

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

RONNIE JONES, ET AL.,

Plaintiffs,

v.

CITY OF BOSTON, ET AL.,

Defendants.

CIVIL ACTION
NO. 05-11832-GAO

**EXPERT REPORT OF J. MICHAEL WALSH, PH.D.,
SUBMITTED BY PLAINTIFFS**

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I. QUALIFICATIONS

- 1.** My name is J. Michael Walsh. I am an expert in workplace drug detection technologies and workplace drug testing policy. My education includes a Bachelor of Science degree in Experimental Psychology from the University of Maryland (1966), and a Masters degree (1970) and a Doctoral degree in Psychology (1972) from the American University in Washington D.C. I am licensed to practice as a Psychologist in Maryland (License No. 00839), Delaware (License No. 1-0000539), and Florida (License No. PY-6262). I am an active member of various professional organizations including the American Academy of Forensic Sciences, The International Association of Forensic Toxicologists, the International Council on Alcohol, Drugs and Traffic Safety, and the American Psychological Association.
- 2.** I have authored more than 100 scientific publications including book chapters, peer-review journal manuscripts, monographs, and other articles (*see* attached CV in Appendix A). I have provided testimony in a variety of workplace drug testing cases in the United States and Canada including many U.S. federal cases challenging the federal employee drug-testing program and in other cases involving corporate drug testing programs.
- 3.** I started my research career as a bench scientist at the U.S. Naval Medical Research Institute in Bethesda, Md. where I spent 14 years (1966-1980). During that time I conducted extensive research focusing primarily on the behavioral effects of drugs on performance. Subsequently I was employed at the National Institute on Drug Abuse ("NIDA") for nearly 10 years (1980-1989) directing workplace drug policy initiatives and as the Director of Applied Research programs.

4. In 1989 I was asked to serve as the Executive Director of The President's Drug Advisory Council in the Executive Office of the President of the United States. I served for nearly 5 years in this White House position until my retirement from Federal Service in 1993. During my 27 years of Federal service I received numerous awards including the Distinguished Service Medal (the highest civilian award given by the U.S. Department of Health and Human Services) for my efforts in developing the Federal Drug-Free Workplace Programs. In 1993 I retired from Federal service and formed The Walsh Group, P.A., a research and consulting firm. For the last 15 years The Walsh Group (www.walshgroup.org) has focused on workplace drug testing, drug policy, drugs in sports, drugged driving and the development of new drug detection technologies.
5. For the last 25 years my work and research in general have been focused on the use of drug detection technologies in the workplace, in amateur and professional sports, in schools, in drug abuse treatment programs, in detecting drugged drivers, and in the development of new drug testing technologies.
6. During the early 1980's I was assigned as the liaison between NIDA and the Department of Defense to assist in the implementation of a worldwide drug-testing program of all U.S. military personnel. Subsequent to that experience I became involved in the policy development for the use of drug testing in major corporations here in the United States. In 1986 President Reagan issued an Executive Order (EO #12564) to establish a Federal "Drug-Free Workplace" program including drug testing for more than two million civilian employees across all federal agencies. The responsibility for establishing the scientific and technical standards for the drug-testing program was assigned to the Department of Health and Human Services and was delegated to NIDA.

7. As the Director of Applied Research and workplace initiatives at NIDA I was assigned the task to develop the scientific and technical guidelines for this new federal drug-testing program. I formed and chaired a task force of substance abuse, drug testing, and forensic experts that worked for nearly two years to develop the "Mandatory Guidelines" for federal drug testing programs. These "Mandatory Guidelines" or so-called "NIDA Guidelines" have been used for all federal drug testing programs since 1988.
8. During this time I was also directed to establish a new laboratory certification program (the National Laboratory Certification Program ("NLCP")) to specifically accredit laboratories to perform forensic drug testing on specimens collected under federal regulatory authority. The NLCP program has been in place certifying commercial laboratories since 1988. I also chaired an Interagency Coordinating Group ("ICG") to work with the Department of Justice and the Office of Personnel Management to establish a model plan for the policy implementation of drug testing programs in all federal entities. I also coordinated with the Department of Transportation to integrate the "Mandatory Guidelines" into the Federal regulations for the industries regulated by the Department of Transportation (*i.e.*, the airlines, the railroads, mass transit and the trucking industry).
9. During the early 1990's the federal-wide oversight responsibilities for drug testing programs, along with the NIDA applied research staff, were transferred from NIDA to the newly created Substance Abuse and Mental Health Services Administration ("SAMHSA"). Since my retirement from government service I have continued to conduct research in this area and serve as a consultant with SAMHSA and the Department of Transportation on drug testing technology and workplace policy issues.
10. The hours used in producing this report are billed monthly through the Walsh Group, P.A. My hours are billed at my billing rate of \$250 per hour plus reimbursement for direct costs.

II. ASSIGNMENT

11. I have been asked by counsel for the Plaintiffs to evaluate whether Psychemedics's hair analyses can accurately and reliably distinguish illegal drug use from environmental exposure, and, relatedly, whether Defendants' reliance on Psychemedics's hair test as the sole determinant of illegal drug use (*i.e.*, a policy violation) by its employees and applicants is scientifically and procedurally sound.

III. SUMMARY OF OPINIONS

12. Psychemedics's ability to accurately, reliably, and conclusively distinguish illegal drug use from passive exposure is unproven, and subject to serious doubt within the scientific and drug policy communities.
13. Defendants' reliance upon Psychemedics's hair test as the sole evidence of illegal drug use is neither analytically sound nor procedurally reasonable.
14. These opinions are supported by the following facts:
- unlike other, more established forms of drug testing (*e.g.*, urinalysis, and blood testing) hair testing for drugs lacks agreed upon nationwide standards, national certification programs, and nationwide proficiency testing programs;
 - hair that is dark in color or damaged by chemical treatments can be especially susceptible to external contamination;
 - the amount of cocaine identified and quantified in hair during hair testing is extremely small, and presents challenges to the limits of hair testing technology;
 - the hair test conducted for the Boston Police Department program identified a disproportionate number of African-Americans as cocaine users;
 - Psychemedics, the laboratory that conducts the hair test relied upon by Defendants, made frequent, critical changes to its Standard Operating Procedures between 1999 and 2005;
 - these changes included repeated revisions to the criterion for a positive cocaine test;

- Psychemedics's laboratory and testing procedures are not subject to any routine, independent oversight to provide assurances of accuracy or reliability;
- Psychemedics's participation in independent proficiency testing is very limited;
- the Defendants did not properly evaluate whether Psychemedics's test was accurate or reliable;
- the Defendants routinely disregarded evidence that Psychemedics's test results were inaccurate, even when that evidence was generated by Psychemedics itself;
- the patterns of drug use detected by the hair test do not reflect established patterns of drug use nationwide; and
- for all of these reasons, and despite 20 years of political pressure supporting the hair test and millions of federal research dollars spent evaluating the hair test, the U.S. government has concluded that hair testing is not yet fit for use in federal workplace drug testing regimes.

IV. NOT ALL DRUG TESTING IS THE SAME.

15. In the scientific literature, blood and urine testing are well established and the anatomy and physiology of exactly how drugs get into blood and urine is well understood. Hair testing is a relatively new technology. The way in which drugs get into hair is relatively poorly understood. In hair some drug gets into the hair follicle via the blood, some is deposited through sweat, and some through the oily glands in the skin and hair. The scientific community is not really certain about the relative contribution of each of these pathways, and this lack of a fundamental understanding of exactly how drugs are deposited and retained in hair contributes to the potential for inaccuracies in the interpretation of hair test results. For example, we do know that some drug can get into the hair from external environmental exposure and become fully incorporated into the hair.¹ Once the drug becomes fully incorporated into the hair, laboratory analysis cannot conclusively determine how it got there.

¹ See, e.g., Romano, G., Barbera, N., Spandaro, G. and Valenti, V., Determination of Drugs of Abuse in Hair: Evaluation of External Heroin Contamination and Risk of False Positives, Forensic Science International, Vol. 131, 2003, pgs 98-102; Romano, G., Barbera, N., and Lombardo, I., Hair Testing for Drugs of Abuse: Evaluation of External Cocaine Contamination and Risk of False Positives, Forensic Science International, Vol. 123, 2001, pgs 119-129.; Kidwell, D.A., and Blank, D.L., Mechanisms of Incorporation of Drugs into Hair and the Interpretation of Hair Analysis Data, in Hair Testing for Drugs of Abuse, International Workshop on Standards and Technology, Cone, E.J., Welch, M.J. and Grigson-Babecki, M.B. Eds., National Institutes on Health Pub. 95-3727, U.S. Govt. Printing Office, Washington, DC 1995; Stout, P.R., Roper-Miller, J.D., Baylor, M.R. and Mitchell, J.M., External Contamination of Hair with Cocaine: Evaluation of External Cocaine Contamination and Development of Performance-Testing Materials, Journal of Analytical Toxicology, Vol. 10, October 2006, pgs. 490 – 500.

16. To cite some clear differences between blood, urine, and hair testing, the amount of drug or drug metabolite being measured in the hair sample is extremely small -- significantly less than typically found in blood or urine (by a factor of 1000). The scale of difference here is noteworthy. In the case of blood and urine the analytical technology is capable of detecting drugs in the nanogram per milliliter (*i.e.*, parts per billion) range with a high degree of accuracy and reliability. One nanogram equals one billionth ($1/1,000,000,000$) of a gram, a very small amount. Finding one nanogram of drug in one milliliter of blood or urine is roughly equivalent to identifying one specific second within a time-span of 27 years. In hair testing, the levels of drug being detected in hair are even smaller and laboratories are attempting to detect drugs at the picogram (*i.e.*, parts per *trillion*) level. In fact, Psychemedics's initial cutoff for cocaine is actually 500 picograms or 0.5 nanograms per milligram of hair. However, in all the marketing material Psychemedics states their initial cutoff for cocaine as 5 nanograms per 10 milligrams of hair. Stating the cutoff in 10 milligrams of hair rather than the more common forensic terminology, units per 1 milligram of specimen, is rather unusual, but it does allow Psychemedics to state the cutoff threshold in nanograms (*i.e.*, parts per billion) rather than picograms (*i.e.*, parts per trillion).
17. Laboratories routinely establish "Limits of Detection" -- referring to the lowest quantity of a substance that can be distinguished from the absence of that substance -- for each drug assay they use. However, attempting to detect extremely low levels such as parts per trillion pushes at the limits of the analytical technology. In my experience, when a laboratory is attempting to operate at very low levels close to these Limits of Detection the probability for error becomes maximized.

18. In addition to the very small quantities of drug being detected in hair, cocaine presents a unique problem for drug testing in hair. Because cocaine is a fine powder it can easily become airborne and can contaminate all the surfaces in rooms where it is being used or handled. It can also get onto the skin and hair of those who passively come in contact with the air or the surfaces in such a room where the drug has been used. Hair is a sink-trap for airborne contaminants. Think about being exposed to smokers in a bar and how your hair and clothes trap the smoke and smell after being in the presence of smokers. Research has shown that small children of cocaine users have cocaine concentrations in their hair comparable to their drug-using parents without ever ingesting the drug.²

V. ENVIRONMENTAL CONTAMINATION AND OTHER FACTORS CONFOUND HAIR TEST RESULTS.

19. Environmental contamination is a major issue for the determination of cocaine use in hair. This issue centers around the potential for a drug that is present in the environment to be transferred to the hair without intentional ingestion. This phenomenon is often referred to in the literature as “passive contamination.” As reported in a recent comprehensive review on hair testing³ most review articles on hair testing contain a section on “contamination” and confirm that the issue is a “central concern to the validity of hair testing.” Stout cites at least 30 review articles that have been published on the issue of “drug contamination” of hair since 1989, and states that all of the authors recognize the seriousness of the contamination issue. The single most important and controversial point in any analysis of the accuracy, reliability, and validity of hair testing is the risk of reporting a false positive result -- especially for cocaine -- due to external contamination.

² Smith, F.P., and Kidwell, D.A., Cocaine in Hair, Saliva, Skin Swabs, and Urine of Cocaine Users’ Children, Forensic Science International, Vol. 83, 1996.

³ Stout, P.R. Hair Testing for Drugs – Challenges for Interpretation, Forensic Science Review, Vol. 19 (2), July 2007, pages 70-84.

20. In addition to the contamination issue, there are two other potential confounding variables that need to be considered in this case: (1) the potential for bias in results due to hair color (dark black hair has repeatedly been shown to retain more drug than blond or grey hair)⁴, and (2) the potential impact of cosmetic treatments that damage the hair which can increase the risk of environmental contamination.⁵ Clearly these are both important issues for individuals of African American heritage. It has been known for many years that most drugs have an affinity to bind with melanin (pigment). Melanin is a substance that gives the skin and hair its natural color. In humans, those with darker hair have higher amounts of melanin. By contrast, those with less melanin have lighter or fair hair coloring. In general, the hair of Caucasian individuals will incorporate less drugs than the hair of African Americans.⁶ There are two major types of melanin found in hair: eumelanin and pheomelanin. Eumelanins are dark brown or black pigments. Pheomelanins are pigments that create red to yellow color in hair. While drug binding has been demonstrated to be greater in hair containing eumelanin than pheomelanin, the chemistry of why this happens is not well understood.⁷

⁴ Kidwell, D.A., and Smith F.P., Passive Exposure, Decontamination Procedures, Cutoffs and Bias: Pitfalls in the Interpretation of Hair Analysis Results for Cocaine Use, in Hair Testing for Drugs of Abuse, Pascal Kintz (Ed.), CRC Press, Boca Raton, FL, 2006, pages 25-72.

⁵ Kidwell and Smith (2006); Stout (2007).

⁶ Kidwell and Smith (2006).

⁷ Slawson, MH, Wilkins, DG, Rollins, DE, The incorporation of drugs into hair: Relationship of hair color and melanin concentration to phencyclidine incorporation, J. Analytical Toxicology, 22:406, 1998.

21. With regard to hair damage from cosmetic treatments such as hair dyes, straighteners, and perming products it has been demonstrated that hair-shaft damage increases drug binding whether from actual drug-use or passive exposure. Cosmetic hair treatments are big business in the United States and Kidwell and Smith have cited numerous studies showing that “the very characteristics of African hair that make it more susceptible to damage from combing, brushing, washing, etc. make it more susceptible to damage from cosmetic treatments and chemicals, as well, such as hot-curl straightening, perming, swimming pool water, bleaching, and dyeing.”⁸
22. Dozens of papers have been written in the scientific literature about these confounding variables (hair color, cosmetic damage etc.) and how they can affect hair analysis results.² From my reading of the research, I have come to the conclusion that there is no clear consensus within the scientific community, or a clear understanding of the dynamics and chemical processes of what is occurring to the physical properties of the hair sample when exposed to cocaine contamination. Therefore in my opinion it cannot be ruled out that these factors could play a role in the disproportionate identification of African American officers as cocaine users.

⁸ Kidwell and Smith (2006); Stout (2007).

² See, e.g., Kidwell and Smith (2006); Stout (2007).

23. Psychemedics claims that its proprietary wash procedures can remove external drug contamination from hair samples. However, over the last few years many researchers have demonstrated that while wash procedures can remove some of the cocaine present in hair, they cannot remove it all. Psychemedics obviously knows this and has acknowledged this fact by setting in place elaborate “wash criteria” which use ratios of parent cocaine to its metabolites to allow Psychemedics technicians to infer illegal drug use rather than contamination. These so-called “wash criteria” appear to be based on assumptions which in my opinion have provided a false security to Psychemedics and the Boston Police Department. The wash criteria are essentially unproven and do not take into account the impurities (*e.g.*, norcocaine and benzoylecgonine) found in street cocaine.
24. In preparing this report, I reviewed “strength” reports describing the makeup of the Boston Police Department by race during the time period 1999-2005.¹⁰ From these reports I noted that Caucasian officers made up roughly 65% of the force and African Americans approximately 25%, with Asian and Hispanic officers making up the remaining 10%. The relative percentages of white, black, Asian, and Hispanic officers have remained very consistent during the 6-year period. When I compared the relative percentages of officers testing positive for illegal drug use by hair testing analysis -- 62% of positive tests were African Americans, 35% white, and 3% Hispanic -- it was clear that a disproportionate number of African Americans were being identified as drug users.

¹⁰ These documents are labeled COB5794-5799, COB7026-7027, COB7032-7035, 35872-35970, PMD13471-13472, PMD13573-13575, and PMD14812-14813.

VI. DATA INDICATE THAT THE HAIR TEST GIVES POSITIVE RESULTS FOR THE PRESENCE OF COCAINE IN HAIR AT AN UNUSUALLY HIGH RATE COMPARED TO OTHER DRUGS AND TO KNOWN PATTERNS OF DRUG USE

25. I observed that cocaine was being detected by hair testing in the Boston Police program roughly 5 to 10 times as often as marijuana. For example, in 1999 there were 31 cocaine positives, 3 marijuana positives and 4 combinations of cocaine and marijuana. For every marijuana positive hair test there were 5 cocaine positives, a ratio of 1:5.¹¹ Psychemedics's own marketing materials refer to data concerning the Chicago Police Department and indicate that Psychemedics's hair analyses found cocaine use in the Chicago Police at a rate five times that of marijuana.¹² These findings of relatively high cocaine use and low marijuana use seemed odd to me as marijuana use in the United States has always been significantly greater than cocaine use, as discussed in detail below.

¹¹ Document COB7032-7033, a letter from Sandra DeBow of the BPD, dated January 17th, 2006 summarizes the list of officers who tested positive during the period from May 1999 to July 2005. The letter indicates that of the 69 first-offense positive tests reported, 52 were for Cocaine, 8 for Marijuana, 5 for Cocaine and Marijuana, 1 for Cocaine and MDMA, 2 for Heroin, and 1 for MDMA. That means more than 80% of all positive tests were for cocaine, and a ratio of marijuana to cocaine positives of 1:5.

¹² "Psychemedics in the News" Marketing Video Tape, available from Psychemedics.

26. The Center for Forensic Sciences at RTI International, with funding from the U.S. Substance Abuse and Mental Health Administration ("SAMHSA"), conducted an evaluation of the dynamics of the external contamination of hair with cocaine. The results were reported in the *Journal of Analytical Toxicology*.¹³ Hair locks of different color were contaminated with cocaine and treated with a synthetic sweat solution. The hair locks were shampooed daily (Monday through Friday) for 10 weeks to simulate real-world conditions. The hair samples were then analyzed using decontamination procedures by three commercial laboratories (including Psychemedics) for cocaine, benzoylecgonine ("BE"), cocaethylene and norcocaine. Results indicated that "substantial and persistent" levels of all four compounds remained in all hair types that were externally contaminated. Even though they were simply contaminated with cocaine externally, many samples contained more than 10,000 pg/mg of cocaine after 10 weeks of daily washing.¹⁴ The only hair samples below detection limits for all four compounds were those that were decontaminated 1 hour after contamination.

¹³ Stout, P.R., Roper-Miller, J.D., Baylor, M.R. and Mitchell, J.M., External Contamination of Hair with Cocaine: Evaluation of External Cocaine Contamination and Development of Performance-Testing Materials, *Journal of Analytical Toxicology*, Vol. 10, October 2006, pgs. 490 – 500.

¹⁴ Plaintiff Ronnie Jones was terminated because of a test result allegedly showing cocaine concentration of only 600 pg/mg.

27. A very important finding in this study was the fact that the BE/cocaine ratios in these externally contaminated hair samples continued to increase significantly over the 10 week study (regardless of the decontamination procedure) and the average BE/cocaine ratio exceeded 5% by day 21 post-contamination. What this means is that BE can form over time either through hydrolysis or some other non-metabolic process. When the RTI researchers applied the criteria of cocaine greater than 500 pg/mg, BE greater than 50 pg/mg and BE/cocaine ratio greater than 0.05 to designate a result as positive, they found that roughly 38% of the decontaminated specimens still contained cocaine levels, and BE/cocaine ratios that would indicate a positive result. Applying the “wash criteria” as described by Cairns *et al.*¹⁵ improved the ability to distinguish externally contaminated specimens, but some samples still would have been reported positive using the aforementioned criteria.
28. The results of the RTI study raises many doubts about the ability of the criteria Psychomedics uses to define a positive test result for cocaine. These criteria and the many changes in these criteria will be discussed in more detail below.

¹⁵ Cairns, T., Hill, V. Schaffer, M. and Thistle, W., Removing and identifying drug contamination in the analysis of human hair, Journal of Forensic Science International, Vol. 145: 97-108, 2004.

VII. HAIR TESTING IS NOT NATIONALLY STANDARDIZED.

29. The Federal Drug-Free Workplace Program was initiated by Presidential Executive Order 12564¹⁶ which established the goal of a Drug-Free Federal Workplace and made it a condition of employment for all Federal employees to refrain from using illegal drugs on- or off-duty. The following year, Congress passed legislation¹⁷ designed to establish uniformity among Federal agencies' drug testing plans, insure reliable and accurate drug testing, employee access to drug testing records, confidentiality of drug test results, and centralized oversight of the entire federal drug testing program. This program was designed to provide sufficient procedural protections to cover all aspects of the program.
30. Certification and oversight of federal agency plans is accomplished under a delegation of authority by an Interagency Coordinating Group Executive Committee, convened by the Office of National Drug Control Policy and staffed by SAMHSA's Division of Workplace Programs. The Executive Committee consists of representatives of the Division of Workplace Programs (which coordinates policy oversight, facilitates the certification and review of agency plans, convenes the Drug Testing Advisory Board to oversee scientific and technical issues involving drug testing, issues program guidance, and maintains the currency of the Mandatory Guidelines), the U.S. Department of Justice, Civil Division (which designates an attorney to serve as the legal advisor and special counsel to the Federal Program), and the Office of Personnel Management (which provides policy guidance to agencies on all personnel issues).¹⁸

¹⁶ The Drug-Free Federal Workplace Act of 1986.

¹⁷ U.S. Public Law 100-71 §503.

¹⁸ A more detailed description can be found at www.workplace.samhsa.gov.

31. Since the inception of the Federal Workplace program in 1988, all federally regulated testing has been required to be in compliance with the "Mandatory Guidelines" which establish specific protocols for the collection and analysis of specimens. Furthermore, the "Mandatory Guidelines" require that all testing must be done in a laboratory certified by the federally operated National Laboratory Certification Program ("NLCP"). NLCP certification, which includes quarterly proficiency testing and semiannual inspections, was designed to ensure the quality, accuracy and reliability of testing needed to allow agencies and corporations to make employment decisions (*e.g.*, hiring and firing) based on laboratory results.
32. As I was the original federal official responsible for establishing the rules for implementing the largest drug-testing program in the world, I spent an enormous amount of time researching all of the available technologies, and considering all specimen matrices. During the years the task force was developing the "Mandatory Guidelines," I met with representatives of all of the available technologies -- including representatives of Psychomedics -- to discuss the accuracy and reliability of the technology required to be included in the Federal program. In addition, during this process I had to deal with significant political pressure to include hair testing in the federal program. This pressure was the result of extensive lobbying efforts on behalf of Psychomedics.¹⁹
33. Since the inception of the Federal Workplace program in 1988, urine is and has been the only approved matrix for federally mandated drug testing programs. While the science of blood testing was initially considered scientifically acceptable, the physical intrusion of drawing blood was considered too invasive for the federal program. The science and technology of the other matrices (hair, oral fluid, and sweat) were considered too immature and unreliable for inclusion in the program.

¹⁹ See examples including letters to the Secretaries of Health (Sullivan, and Shalala), Housing and Urban Development (Kemp), and the Dept. of Navy in Exhibit B hereto.

34. Over the last twenty years alternative matrices such as hair, oral fluid and sweat have been exhaustively researched for use in the Federal program as alternatives to urine. In 2004 SAMSHA published a notice of proposed revisions to the “Mandatory Guidelines” for a 90-day public comment period²⁰ suggesting the expansion of the federal drug testing program “to include use of alternative specimens including testing hair, oral fluid, and sweat-patch specimens.” Recently, on November 28, 2008, after four years of deliberation, SAMHSA finally published a “Final Notice of Revisions to the Mandatory Guidelines” in the Federal Register. In this final notice, urine continues to be the only approved specimen. The explanation for this decision in the Federal Register notice stated that “The submitted public comments and additional comments raised by Federal Agencies during the subsequent internal review of the proposed changes to the Guidelines raised significant scientific, legal, and public policy concerns about the use of alternative specimens...”
35. The bottom line here is that after 20 years of workplace drug testing and millions of dollars of research on testing technology, the federal government still does not believe that hair testing, at this point, is a valid method for inclusion in federally regulated drug testing programs.
36. The basic philosophy that we used in developing the federal standards for workplace testing was that if a man or woman was to lose their job, or be denied a job, solely on the basis of a laboratory test, that the federal government had to have absolute confidence in the accuracy and reliability of that test result and the laboratory that conducted that test.

²⁰ Federal Register April 13, 2004.

37. As stated, the Federal Government does not authorize hair testing nor certify laboratories to conduct hair testing for federally regulated workplace testing. The Boston Police Department is not federally regulated, so they are not required to follow these standards. Unfortunately, there are no national standards for hair testing, there is no national laboratory certification program to certify labs to conduct hair testing, and there are no national ongoing proficiency testing programs. So, one wonders on what scientific basis did the Boston Police Department decide to conduct hair testing on their police officers, what credentials did the BPD use to select the Psychemedics laboratory to perform this work, and how did they know whether Psychemedics could do a good job? The stigma of being labeled as an illegal drug user by a government entity is not something that should be taken lightly.
38. The basic purpose in having national standards, proficiency testing and certification programs is to provide independent methods to measure the ongoing accuracy and reliability of the laboratory's performance and to provide consumers of these services some confidence that the lab can do what it claims. Not only are there no national standards for hair testing; Psychemedics's unequivocal position is that no other laboratories use the same procedures as theirs.²¹ They are unique.
39. Since there are no national standards or any national certification programs for hair testing laboratories, the fallback position for consumers is to make sure that laboratories use FDA cleared analytical methods, and have establish standard operating procedures ("SOP" or "SOPs") for all methodologies being used in the laboratory.

²¹ See Transcript of Deposition of Thomas Cairns, dated October 2, 2008 ("Cairns Dep.") at 150:11-13.

40. In fact, the federal lab certification program requires that laboratories must have a complete and current SOP manual that describes, in detail, all laboratory operations. The purpose of this requirement is to ensure that all specimens are tested in a consistent manner using the same procedures. NLCP laboratory inspectors review these SOPs during their twice-yearly inspections to ensure they are current and that the technicians are following the procedures as required. This is generally accepted as good laboratory practice.

VIII. PSYCHEMEDICS MADE NUMEROUS, IMPORTANT CHANGES TO ITS STANDARD OPERATING PROCEDURES DURING THE PERTINENT TIME PERIOD.

41. Psychemedics does appear to have SOPs for its various procedures, and Psychemedics reluctantly provided the SOPs it uses for the cocaine analysis including screening and confirmation techniques for review. Initially large sections of the documents produced were redacted based on claims of propriety. After some legal challenges the cocaine SOPs were provided and I had the opportunity to review them. During the review of the cocaine confirmation SOPs, I noted that the "Standard Operating Procedure" was not so "standard," as it changed frequently -- at least 13 times between October 1999 and October 2005. This seemed unusual to me in that changes in "standard procedures" typically require extensive validation studies to be carried out to document the efficacy of the new procedure. Validating new procedures is usually very costly. SOPs are generally developed and established by extensive testing and verification before they are ever implemented. In most laboratories, once a method is established and validated the laboratory sticks with that method unless they are having major problems with the method. The fact that Psychemedics initiated so many changes in the cocaine analysis procedures during this time period suggests to me that Psychemedics had a problem with their cocaine testing procedures that they were trying to fix.

42. During this time in which the Psychomedics cocaine SOP kept changing (1999 -2005), Psychomedics was actively lobbying SAMHSA to include hair testing in the federal program. In addition, Psychomedics was participating in a SAMSHA informal “working group on hair testing” to propose standards for hair testing. Some of the changes I observed in the Psychomedics “Standard Operating Procedures” seem to coincide with some of the recommendations being made by this working group. In fact, Dr. Donald Kippenberger, who was a Psychomedics Lab Director, served at one point as the Chairman of this “working group.” Dr. Cairns suggests in his deposition²² that many of the changes in the cocaine SOP during this time did result from discussions and recommendations of the working group.
43. In addition to the many changes in the Standard Operating Procedures during this timeframe, there were also many changes made to the criteria for what constitutes a positive test result.
44. In the illustration that follows, I use the October 1999 Version 1099A of Psychomedics’s cocaine confirmation SOP as a baseline, and compare subsequent versions of the cocaine confirmation SOP to the baseline, focusing primarily on the section of each SOP that pertains to the “criteria for reporting results,” as these determine what constitutes a positive test result for cocaine.
45. The following changes in what defined a positive test were noted in the SOPs dated between October 1999 and October 2005:



²² See, e.g., Cairns Dep. at 123:19-24.

²³ NB: The SOPs provide no explanation of the reasoning behind this calculation.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

²⁴ NB: This is a *10-fold* reduction down to 20 pg/mg.

46. The numerous changes both in the SOPs and the criteria for what constituted a positive test result that occurred during this five year period (1999-2005) raise the distinct possibility that some of the specimens that met the existing criteria and were reported as “positive” at certain times would have failed to meet the criteria and been reported as “negative” at other times and vice versa. Clearly, consistency in methodology was lacking over time.
47. The many, many changes in the cocaine SOP and the many, many changes in the criteria regarding what defines a positive test, and the wide degree of discretionary powers of the lab director to make exceptions at will, beg the question of who besides Psychomedics staff was monitoring all these changes and/or providing any external oversight to these processes to assure that all of these changes were scientifically sound, and that the procedural protections for the police officers were sufficient.

IX. PSYCHEMEDICS IS NOT SUBJECT TO ADEQUATE INDEPENDENT OVERSIGHT.

48. This leads me to the critical questions of whether, in fact, there was any independent outside review body monitoring the performance of the Psychomedics laboratory who could provide some assurances of the quality of the work, and whether any independent organization was reviewing all of the changes in methods. Throughout the deposition of Psychomedics's Senior Scientific Advisor, Dr. Thomas Cairns,²⁵ Dr. Cairns alleges close oversight by "government" and various "regulators" whom he claims do inspections of Psychomedics all the time. Dr. Cairns makes many statements referring to FDA review; however, in a careful review of the deposition, as well as the affidavits submitted by Dr. Cairns in the litigation packages related to the plaintiff's cases, I did not find any clear indication of any ongoing outside review. Dr. Cairns often makes contradictory statements about outside reviewers and uses terms such as "licensed," "certified," and "accredited" interchangeably. In reality, the various licenses, accreditations, and certifications that Psychomedics does hold from State and Federal entities do not provide the kind of oversight necessary for workplace drug testing or anything comparable to the National Laboratory Certification Program, which was designed specifically for workplace testing (and mandates, *e.g.*, twice yearly inspections and quarterly proficiency testing). Psychomedics does not adhere to such a standard.

²⁵ See, *e.g.*, Cairns Dep. at 38:16-18; 55:22-24; 95:3-24; 123:23-24; and 151:5-152:3.

49. Psychemedics's certificate of CLIA compliance, the accreditation by the College of American Pathologists ("CAP"), and most of the State licenses and certificates to operate a clinical laboratory cited by Dr. Cairns typically involve a laboratory inspection at the onset of application for accreditation and at best follow-up inspections every two years. Generally these kinds of accreditations may be acceptable for clinical work where a physician does not rely solely on the lab test but rather takes the laboratory result into consideration along with the clinical assessment of what he/she personally sees during the examination of the patient before a treatment decision is made. In my opinion the State Licenses, CLIA compliance and CAP accreditation that Psychemedics has obtained do not afford the level of scrutiny needed for workplace testing where the lab result is the only consideration. For example, with regard to the CAP and State Accreditations and Licensure, when laboratory deficiencies are identified the lab typically is not decertified, but is simply warned that the deficiencies will be reviewed at the next biennial inspection, two years hence. This is not adequate when a man or woman's career and livelihood depends entirely on the accuracy of a laboratory test result. At the absolute minimum the Boston Police Department should have had an ongoing blind quality control program, and initiated other safeguards to insure sufficient procedural protections for its officers.

50. Throughout the October 2, 2008 deposition, Dr. Cairns suggests that many changes in the Psychomedics SOPs were directed by the “government.”²⁶ He often invokes the FDA name to justify all sorts of Psychomedics actions, and cites SAMHSA proposed regulations as the reason for changes in the criteria for what constitutes a positive test result. I do not believe these statements provide the answer to the basic question of whether there was anyone outside Psychomedics monitoring the changes in protocols. In my opinion, there has been virtually no independent oversight of SOP changes, and no one outside Psychomedics has reviewed or questioned the many changes in methodologies and the changes in criteria for what constitutes a positive test. In reality, the Psychomedics lab directors were changing the SOPs at will without notifying any outside body. These conclusions are based upon the following deposition testimony of Dr. Cairns (my commentary appears in italics):

- Page 53, line 16: In response to a question “Does Psychomedics conduct research studies to determine whether its testing is accurate?” Dr. Cairns states “So all of our techniques have been submitted to FDA in entirety for evaluation and clearance as safe, reliable, accurate and precise”. *In fact, the cocaine assay was not cleared by the FDA until 2001 and the SOP has experienced many significant changes since the FDA cleared it. Cairns admits that after approval in 2001 Psychomedics never informed FDA of the changes.*
- Pages 139-140: Dr. Cairns was asked whether it was common for Psychomedics to revise its SOPs as frequently as it did during the 2000-2001 timeframe. He responded that it was a period of “particular activity because of the transition from ion trap to LC/MS. So it was acute in the sense that we were making a large scientific change to the positive sample criteria, the limit of detection, using the two metabolites.” *Again Cairns admitted that after approval in 2001 Psychomedics never informed FDA of the changes.*
- Pages 147-148: When asked “Has Psychomedics made revisions to its SOPs on the basis of external data or research considered in conjunction with internal data? Cairns replies “But please remember, the techniques used by Psychomedics are not used by anybody else, so it is difficult at best to compare external work with the ongoing hair analysis conducted at Psychomedics”. *He goes on to reiterate that the key is to have a method approved by the FDA.*

²⁶ See, e.g., Cairns Dep. at 36:16-19; 53:12-19; 120:8; and 121:21-23.

- Pages 151- 154: Dr. Cairns admits that prior to 2001 Psychemedics was not using an FDA cleared method for cocaine, and that no one from the FDA ever visited Psychemedics in the process of determining whether to grant clearance for its methods. *When Dr. Cairns was asked whether the FDA conducts an annual review, he replied that he doesn't know. He also replies that he doesn't know whether they [FDA] conduct any periodic reviews. This lack of knowledge is peculiar in that Cairns indicated that he is the key person at Psychemedics responsible for interacting with the FDA, yet he doesn't seem to know what the FDA rules or functions are.*
- Page 36, line 16: When asked about changes in the criteria for a positive test, Dr. Cairns cites a Federal Register document that proposed procedures for hair testing and implies the changes in criteria for a positive test were made to comply with the proposed guideline. *In 2004 SAMHSA published a "proposed rulemaking" for a review and comment period. In fact the "government" has decided not to approve hair testing for federal workplace testing²⁷ and has issued no rules or cutoffs of any kind for hair testing. Stating that Psychemedics was in compliance with a "notice of a proposed rule" is nonsense.*
- Page 121, lines 19 thru 22: In response to a question regarding changes in the criteria for what constitutes a positive test result, Dr. Cairns states "There was a number of compelling reasons [for changing the SOP]." Among the reasons was that the "Hair Working Group of the federal government" agreed with it. *Implying that the "Hair Working Group" had the authority of "government" is really a stretch. The "Hair Working Group" was an informal advisory group formed by SAMHSA to include the industry in the shaping of possible new regulations. Psychemedics was a very vocal member of this group [Dr. Kippenberger, a lab director from Psychemedics served as chairman of the working group] and had significant input to all the recommendations from the group to SAMHSA. In fact, the working group had no real official status with the federal government; it was purely an informal advisory group and had no regulatory authority of any kind.*

²⁷ Final Rule published in Federal Register Nov. 2008.

X. HAIR TEST RESULTS DO NOT ACCURATELY REFLECT RECOGNIZED PATTERNS OF DRUG USE.

51. One final issue I would like to discuss is the fact that national survey data have consistently shown over the last 30 years that marijuana is by far the most frequently used illegal drug in the USA. The table below contains data from the 2005 and 2006 National Survey on Drug Use and Health ("NSDUH") conducted by the US Department of Health and Human Services. The data show the percentage of Americans using marijuana and cocaine in the month preceding the survey by age groups. Depending on the age group, the data show ratios of illegal marijuana use to illegal cocaine use ranging from 5:1 to 9:1, reflecting rates of marijuana use 5 to 9 times greater than that of cocaine.

52. Percentage of Illegal Drug Use by Age Groups in Last 30 Days

Ages	Marijuana 2005	Cocaine 2005	Marijuana 2006	Cocaine 2006
18-20	18.9%	2.3%	18.6%	2.6%
21-25	15.0%	2.7%	14.8%	2.0%
26-34	8.6%	1.3%	8.5%	1.7%
35+	3.0%	0.6%	3.2%	0.6%

53. It is important to note that data from large scale workplace drug testing programs that use urine and oral fluid to identify drug use patterns always yield results that parallel the national surveys of drug use (*i.e.*, they show significantly greater number of marijuana positives than cocaine positives). As noted above, the hair testing program at the Boston Police Department found significantly higher rates of cocaine use than marijuana use, with ratios of 1:5 marijuana to cocaine use.
54. Recently, The Walsh Group, P.A. conducted a study reviewing workplace drug-testing data from thousands of U.S. companies over a 5-year period (2003-2007). We examined the results of drug tests from millions of samples including urine, and oral fluid. Both urine and oral fluid workplace testing produced quite comparable results, with marijuana making up the clear majority of the positives with ratios of 4:1 in urine (marijuana to cocaine use), and 3:1 in oral fluid (marijuana to cocaine). These urine and oral fluid data generally reflect the national survey use patterns.²⁸
55. In my opinion hair testing for drugs of abuse produces results quite different from urine and oral fluid testing and does not provide an accurate assessment of illegal drug use as we know it in America. Hair test results would lead one to believe that cocaine use is much greater than marijuana use in the United States, which is not the case. These hair test findings from the Boston Police program suggest to me that the hair analysis is relatively insensitive to marijuana use and identifies an unusually high rate of cocaine positives, which are likely to be the result of something other than illegal drug use, and possibly the result of external contamination.

²⁸ Data presented at the Annual Meeting of the Society of Forensic Toxicologists, Phoenix, AZ, October 2008.

56. In both Boston Police Department Rule 111 and documents posted on the BPD website²⁹, the basic goal of the program is stated as follows: “to achieve and maintain a work force that is 100% drug-free.” Hair-testing technology as it currently exists will never get you to that goal due to its insensitivity to marijuana, the most commonly abused drug.

XI. CONCLUSION

57. Psychemedics’s ability to accurately, reliably, and conclusively distinguish illegal drug use from passive exposure is unproven, and subject to serious doubt within the scientific and drug policy communities.

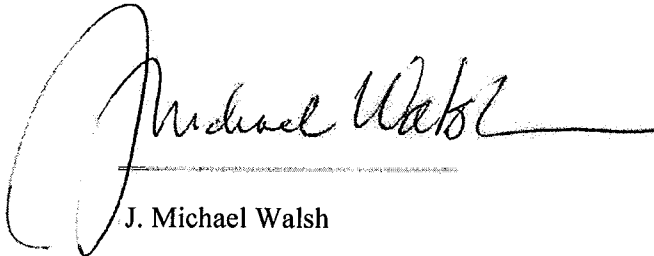
58. Defendants’ reliance upon Psychemedics’s hair test as the sole evidence of illegal drug use is neither analytically sound nor procedurally reasonable.

59. These opinions are supported by the following facts:

- unlike other, more established forms of drug testing (*e.g.*, urinalysis, and blood testing) hair testing for drugs lacks agreed upon nationwide standards, national certification programs, and nationwide proficiency testing programs;
- hair that is dark in color or damaged by chemical treatments can be especially susceptible to external contamination;
- the amount of cocaine identified and quantified in hair during hair testing is extremely small, and presents challenges to the limits of hair testing technology;
- the hair test conducted for the Boston Police Department program identified a disproportionate number of African-Americans as cocaine users;
- Psychemedics, the laboratory that conducts the hair test relied upon by Defendants, made frequent, critical changes to its Standard Operating Procedures between 1999 and 2005;

²⁹ “Hair Drug Testing: Fact vs. Fiction”, Boston Police Department, 2005 (Exhibit 22 to October 12, 2006 Deposition of Kathleen O’Toole).

- these changes included repeated revisions to the criterion for a positive cocaine test;
- Psychemedics's laboratory and testing procedures are not subject to any routine, independent oversight to provide assurances of accuracy or reliability;
- Psychemedics's participation in independent proficiency testing is very limited;
- the Defendants did not properly evaluate whether Psychemedics's test was accurate or reliable;
- the Defendants routinely disregarded evidence that Psychemedics's test results were inaccurate, even when that evidence was generated by Psychemedics itself;
- the patterns of drug use detected by the hair test do not reflect established patterns of drug use nationwide; and
- for all of these reasons, and despite 20 years of political pressure supporting the hair test and millions of federal research dollars spent evaluating the hair test, the U.S. government has concluded that hair testing is not yet fit for use in federal workplace drug testing regimes.



J. Michael Walsh

March 16, 2009

Exhibit A

Documents Reviewed In Preparation of Expert Report of J. M. Walsh, Ph.D.

Journal Articles

Smith, F.P., and Kidwell, D.A., Cocaine in Hair, Saliva, Skin Swabs, and Urine of Cocaine Users' Children, Forensic Science International, Vol. 83, 1996.

Stout, P.R. Hair Testing for Drugs – Challenges for Interpretation, Forensic Science Review, Vol. 19 (2), July 2007, pages 70-84.

Chamberlain, R.T., Legal Review for Testing of Drugs in Hair, Forensic Science Review, Vol. 19 (2), July 2007, pages 85-94.

Kidwell, D.A., and Blank, D.L., Mechanisms of Incorporation of Drugs into Hair and the Interpretation of Hair Analysis Data. In Hair Testing for Drugs of Abuse, International Workshop on Standards and Technology, Cone, E.J., Welch, M.J. and Grigson-Babecki, M.B. Eds., National Institutes on Health Pub. 95-3727, U.S. Govt. Printing Office, Washington, DC 1995.

Kidwell, D.A., and Smith F.P., Passive Exposure, Decontamination Procedures, Cutoffs and Bias: Pitfalls in the Interpretation of Hair Analysis Results for Cocaine Use, in Hair Testing for Drugs of Abuse, Pascal Kintz (Ed.), CRC Press, Boca Raton, FL, 2006, pages 25-72.

Stout, P.R., Ropero-Miller, J.D., Baylor, M.R. and Mitchell, J.M., External Contamination of Hair with Cocaine: Evaluation of External Cocaine Contamination and Development of Performance-Testing Materials, Journal of Analytical Toxicology, Vol. 10, October 2006, pgs. 490 – 500.

Romano, G., Barbera, N., Spandaro, G. and Valenti, V., Determination of Drugs of Abuse in Hair: Evaluation of External Heroin Contamination and Risk of False Positives, Forensic Science International, Vol. 131, 2003, pgs 98-102.

Romano, G., Barbera, N., and Lombardo, I., Hair Testing for Drugs of Abuse: Evaluation of External Cocaine Contamination and Risk of False Positives, Forensic Science International, Vol. 123, 2001, pgs 119-129.

Mieczkowski, T., Distinguishing Passive Contamination from Active Cocaine Consumption: Assessing the Occupational Exposure of Narcotics Officers to Cocaine, Forensic Science International, Vol. 84, 1997, 87-111.

Mieczkowski, T., Passive Contamination of Undercover Narcotics Officers by Cocaine: An Assessment of their Exposure using Hair Analysis, Microgram, Vol. 28 (6), 1995, 193-198.

Schaffer, M.I., Wang, W., and Irving, J. An Evaluation of Two Wash Procedures for the Differentiation of External Contamination versus Ingestion in the Analysis of Human Hair Samples for Cocaine, Journal of Analytical Toxicology, Vol. 26, 2002, 485-488.

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, Vol. 63, 1993, pgs. 85-98.
Mieczkowski, T., and Newel, R. An Analysis of the Racial Bias Controversy in the Use of Hair Assays, Drug Testing Technology, Chapter 15, 1999 CRC Press.

Mieczkowski, T., The Further Mismeasure: The Curious Use of Racial Categorizations in the Interpretation of Hair Analyses, Inter. J. of Drug Testing [online e-journal], Vol. 2, see <http://www.criminology.fsu.edu/journal/mismeasure.html>.

Mieczkowski, T., Lersch, KM, and Kruger, M. Police Drug Testing, Hair Analysis, and the Issue of Racial bias, Criminal Justice Review, Vol. 27, (1), Spring 2002, pgs. 124-139.

Mieczkowski, T., Sullivan, C., and Kruger, M. The Use of Bayes Coefficients to Assess the Racial Bias-Hair Analysis Conjecture for Detection of Cocaine in Hair Samples, Forensic Science Communications, Vol. 9 (2), April 2007.

DeLauder, S. Considering Issues of Racial Bias in Drug Testing Where Hair is the Matrix, Transforming Anthropology, Vol. 11 (2) pp 54-59, 2004.

Cairns, T., Hill, V. Schaffer, M. and Thistle, W., Removing and Identifying Drug Contamination in the Analysis of Human Hair, Journal of Forensic Science International, Vol. 145: 97-108, 2004

Slawson, MH, Wilkins, DG, Rollins, DE, The Incorporation of Drugs Into Hair: Relationship of Hair Color and Melanin Concentration to Phencyclidine Incorporation; J. Analytical Toxicology 22:406; 1998

Federal Government Documents

Minutes of the U.S. Substance Abuse and Mental Health Services Administration's (SAMHSA) Drug Testing Advisory Board Meeting 12/12/2006.

SAMHSA Drug Testing Advisory Board Presentations:

“NLCP hair and oral fluid pilot PT programs” – John Mitchell, 6 June 2004

“Pilot PT Program for Hair: Cycle 8” J.D. Roper-Miller & J. Mitchell, 7 Sept. 2005

“NLCP Hair Pilot Performance Testing Program Update” J. Mitchell & JD Roper-Miller, 7 March 2006.

FDA letter of clearance for 510K for RIA Cocaine Assay dated Nov. 2001.

Materials Provided by Psychomedics

- All standard operating procedures (SOPs) for Cocaine screening and confirmation analytical methods (documents dated from October 1999, thru October 2005)
- Litigation packages for all plaintiffs listed in the case (documents dated from October 1999, thru October 2005)

Boston Police Documents

Strength reports by rank, gender, and ethnicity (COB5794-5799, COB7026-7027, COB7032-7035, 35872-35970, PMD13471-13472, PMD13573-13575, and PMD14812-14813)

Summary reports of drug testing data

Memos from Sandra DeBow to the Sandulli Grace law firm with statistical summaries of positive hair tests (COB7032-7033)

“Hair Drug Testing: Fact vs. Fiction”, Boston Police Department, 2005 (Exhibit 22 to October 12, 2006 Deposition of Kathleen O’Toole)

Depositions of Psychomedics Staff

Transcript of the Deposition of Dr. Cairns dated 10/02/2008

Transcript of the Deposition of Mr. William Thistle dated 10/14/2008

Lobbying letters to federal agency heads from Psychomedics and other supporters (Exhibit B to report)

Clint Allen letter to HHS Sec. Louis Sullivan dated 4/30/90

John Kerry letter to HHS Sec. Louis Sullivan dated 3/19/90

Clint Allen letter to HUD Sec. Jack Kemp dated 5/10/90

Gov. Martinez letter to HHS Sec. Louis Sullivan dated 4/11/90

James Bayless letter to Sec. of Navy Garrett dated 1/15/90

Cong. Solomon letter to HHS Sec. Shalala dated 5/25/95

Exhibit B



PSYCHEMEDICS

C O R P O R A T I O N

SANTA MONICA • BOSTON • FORT LAUDERDALE • DALLAS

April 30, 1990

Secretary Louis W. Sullivan
Department of Health and Human Services
200 Independence Avenue S.W.
Washington, D.C. 20201

Dear Secretary Sullivan,

It was a great honor and pleasure to meet with you last Friday in Ft. Lauderdale. We all enjoyed the opportunity to brief you on our new "state-of-the-art" drug test using human hair instead of urine and hope you left with an expanded knowledge of the options available in drug testing.

Mark Barnes has been helpful in "breaking the logjam" we were experiencing with NIDA and we hope that with yours and Mark's continued help, we will be accorded a "level playing field" with the big, powerful urine testing companies.

On a personal note, I applaud your efforts with the "no smoking" campaign. My wife and I have long been active on that front and couldn't be happier that a person of your talent and visibility is so actively involved.

Thank you again for your time and interest.

Sincerely,



A. Clinton Allen

cc: Wayne Huizenga

900502007B



STATE OF FLORIDA

OFFICE OF THE GOVERNOR

BOB MARTINEZ

April 11, 1990

Honorable Louis Sullivan
Secretary of Health and
Human Services
Washington, D.C. 20220

Dear Mr. Secretary:

I have been hearing of a new test for drug abuse which uses human hair instead of urine. A number of major companies in my area are excited about this new technology.

I understand that the National Institute of Drug Abuse has yet to certify this process but rather concentrates exclusively on urinalysis which, as most everyone knows, is easy to beat and has come under a great deal of criticism of late. It makes sense to me that all due speed should be accorded the certification of this new method which has already found wide-spread acceptance among large, well known and highly respected companies and organizations. In our state alone, the two largest banks, a probation department, several police departments and one of the country's fastest growing companies now use, or will shortly implement, this new hair test.

Thank you for your consideration of a speedy review process for this test of drug abuse.

Sincerely,

A handwritten signature of Bob Martinez in cursive script, written in dark ink. The signature is stylized and fluid, with the first letters of the first and last names being capitalized and prominent.

Governor

BM/rss



STATE OF FLORIDA

OFFICE OF THE GOVERNOR

BOB MARTINEZ

April 11, 1990

Honorable Louis Sullivan
Secretary of Health and
Human Services
Washington, D.C. 20220

Dear Mr. Secretary:

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Thank you for your consideration of a speedy review process for this test of drug abuse.

Sincerely,

A handwritten signature in cursive script, reading "Bob Martinez", is written over the word "Governor".

Governor

BM/rss

United States Senate

WASHINGTON, DC 20510

March 19, 1990

The Honorable Louis Sullivan
Secretary
Department of Health and Human Services
200 Indiana Avenue, SW
Room 615 S
Washington, DC 20201

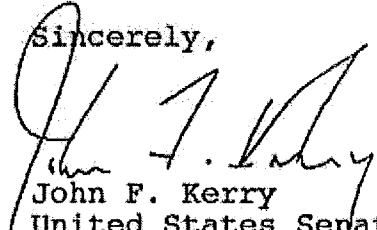
Dear Secretary Sullivan:

As reported in the Washington Post last Wednesday, hair analysis can now be used to test for drug abuse. According to the article, hair analysis is not only accurate, but will enable the tester to look back months and determine whether, when and how long a person used illegal drugs. Law enforcement authorities believe this method may prove to be an important new weapon in the war on drugs.

One of the leaders in this new technology is Psychomedics Corporation of Boston, Massachusetts. The Psychomedics testing method is currently being used by over 70 companies across the nation.

The RIAH hair test needs to be certified by the National Institute for Drug Abuse. I ask your help in encouraging NIDA to undertake their review of this testing procedure as quickly as possible. Drug testing remains a controversial issue, but there can be little doubt that an accurate and cost effective test for drugs would be a positive development.

Sincerely,



John F. Kerry
United States Senate

9003200106

A.C. Allen & Co., Inc.
99 Summer Street - Boston, Massachusetts 02110 (617) 951-0884

A. Clinton Allen
Chairman

*Assign to
Bud Albright
Per 52*

Honorable Jack Kemp
Secretary HUD

by fax

May 10, 1990

Dear Secretary Kemp,

I'm sure you have been hearing, seeing and reading more and more about hair testing for drugs which has, since our first meeting early last Fall, gained a large measure of national publicity.

In the past two weeks alone we were seen on the NBC Nightly News with Tom Brokaw, a half dozen local television newscast and "Magazine" type shows, and were written about in many national and local newspapers. The story line is the same: "New Drug Testing Method More Efficient In Detecting Drugs Of Abuse."

Thanks, I believe, to some "spirited" help from Secretary Louis Sullivan's office, NIDA has agreed, finally, to speed up their certification process for us. We now have almost 100 major corporate clients and are opening new accounts at the rate of 1 per day! We got a good deal of "tail wind" from the FBI hair testing of Mayor Barry which proves that the agency believes our method is not only accurate, superior to urinalysis, but will stand up in a highly visible, publicized trial.

You were our first "advocate" in Washington and I, and John Mackey, are grateful for your early help and support. I'm hoping that we might now be able to help you and your agency's drug problem with our test. I know we can be of great help in testing your new housing "patrol force" to avoid any problems which might arise should you inadvertently hire a drug user or one slips through the "urine test."

In any case we are here should you want any of your staff to discuss it. Again, many thanks for your help and support and I hope to see you soon.

Sincerely,

Clinton Allen

BAYLESS & BOLAND, INC.

1072 THOMAS JEFFERSON STREET, N.W.
WASHINGTON, D. C. 20007

(202) 342-0040

January 15, 1990

The Honorable H. Lawrence Garrett, III
Secretary of the Navy
Suite 4E686, The Pentagon
Washington, D. C. 20350

Dear Larry:

I noted with interest CNN's newscast last night which featured a story about the U. S. Navy's recent drug testing breakthrough in San Diego which allows it to detect more precisely the use of methamphetamines by its personnel.

While I congratulate you on making good progress on what certainly is one of the most pervasive problems facing the armed forces, the Navy should be aware of an alternative, no-nonsense methodology which is far more reliable than drug testing schemes that depend on random urine testing as a means of identifying drug users.

This "better mousetrap," developed by our client, Psychemedics Corporation of Santa Monica, California, analyzes not urine, but human hair--a medium demonstrated to be vastly superior in verifying and accurately measuring drug use, as well as in differentiating the casual from the more serious drug user.

The fact is, urine testing has at most only a four-day "window of detection," as opposed to hair analysis, which detects drug usage over a period of three months or more with precision. Random urine tests are easy to beat, and are, at best, of little help to the employer or superior officer in charting the tested individual's drug history and thus classifying the severity of the drug problem at hand. Wouldn't the Navy be far better off, then, by utilizing a drug testing scheme that does more than catch "just the dumb ones," and that at the same time provides truly meaningful information on the tested individual so that he may be treated accordingly?

For your review, I enclose additional materials on hair analysis which I believe you should find interesting. Should you or your staff desire additional information, please feel free to contact me any time.

ma

Kind personal regards,


James L. Bayless, Jr.

*Larry -
Hope you're doing well - JB*

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GERALD L. SOLOMON

MEMBER OF CONGRESS
11th DISTRICT, NEW YORK

ROOM 2200 HAYTHORN BUILDING
WASHINGTON, DC 20545-3377
(202) 225-5614

MEMBER
HOUSE TASK FORCE ON AMERICAN
PRISONERS OF WAR AND
MISSING IN SOUTHEAST ASIA

RULES COMMITTEE
CHAIRMAN

MEMBER
HOUSE TASK FORCE ON
CHILD CARE, DRUGS
EDUCATION AND THE ELDERLY

Congress of the United States

House of Representatives

Washington, DC 20515-3222

May 25, 1995

Secretary Donna Shalala
Department of Health and Human Services
200 Independence Avenue., SW
Washington, D.C. 20201

Dear Madam Secretary:

This letter is to ask for your immediate action to bring up to date the regulations governing the technology used in our country to test for and combat drug abuse. The Department of Health and Human Services should revise its Mandatory Guidelines for Federal Workplace Drug Testing Programs to include testing of hair and any other appropriate human body substances for the presence of illegal drugs.

The current HHS Guidelines, reissued by the Substance Abuse and Mental Health Services Administration as a Notice in the Federal Register of June 9, 1994, address only the testing of urine. As you know, when the original guidelines were written in the 1980's, they were written for only the one technology.

The limitation of the HHS Guidelines to urine testing technology constrain the application of other advanced detection technology not only by government agencies but by regulated and unregulated industry. While these Guidelines are directed at workplace drug testing by Federal Agencies, they are incorporated by reference in statutes and regulations pertaining to a wide range of government and private testing. For instance, they are specifically incorporated by the Omnibus Transportation Employee Testing Act of 1991. Moreover, they are used or referred to widely in private industry.

The HHS Guidelines were not meant to inhibit the development and application of advanced drug testing technology. The current limitation of urine testing, however, is another unfortunate example of regulations and a regulatory framework not keeping up with current technological development.

Testing hair for the presence of illegal drugs by radioimmunoassay and ultra-sensitive gas chromatography/mass spectrometry procedures has been accepted in numerous private and government drug testing applications that are not affected by the HHS Guidelines. Over 400 corporations from a wide spectrum of business have found the method to be the most efficient, accurate, and cost-effective test available. Over 80 government and medical/research entities also depend on this testing method. It has consistently passed quality assurance tests. It is used by the Federal Bureau of Investigation, prison authorities, police forces and local governments. It has been approved by, among other jurists, Jack Weinstein, an eminent judge of the U.S.

DISTRICT OFFICES

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SARATOGA SPRING, NY 12108
518-581-0000

BUSINESS OFFICES
518-411-2201

P.O. Box 11
Rensselaer, NY 12152
518-875-7700

District Court of the Southern District of New York, to determine illegal drug use.

Testing of hair has numerous advantages. It provides a wide window of detection -- 90 days is standard. It is resistant to evasion, tampering, and intermittent and planned abstinence. Accurate information about the pattern and quantity of drug abuse is provided by hair testing because drug use is recorded in the medium in amounts proportional to those consumed.

Very importantly, hair testing is less intrusive and logistically simpler than urine collection and testing. Moreover, if the results of the first test of a hair sample are challenged, a second, newly collected sample can be analyzed which will provide information as current and accurate as a first sample.

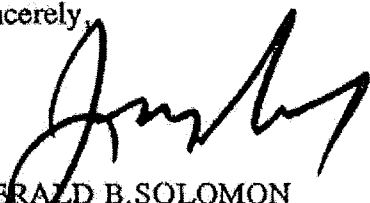
Because of the numerous advantages provided by hair testing and because of its established and growing acceptance, it should be included with urine testing in the HHS Guidelines. Urine testing remains more advantageous in certain circumstances, of course, such as determining the immediate presence of drugs. We should, however, include all appropriate technologies in our arsenal for use in the national campaign to find and eliminate drug abuse.

For all above reasons, I urge that the Department of Health and Human Services take immediate action to revise its Guidelines. The revised Guidelines should include hair testing (and any other appropriate testing) for the presence of illegal drugs. Such action would bring outdated government regulations up to date and eliminate their drag on the application of more advanced technology. Encouragement and assistance in the use of advanced detection technology would be consistent with the claims that this Administration is ready to address our nation's persistent drug abuse problems.

If, however, the Department of Health and Human Services chooses not to act immediately on this issue, please provide me with an explanation and reasons for not acting. The explanation should include technical information, the identities of researchers and research papers and literature that form the basis for such a determination. Also, please identify the specific references within the technical information, papers and documents that pertain to hair testing for the presence of illegal drugs and which are relied upon in any decision not to take action.

Drug abuse continues to be an issue of critical importance to our nation. This Congress will be acting to address and confront the issue. I hope that we can do so with your enthusiastic assistance.

Sincerely,



GERALD B. SOLOMON
Member of Congress