APPENDIX D

Hair Analysis Bibliography

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http://www.doctorsdata.com/RESPONSE.HTM (Initial response to the recent JAMA article on hair analysis, dated January 8, 2001)

http://www.ctq.qc.ca/icpms.html (Centre de Toxicologie du Quebec's Interlaboratory ICP-MS Comparison Program)

APPENDIX E

Meeting Agenda

Agency for Toxic Substances and Disease Registry
Division of Health Assessment and Consultation

Hair Analysis: Exploring the State of the Science

Agenda

Day 1 **Tuesday, June 12, 2001**
Discussing the State of the Science in Hair Analysis

8:00 AM	Registration	
8:30 AM	Introductory remarks	*Robert Amler, MD* *ATSDR Chief Medical Officer*
8:45 AM	Purpose of meeting and review of the charge	*Allan Susten, PhD, DABT* *Assistant Director for Science, DHAC*
9:00 AM	Impetus for panel discussions—a case example	*Deanna K. Harkins, MD, MPH* *Medical Officer, DHEP*
9:10 AM *Panel Chair*	Introduction of panelists	*LuAnn White, PhD, DABT*
9:20 AM	General physiology of hair—an overview	*Robert Baratz, MD, PhD, DDS*
9:40 AM	*Topic #1*: Analytical methods	*Panelists*
10:30 AM	Break	
10:45 AM	*Topic #1*: Analytical methods (continued)	*Panelists*
11:30 AM	Observer comments	
12:00 PM	Lunch	
1:00 PM	*Topic #2*: Factors influencing the interpretation of analytical results	*Panelists*
3:15 PM	Break	
3:30 PM	*Topic #3*: Toxicologic considerations	*Panelists*
4:45 PM	Observer comments	
5:15 PM	Adjourn	

(over)

Day 2 **Wednesday, June 13, 2001**
Developing Recommendations

8:00 AM	Review of day 1 issues	*Panel chair*
8:15 AM	*Topic #4*: Data gaps and research needs	*Panelists*
9:00 AM	*Topic #5*: Identifying scenarios for which hair analysis may be appropriate	*Panelists*
10:15 AM	Break	
10:30 AM	Observer comments	
11:00 AM	Conclusions/recommendations	*Panelists*
12:30 PM	Adjourn	

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Hair Analysis: Exploring the State of the Science

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APPENDIX G

Post-Meeting Observer Comments

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Comments Concerning the Interpretation of Hair Analysis

I have used only data from hair analysis to help determine when an exposure occurred (see Item 1). There are too many variables to use hair data for any other purpose (see Item 2). I have commented on several instances in which hair data had been misused/misinterpreted by citizens and health care providers. Example: I received a call from a concerned parent. His son's symptoms were as follows: dizziness, poor skin color, poor mental acuity, and blackouts (petit mal seizure like symptoms). A physician had analyzed his son's hair for metals and recommended chelation therapy at a cost of $6,000. His son's hair levels were within levels typically reported for control groups in hair analysis studies. Neither a source nor a pathway had been identified. No one else was in the area was having similar health problems. Their water was not contaminated. I told the parent to get a second opinion. Additional testing was needed to determine his son's health problems; hair analysis was inadequate. Moreover, chelation therapy is not risk free. I suggested the closest Association of Occupational Environmental Clinics clinic or a pediatrician trained to diagnose neurological symptoms before proceeding with chelation therapy.

General Questions (page 2)

1. When is it appropriate to consider hair analysis in assessing human exposures to environmental contaminants?

COMMENT: If a source and pathway have been identified, hair analysis <u>may</u> provide information concerning episodic exposures (i.e., frequency and duration of exposure).

2. When is it inappropriate to consider hair analysis in assessing human exposures to environmental contaminants?

COMMENT: Information concerning sources, pathways, etc. (i.e., is exposure plausible), of interest to ATSDR is required before attempting to interpret hair data. Interpretation of data from hair analysis in the absence of environmental data is conjectural.

3. What data gaps exist that limit the interpretation and use of hair analysis in the assessment of environmental exposures? What research is needed to fill these data gaps?

COMMENT: Internal sources of metals detected in hair need to be distinguished from external sources.

COMMENT: External sources of arsenic need to be distinguished (e.g., air, food, water, medicinals, and hair dyes). Is there a hazardous waste site involved?

COMMENT: Analytical methods that result in elimination of intra- and inter-laboratory data variability are needed.

Specific Questions

4. Topic #2 (page 3)

Factors Influencing the Interpretation of Analytical Results.

COMMENT: This section lists many of the factors that confound interpretation of hair data. I agree with Dr. Baratz's comment: I do not want information that I cannot interpret. Even under the best circumstances, hair data are exceedingly difficult to interpret. In cases where hair levels exceed levels expected in a population, additional information is needed.

5. Topic #3, Toxicologic Considerations (page 4)

Is information available defining "normal" ranges of chemical concentrations in hair that have physiological and health significance?

COMMENT: Terms such as standard or normal hair levels of metals or reference ranges for metal levels in hair need to be carefully defined—i.e., what constitutes normal? All reference values for hair need to be representative of the population being evaluated. For example, groundwater levels of arsenic (e.g., 100 ppb) have been reported to be elevated in some areas of Utah, Michigan, and Maine. Hair levels of arsenic in these areas are likely to be greater than hair levels in areas with low levels of arsenic in groundwater (e.g., 2 ppb).

COMMENT: What do hair levels above a reference value mean? How will hair data be interpreted? Reference values are frequently used for purposes for which they were not intended. A law firm sent a letter to the U.S. EPA citing the CDC lead guidance as a basis for not conducting an environmental investigation requested by EPA. The letter stated that the blood lead levels in the community were not above 20 microgams per deciliter (µg/dL) and did not consistently exceed 15 µg/dL; therefore, an environmental investigation was not needed.

Michael Schaffer
Psychemedics Corporation

- Partial listing of cases demonstrating judicial acceptance of the Psychemedics hair analysis method.
- Information on hair testing and racial or color bias.
- Information on the effectiveness of Psychemedics washing procedures for ruling out external contamination

PARTIAL LISTING OF THOSE CASES DEMONSTRATING JUDICIAL ACCEPTANCE OF THE PSYCHEMEDICS HAIR ANALYSIS METHOD

A. Employment Cases

Scott v. The City of New York. et al., Civil Action No. 98-C V-1902 (ERK), (U.S.D.C., Eastern Dist. NY, March 21, 2001), a case involving a claim of constructive discharge based on race and gender, was dismissed via summary judgment. In making its decision, the court relied on the plaintiff's hair test result, which was positive for marijuana, as well as plaintiff's prior admission of use.

In Jones et al. v. City of Chicago, Civil Action No. 99 C 8201, (U.S.D.C., Northern Dist. IL, November 28, 2000), a case involving claims of race bias in hair testing, the United States District Court granted summary judgment in favor of the City of Chicago and dismissed the case. The Court found that not only was some of the evidence inadmissible, but also that "the remaining admissible evidence would be insufficient for a trier of fact to find that the [Psychemedics] hair test is more likely to result in false positive results for African-American applicants that for white applicants..."

In Cruse v. Whirlpool Corp., Civil Action No. 99-2129, (U.S.D.C., Dist. AR, June 23, 2000), the United States District Court found no merit to plaintiff's allegations that the Psychemedics hair test ("RIAH") was racially biased against African Americans and, as such, granted the defendant's motion for summary judgment. "Summary judgment is not appropriate unless all the evidence points toward one conclusion . . ." (citing Hardin v. Hussman Corp., 45 F. 3d 262 (8th Cir. 1995)). The defendant's expert offered through written testimony that "there is absolutely no scientific support for the notion that plaintiff's test result could be positive because of her race." The court considered the plaintiff's failure to offer any statistical evidence in support of her claim of racial bias in granting the defendant's motion.

In Gregory Hicks et al. v. City of New York et al., Index No. 119154 (1999), the Supreme Court of the State of New York upheld the termination of three officers through the use of Psychemedics' hair analysis drug testing.

In Brinson v. Howard Safir, et al, 680 N.Y.S. 2d 500, 255 A.D. 2d 247, (N.Y.A.D. 1 Dept. 1998), the New York Supreme Court Appellate Division upheld the lower court's determination of the accuracy of Psychemedics hair testing performed on an NYPD officer. Subsequent to this decision, the plaintiff filed suit in federal court, (E.D.N.Y. Civil Action No. 98-CV-2784 (ERK)(JMA)), claiming, in part, that he had not been afforded procedural due process before he was terminated from his position. The court, in granting the defendants' motion for summary judgment, found that the plaintiff was afforded, and took advantage of, every opportunity to appeal his dismissal. The court also referenced the Appellate Division's holding that "there was reasonable suspicion to order the testing...and there was no reason to doubt the accuracy of the test results."

In Matter of Brown v. City of New York, 250 *AD2d* 546, 673 NYS2d 643, (1998), the New York Supreme Court Appellate Division affirmed the New York Police Department's discharge of a New York City police officer for failure to pass a Psychemedics hair analysis drug test. Claims of contamination and inadequacies of testing were determined to be devoid of merit.

In Nevada Employment Security Department et al. v. Cynthia Holmes, 914 P.2d 611 (Nev.1996), the Nevada Supreme Court held the following with regard to a stand alone Psychemedics hair test utilized to deny unemployment benefits:

> We acknowledge that there are, arguably, no certainties in science. See Daubert v. Merrell Dow Pharmaceuticals, Inc., _U.S._, 113 S.Ct. 2786, 2795 (1993). Nonetheless, we conclude that RIA [hair] testing especially when coupled with a confirmatory GC/MS test, is now an accepted and reliable scientific methodology for detecting illicit drug use.
>
> ...we conclude that Holmes' ingestion of cocaine, subsequently proven by the RIA screening and confirmatory GC/MS test constitutes misconduct within the definition of NRS. 6 12.385.

In Bass v. Florida Department of Law Enforcement, Criminal Justice Standards and Training Commission. 627 So.2d 1321 (Fla. Dist. Ct. of Appeals, 1993), the plaintiff, a corrections officer, appealed from the decision of a hearing officer that her criminal justice certification should be revoked based on a positive urinalysis. The Court in Bass held that evidence of a negative Psychemedics hair analysis was erroneously excluded and that "the radioimmunoassay analysis of human hair to determine cocaine use is generally accepted in the scientific community." On remand, the hearing officer disregarded the hair analysis results as well as a subsequent negative urinalysis result and again recommended the revocation of the plaintiff's certification. The plaintiff appealed a second time in Bass v. Fla. Dept. of Law Enforcement, 712 So. 2d 1171 (Ct. App. Fla 1998), in which case the Court affirmed the ruling of the lower court holding that hair analysis should be admitted as it is "precisely the tool which is used when there is a claim of error in a urinalysis for cocaine."

B. Parole Revocation

In United States v. Medina, 749 F. Supp. 59 (E.D. N.Y. 1990), the court ordered a hair test to determine if a probationer, in a parole revocation hearing, had violated his parole by utilizing drugs in the preceding months. In revoking parole, after a positive Psychemedics hair test, the court found that:

> Extensive scientific writings on RIAH hair analysis establishes both its reliability and its acceptance in the field of forensic toxicology when used to determine cocaine use.

In his decision, Judge Weinstein, the author of a treatise on evidence, analyzed the admissibility of hair analysis in the Medina case under the Federal Rules of Evidence as well as the older Frye evidence standard and concluded hair analysis was admissible under both. In addition, Judge

Weinstein took judicial notice of extensive writings which support the acceptance of the reliability of RIAH.

C. Unemployment Insurance Appeal Board/Administrative Law Judge Decisions

The decisions of the Department of Labor to deny benefits to claimants who are terminated after receiving positive hair test results for drugs of abuse are routinely upheld by Administrative Law Judges and the State's respective appeal or review boards. The decisions are upheld based on the established reliability of Psychemedics' hair analysis, which is demonstrated in numerous peer reviewed scientific publications.

In In the Matter of Patrick Forte, New York Appeal Board No. 477610 (4/7/00), the Unemployment Insurance Appeal Board upheld the determination of the Administrative Law Judge, (A.L.J. Case No. 097-0852 1), in affirming the decision of the Department of Labor to disqualify a probationary police officer, ("claimant"), from receiving benefits. The claimant was disqualified after his termination due to willful misconduct. The claimant submitted to a hair test, which results were positive for cocaine use. The claimant argued that either the hair sample was contaminated due to his exposure to crack cocaine vapors, or that he "passively ingested" small amounts of cocaine. The Appeal Board found that due to the fact that the claimant's results showed a cocaine level 4-8 times the cutoff level and that benzoylecgonine, a cocaine metabolite, was also detected, it was unlikely that the claimant "passively ingested" cocaine. The Appeals Board recognized that it had previously been demonstrated to the Board successfully that Psychemedics' laboratory's washing techniques eliminated the issue of external contamination.

In In re Claim of Delbert Otto, B 95-02542-000 (1996), the State of Ohio Unemployment Compensation Board of Review, ("Board of Review"), overturned the Hearing Officer's ruling that the claimant was discharged without just cause and was entitled to benefits. The Board of Review found that expert testimony demonstrated the reliability of the Psychemedics hair test which detected quantities of marijuana in the claimant's hair.

See also In the Matter of Otis K. McBride, State of New York, A.L.J. Case No. 099-17766 (1999); In the Matter of James Rawls, State of New York, S.S.A. No.120-42-0562 (1998); In the Matter of Claimant, State of Indiana, Case No. 93-1BA-l lOB (1994); and In the Matter of Brian J. Berrigan, State of New York, Index No. 121899 (1998).

D. Arbitrations

Hair analysis has been upheld in arbitrations between Anheuser-Busch, Inc. and its unions:

- In an October 1999 decision, the collection of body hair for analysis was upheld.

- In a July 1999 decision, union claims of improper specimen collection, and age, race and gender bias related to slow hair growth were found to have no merit and the issues were resolved in favor of the Company.

- In an August 2000 decision, it was determined that random hair testing of employees in safety sensitive positions did not violate their state constitutional rights to privacy. The Psychemedics hair test was deemed "a reliable method for detecting employee drug use, [which] therefore served to further the Employer's legitimate safety interest."

In United States Steel, A Division of USX Corp. and United Steelworkers of America, Local 1557, Case No. USS-38, 287 (1999), the Arbitrator ruled:

> We find that hair testing for drugs is legitimate under the LCA and scientifically valid. Psychemedics' wash procedures are effective in removing environmental contamination. The 5.0ng/10mg cutoff level for cocaine is appropriate in light of field studies. There was no bias here on the basis of race or hair color. The chain of custody was unbroken. The Company has satisfied us that Grievant ingested cocaine during the period covered by the Last Chance Agreement. That material violation of the LCA was proper cause for discharge.

Hair analysis was also upheld in US Steelworkers Local 4134 & Lone Star Steel Co., Case No. D22-96 (1997); Battle Mountain Gold Co. & Operating Engineers Local 3 (1998); Cooper Tools and United Automobile, Aerospace, Agricultural Implement Workers of America, AFL-CIO, Local 1774, Grievance No. 005 (2000); and United States Steel, A Division of USX Corp. and United States Steelworkers of America, Local 1014, Case No. USS-41, 820 (2001).

Hair Testing and Racial or Color Bias

Every large scale population study dealing with race and or color bias has concluded that hair color or race as factors do not lead to any statistically significant variations that would create a "bias." Several studies utilizing Psychemedics' methodology, (extensive washing of the sample, complete digestion and removal of melanin, the color component of hair), have established that there is no systematic bias occurring with this specific technology.

A large study on the issue of possible racial bias and drug testing was originally reported in *Forensic Science International* in 1993. The study involving 1200 real world cases showed that with all three methods of reporting utilized, (self-reports, urine testing and hair analysis) the same positive percentage ratio between Caucasians and African-Americans was achieved.

An even larger study, published in the July 1999 *Journal of Occupational and Environmental Medicine* by Dr. Benjamin Hoffman, compared the 1997 results of hair and urine tests on over 1800 black and white candidates for a large municipal police force. Again, no racial bias was found comparing hair testing to urine testing.

In a 1999 study, published in Drug Testing Technology – An Assessment of Field Applications, "An Analysis of the Racial Bias Controversy in the Use of Hair Assays" concluded from the analysis of numerous data sets that any effect of hair color or race would be negligible as a factor in the outcome of a hair test. The authors of the study reported that in side-by-side comparison with hair, urine and self-reports, the racial differential in positive rates compared to self-reports was actually greater in urine than in hair analysis.

In January 2000, Dr. Mieczkowski's meta-analysis of all available published studies that included data on drug test results matched to race or hair color was published in *Forensic Science International.* These studies included European research where participants were dosed with known quantities of drugs. In no instance, in any study, was a statistical bias shown to exist.

Most recently, in the *Bulletin of the International Association of Forensic Toxicologists*, an analysis of over 56,000 cases showed no significant relationship between hair color and a likelihood to test positive for cocaine.

The "potential" to create bias issues exists with any specimen, including urine– as any element that affects the matrix could arguably lead to a "biased" result.

A) Diet has a significant impact on urine excretion. Some ethnic diets may greatly influence a urine result.

B) Patterns of water retention/urine excretion in women are influenced by menstrual cycles that may create longer detection times in women.

C) Body weight and size influence the amount of drugs that would be found in urine.

D) Certain medications influence urine output and drug excretion rates.

E) The ability of the body to effectively process drugs is influenced by age which increases retention times.

F) Water intake and activity dramatically influence drug excretion rates in urine. A sedentary person in a wheelchair could retain drugs in urine significantly longer than an athletically active person who hydrates his or her system.

None of these "potential bias" issues have presented much of a problem in workplace testing. This is largely due to the fact that normal biovariability between individuals overwhelms any single element and, of course, a person claiming any sort of bias would first have to admit drug use.

[Note: Dr. Schaffer provided copies of the following supporting journal articles]

Hoffman B. Analysis of race effects on drug-test results. Journal of Occupational and Environmental Medicine. 41(1999) 612-614.

Mieczkowski T and Newel R. An evaluation of patterns of racial bias in hair assays for cocaine: black and white arrestees compared. Forensic Science International. 63 (1993) 85-98.

Mieczkowski T and Newel R. An analysis of the racial bias controversy in the use of hair assays. In: Drug Testing Technology: Assessment of Field Applications (ed: Mieczkowski, T.), CRC Press (1999), Boca Raton, pp. 313-348.

Mieczkowski, T and Kruger, Michael. Assessing the effect of hair color on cocaine positive outcomes in a large sample: a logistic regression on 56,445 cases using hair analysis. Bulletin of the International Association of Forensic Toxicologists. (2001), 9-11.

Environmental Contamination

Psychemedics employs several independent approaches which in combination, rule out the possibility of a positive result from external sources.

a) The rigorous chemical washing of hair for extended periods of time.

b) The analysis of the contents of these washes followed by a comparison of the drugs remaining in the hair.

c) Measurement of metabolites, the unique compounds created by the body's processing of the drugs. These metabolites are normally not present in the environment or in smoke. For example, marijuana smoke does not contain carboxy THC - the metabolite that Psychemedics identifies in marijuana positives.

d) Use of cut-off levels with hair, as with urine, to prevent any passive internal exposure from producing a positive result. Because of the constancy of drug concentrations in hair, these cut-off levels more accurately reflect use, and are therefore safer than those used by urinalysis.

Several studies by Dr. Thomas Mieczkowski of the University of South Florida[1] dealt with the real world issue of external contamination and its removal by appropriate wash procedures. The studies concerned the passive contamination of undercover narcotic officers who, in the course of their duties, had continuing and extensive contact with cocaine, operated in cocaine rich environments and interacted frequently with cocaine users and cocaine dealers. The officers handled cocaine in the process of buying and selling and when they made arrests or seized contraband.

These undercover officers effectively mimicked drug users in all respects, except usage. In his studies, Dr. Mieczkowski found that the officers had some amount of detectable cocaine on the outside of their hair as a contaminant. However, even in this extreme contamination scenario the hair was easily cleansed. Dr. Mieczkowski concluded that the commercial wash procedures utilized (Psychemedics) were effective methods for removing external contamination from hair and that external contamination did not present a difficult problem with properly performed hair analysis.

In a contamination study utilizing an early Psychemedics wash procedure researchers exposed volunteers to crack smoke in a small, unventilated room (2.5 x 3 x 2.5 m) and exposed cut hair to the equivalent of smoke vapors from 5000 lines of cocaine in closed beakers. In all cases, after washing, the exposed contaminated hair tested negative. The authors concluded that deposition of cocaine from even these

[1] Passive Contamination of Undercover Narcotics Officers by Cocaine: An Assessment of Their Exposure Using Hair Analysis. Microgram, 1995.

Distinguishing Passive Contamination from Active Cocaine Consumption: Assessing the Occupational Exposure of Narcotics Officers to Cocaine. Forensic Science International (84) 1997.

extreme contamination scenarios was washable.[2] Also in the study, hair from admitted cocaine users tested positive, hair from non-users tested negative and hair from non-users who admitted being present in crack environments also tested negative. It is not likely that any employee would claim an exposure scenario greater than being in an enclosed room while 5000 lines of cocaine were vaporized or handling cocaine more frequently than an undercover narcotics officer or evidence technician.

Most recently, in a contamination study presented at the Society for Forensic Toxicologists this past October, Psychemedics' extensive wash procedures were compared to the short wash results obtained in an earlier cocaine contamination study and were shown to be effective at distinguishing contaminated hair from user hair.

Due to the hyper-sensitivity of urine tests, it is well recognized by the scientific community that false positives due to passive internal exposure to drugs are far more likely for urinalysis than for hair analysis (e.g., the opiate false positive problem of urinalysis due to poppy seed ingestion). The Department of Health & Human Services found that over 87% of urine opiate confirmed positives were overturned by medical review officers because ingestion of poppy seeds as well as some medications could cause urine opiate cutoff levels to be exceeded. The studies of Dr. Hans Sachs and those of others have shown that even the massive ingestion of poppy seeds is incapable of producing interpretive false positive hair analysis results. Additionally, the hair of heroin users contains stable amounts of the heroin metabolite, 6 MAM (an absolute marker of heroin). Testing for the 6 MAM metabolite in urine is required under the amended NIDA urine guidelines, (the amended guidelines also increase the cut off levels from 300 ng/mL to 2000 ng/mL). Unfortunately, while 6 MAM is identifiable in hair for months, it has an extremely short half-life in urine and for all practical purposes will be detectable at best only in persons who use heroin <u>on the day of</u> <u>their urine test</u>. This makes the confirmation of heroin use extremely problematic for urine testing creating false negatives.

NIDA scientist, Dr. Cone, experimentally demonstrated that as little as one-hundredth of a line of cocaine (i.e., 1 or 2 mg) can produce interpretive false positive urinalysis results.[3] These small quantities can be inadvertently ingested by a non-drug user (e.g., a spouse) who may be in the constant presence of a drug abuser. In contrast to the resistance of hair to drug penetration, the lungs and gastrointestinal tract have absolutely zero resistance. In actual fact, drugs are transported by active transport mechanisms into the interior milieu, i.e., by breathing or by active membrane processes. Such active internalization can cause interpretive false positive urine results by minute amounts of cocaine if the timing of the test is in close proximity to the passive ingestion.

Unlike hair, there is no method to remove this contamination from urine or to differentiate between active drug use and unknowing exposure to a drug that may rise above cut off levels, e.g., spiked food or drink. Unlike urine, hair can be segmented to substantiate or refute these claims. Additionally, a completely new hair sample can be obtained that will replicate the same time frame of the original sample eliminating concerns or claims of sample mix-up. New samples replicating the same time frame cannot be obtained with urine as most drugs are completely flushed from the system in a couple of days.

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[2] Hair Analysis of Cocaine: Differentiation Between Systemic Exposure and External Contamination. Journal of Clinical Pharmacology, 1992.