety of statistical
11 techniques.

12 Analysis that I ran included non-
13 parametric Kruskal-Wallis one way analysis of
14 variance. It's actually a more powerful technique
15 when we can't make assumptions about the standard
16 normal distribution in the parent data set for a
17 population.

18 And even with this, we've again found no
19 statistically significant results either between hair
20 and -- hair color, rather, and morphine
21 concentrations, or curvature and morphine
22 concentrations.

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1 This is a one slide summary of each of
2 these five studies. You see in the first column, the
3 original place where the data was gathered. The n
4 refers to the number of people. This would be drug
5 positive that were analyzed. Analytes were the drugs
6 that we were looking for.

7 The test is a statistical test run on
8 these data to look for associations between color and
9 curvature, and drug concentrations and significance.
10 Again, question mark. They all were non-significant.

11 The significance ranges, as you see up
12 there, are way different from our priority cut off of
13 .05. Nowhere close.

14 Next slide.

15 So, as a summary, all of the large-n
16 studies in most of the small n-studies reviewed, do
17 not demonstrate a statistically significant effect
18 between hair color or curvature and drug
19 concentration.

20 Small-n studies were often initially
21 reported showing differences between mean
22 concentrations, but mean value comparisons can be

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1 deceptive. Significance cannot be determined by
2 visual inspection. That means they're sensitive to
3 extreme scores, and that mean differences cannot be
4 evaluated without consideration of deviation values.

5 And finally, codeine concentration may be
6 uniquely related to melanin, but effects are probably
7 small. In fact, in the Kronstrand study, I believe,
8 the most extreme effect showed that the difference was
9 less than one half of one nanogram.

10 Next slide.

11 I guess before I get into this slide, I
12 just want to make one additional comment. There was
13 another study that I did not summarize on here by Ben
14 Hoffman, who also had 1,800 people, and again found no
15 significant difference, no significant association
16 between hair color and drug concentration.

17 DR. HENDERSON: Where was that study from?

18 MR. NEWEL: I'll have to get the records.
19 I have the citation with me.

20 This is something completely different.
21 This is a little study that we have done outside of
22 this bias issue that I wanted to share with you.

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1 It has to do with external contamination,
2 and I think Tommy made some initial comments about
3 studies that they've done with external contamination.
4 We did this one with 110 undercover police officers
5 who logged their every day exposure to cocaine and
6 other drugs over a 60 day period.

7 The hair samples were analyzed for both
8 cocaine and benzococgoning by Psychemedics. In our
9 study, no officers were found to have drug
10 contaminated hair despite their frequent contact with
11 cocaine, drug paraphernalia, drug users, and their
12 environments.

13 That's all I have for you today. Thank
14 you for your attention.

15 DR. CAIRNS: Thank you, Richard.

16 If we can return to -- we just had done
17 the biased issues, the two slides on the biased issue.

18 Now, getting back to another theme and
19 that theme is the removal, the effective removal of
20 external contamination. Now, let me begin by just
21 outlining the analytical procedure whereby we do
22 washing of the hair.

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1 The first wash is an isopropanol wash, and
2 that wash is conducted mainly to remove any cosmetic
3 preparations that may reside on the external surface
4 of the hairs, such as gels, mousses, hair sprays.

5 The isopropanol is removed. The hair is
6 then placed in a phosphate buffer with agitation, and
7 there are three such phosphate buffer washes at 30
8 minutes each. After those, the hair is put into a
9 phosphate buffer for one hour again with agitation and
10 again for another hour. At that point, the hair is
11 dried and then sent for liquefaction or digestion.

12 However, I want to put on an additional
13 safeguard here on the washing procedure, and that is
14 that we also add a mathematical extrapolation as if we
15 were mimicing an additional five hours of washing.

16 Now, let me explain that. I'm going to
17 show you a graph. I understand where you're coming
18 from. I'm going to show you a typical wash profile
19 for an opiate user. Now, you'll see the yellow bar
20 diagram. The IPA wash is not analyzed in this
21 particular case. But the first buffer wash, which was
22 the half hour wash, contained 4.65 morphine. Removal

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1 from that buffer and placement in the next buffer for
2 30 minutes resulted in a wash value of 1.3 nanograms.
3 Then into the third wash buffer for another half hour,
4 0.54. Then buffer 4 is a one-hour wash with
5 agitation, and buffer 5 is another one-hour wash.

6 Now, I think you can see that the washing
7 sequence is such that each wash contains a diminishing
8 amount of morphine. And we're rapidly approaching a
9 plateau in buffer number 3, 4, and 5. To add an
10 element, a strong element of conservatism, we take the
11 fifth wash value, which is 0.52, and multiply that by
12 five. What we're saying here is that if we were to
13 wash five more hours, the drug concentration would
14 certainly not be greater than 0.5. It would probably
15 be less than 0.5. So, we multiply the 0.52 by five.
16 The hair is then dried, moves into digest and
17 confirmation, and has a value of 31 nanograms of
18 morphine.

19 Now, if you look under the heading
20 profile, what I'm going to do is the digest is 31.
21 I'm going to subtract from that five times the value
22 of buffer 5, which was 0.52. And, so the level after

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1 the extensive wash and the mathematical extrapolation
2 is 28.4.

3 So, what we've done is to add a highly
4 conservative buffer zone as if we were washing five
5 more times. Now, that's important, because when I
6 show you the profile for a soaked hair, a deliberately
7 contaminated hair, you will see the fundamental
8 differences in profile.

9 Now, here's the soaking experiment. We
10 took 33 different hair samples. We soaked them for
11 one hour at room temperature in an aqueous solution
12 containing 1,000 nanograms of morphine per milliliter.
13 We applied the wash procedure, that is the 3.75 hours
14 of washing, and applied the mathematical extrapolation
15 of five more hours, and all samples were negative.
16 But let me show you a typical profile.

17 This is the decontamination profile for a
18 deliberately contaminated soaked hair one hour in
19 aqueous morphine. Now, in this case, we analyzed the
20 isopropanol wash for this experiment, and you'll see
21 that the isopropanol wash, the wash was only 1.2.
22 However, the first buffer, that is the half-hour

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1 washing, 480 nanograms; the second buffer half-hour
2 washing, 98.1 nanograms morphine; the third buffer,
3 30.9; the fourth buffer, 12.9; the fifth buffer, 7.2.
4 This sample, externally, contains a lot of morphine.

5 Then we digest -- dry and digest the
6 sample, we find we have 20 nanograms in the digest.
7 So, if we perform our routine wash criteria, you have
8 the digested 20 minus five times the last wash, which
9 is 7.2, would actually result in a value of minus
10 16.3, showing you how conservative the analytical
11 extrapolation procedure is. We've overcompensated.

12 But if you look at the profile here, the
13 washes contain basically a lot more than the digest.
14 This is a typical contamination profile. The previous
15 profile was a typical user profile. So, we are able,
16 clearly, to use the wash procedure to distinguish or
17 differentiate a user from a contaminated hair.

18 Now, the sweat study. We were asked to
19 respond with this type of study, and it's in volume 3.
20 Here we took three groups of 13 different hair
21 specimens and we soaked at room temperature for 15
22 minutes in a chloroform solution containing this time

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1 10,000 nanograms of morphine and 10,000 nanograms of
2 the metabolite 6-MAM.

3 The specimens were dried, they were then
4 put in contact with synthetic sweat for time periods
5 one, three, and six. So, 13 samples in each of these
6 time zones. The Psychomedics wash procedure applied
7 as I've outlined, 3.75 hours of washing and an
8 analytical extrapolation of five additional hours.
9 The results were that all 39 samples were negative.

10 Now, we were also asked to comment on the
11 cosmetic treatment; that is, can you affect the hair
12 testing result. Data would show that certainly
13 perming, relaxing, and to a lesser extent dyeing of
14 the hair, could reduce the amount. However, the
15 samples at risk if such procedures were performed
16 would only be those samples that are existing between
17 two nanograms and 2.6, because such treatment would
18 take them below the cutoff.

19 So, a calculation of the morphine
20 positives that we have in our database, it would only
21 affect about three percent of all positive heroin
22 tests. And you compare that with a urine test where

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