#04-7984
P.C. 8400144

From: Fred Smith <fsmith@uab.edu>
To: <wvogl@samhsa.gov>
Date: 7/12/04 4:37PM
Subject: FR Docket 04-7984, Proposed revisions to mandatory guidelinesfor federal workplace drug testing programs

My comments, due today July 12, are submitted in the attached pdf file.

****

Prof. Frederick P. Smith
Forensic Science Program
Department of Justice Sciences
The University of Alabama at Birmingham

MAILING ADDRESS (US Mail):
1530 3rd Avenue South, 101 OB 15
University of Alabama at Birmingham
Birmingham, Alabama 35294-2060

CAMPUS ADDRESS (UPS, FedEx, and other commercial carriers):
901 15th Street South, Room 101 OB 15
Birmingham, Alabama 35294-2060

fsmith@uab.edu
telephone (205) 934-8476
fax (205) 934-2067

****

UAB SCHOOL OF SOCIAL AND BEHAVIORAL SCIENCES

Department of Justice Sciences

July 2, 2004

Department of Health and Human Services
Substance Abuse and Mental Health Services Administration
5600 Fishers Lane
Rockwall II, Suite 815
Rockville, MD 20857

Re: FR Docket 04-7984, Proposed Revisions to Mandatory Guidelines for Federal workplace Drug Testing Programs.

To Whom It May Concern:

I am a professor in the Forensic Science Program, Department of Justice Sciences at the University of Alabama at Birmingham. During the past ten years, I have performed research in collaboration with the United States Naval Research Laboratory where I have co-authored numerous published studies regarding workplace drug testing technologies. I have reviewed SAMSHA's proposed revisions to the Federal Employee Work Place Drug Testing Programs and offer the following comments:

Proposed Addition of Head Hair, Oral Fluid and Sweat Specimens

The Department is proposing to expand the kinds of specimens that may be used in federal agency workplace as stand-alone drug tests, including head hair, oral fluid and sweat. I am concerned about the extension of unreliable drug testing technologies to test the estimated 1. million federal employees affected by these proposed guidelines. I also object to the procedure SAMSHA followed in devising these proposed changes to the existing regulations.

The proposed sampling changes are the result of a process that appears to have been driven by drug testing industry representatives. For example, the introduction to the proposed guidelines notes that the Department held a 3-day public meeting to consider new technologies where "industry coordinators selected the presenters for the alternative specimens and technologies" and that this was done "to ensure a thoroughly unbiased review." [1] I respectfully disagree with the notion that industry representatives are unbiased on the subject of the federal government's large-scale adoption of their products. To obtain an unbiased review, SAMSHA should have included a more representative sampling of other scientists and interested parties in the process of selecting presenters for the DTAB meetings.

Moreover, I am an interested scientific professional actively researching in this field, ye was not notified about the public meetings regarding SAMSHA's proposal to begin evaluatin alternative specimens for workplace drug testing. Had I been notified of the time and place of hese events, I would have attended and/or made my objections and opinions known. For these

---

Pro d Re ions to Man ory G lines for Federal Workplace Dr esting Programs, 69 Fed. R Apri

versity
outh | Alaba at Bi
5.93 2069 | Mailin Addre
5.93 2067 | OB15
0 3RD AVE S
MINGHAM AI 06

reasons, I urge SAMSHA to sponsor additional scientific debate regarding these proposed specimen additions and to invite participation of independent scientists as well as industry representatives.

Finally, I am concerned that the addition of new sample sources will undermine the use of urinalysis. As employers turn toward the more expedient and potentially less reliable alternatives of sweat, hair and oral fluid testing, urinalysis laboratories could be forced out of business. The end result could be less reliable drug testing, a reduction in public confidence in work place drug testing programs, and the likelihood that federal employees will unjustly lose their jobs.

Sweat Testing

The proposed regulations include sweat as an alternative specimen; however, the only FDA cleared collection device for sweat testing is a "sweat patch" distributed by PharmChem Inc. As a result, adoption of sweat as an alternative specimen amounts to institutionalizing the widespread use of PharmChem's product to sweat test federal employees. I have several objections to workplace sweat testing with the sweat patch.

First, the sweat patch is not a sufficiently reliable drug testing device to warrant its use as a stand-alone test in federal workplace drug testing. Individuals who are not using drugs may test positive with the sweat patch due to environmental contamination or other factors that have yet to be fully explored. For example, the skin of a person who is not using drugs can be contaminated with drugs before the patch is applied, resulting in false positive interpretation concerning their drug use. Moreover, drugs in the environment can pass directly through the patch cover, thus contaminating the sample. (see Kidwell, Smith. (2001) Susceptibility of PharmChek Drugs of Abuse Patch to Environmental Contamination. Forensic Science International 116:89). In either situation false positive results would be impossible to distinguish from intentional ingestion of controlled substances.

Other studies indicate that seven to forty percent of drug-abstinent individuals tested with the patch falsely tested positive. (see Kidwell, Kidwell, Shinohara, Harper, Roarty, Bernardt, McCaulley, Smith (2003) Comparison of Daily Urine, Sweat, and Skin Swabs Among Cocaine Users. Forensic Science International, 133(1-2):63. Preston K.L., Huestis M.A., Wong C.J., Umbricht A., Goldberger M.A., Cone E.J (1999) Monitoring Cocaine Use in Substance-Abuse-Treatment Patients by Sweat and Urine Testing. J. Analyt Toxicol, 23:313.) These unacceptably high false positive rates should preclude the use of the sweat patch as a stand-alone test.

SAMHSA admits that sweat patch contamination is a "concern" yet proposes to overcome these serious issues by requiring a wash procedure. [2] Moreover, scientific evidence shows that washing of the skin prior to application of a sweat patch does not reliably prevent

---

1. Proposed Revisions to Mandatory Guidelines for Federal Workplace Drug Testing Programs, 69 Fed. Reg. 19676 -7(April 13, 2004).
2. Proposed Revisions to Mandatory Guidelines for Federal Workplace Drug Testing Programs (April 13, 2004)

environmental contamination of the patch. Such a procedure could be useful if the cleaning materials were retained and tested, but the proposed guidelines do not contain such requirements.

The introduction to the proposed regulations also states that the sweat patch detects "drug use shortly before the patch is applied and while the device remains applied to the skin."[3] However, published research has shown how drugs can be stored in the skin for long periods of time and then released into the sweat patch, falsely indicating recent drug use. (see Levisky, Bowerman, Jenkins, and Karch (2000) Drug Deposition in Adipose Tissue and Skin: Evidence for an Alternative Source of Positive Sweat Patches 110 Forensic Science International 35 (2000) and Kidwell, Kidwell, Shinohara, Harper, Roarty, Bernardt, McCaulley, Smith (2003) Comparison of Daily Urine, Sweat, and Skin Swabs Among Cocaine Users. Forensic Science International, 133(1-2):63.) Given the lack of an established window of detection for the sweat patch, federal agencies should not employ this device in any context where recent use must be distinguished from remote exposure. The device is simply unsuited for return to duty or follow up workplace drug testing as proposed in the revised mandatory guidelines. [4]

Hair Testing

I have been involved in the evaluation of hair as an alternative specimen for work place drug testing for over 10 years. I have also conducted and reviewed numerous studies evaluating hair as a sample source for workplace drug testing. (see FP Smith, DA Kidwell. (1996) Cocaine in hair, saliva, skin swabs, and urine of cocaine users' children. Forensic Science International 83:179-189.) Hair is subject to external contamination with drugs. (see Romano, Barbera, Lombardo (2001) Hair Testing for Drugs of Abuse: evaluation of external cocaine contamination and risk of false positives. Forensic Science International, 123:119.) Hair also varies in its external and internal uptake of drugs and this variation can result in a "hair type bias" where, for example, African American test subjects would be more likely to submit positive hair samples due to passive exposure to controlled substances in the environment. (see Reid R.W., O'Connor F.L., and Crayton J.W. (1994) The in vitro differential binding of enzoylecgonine to pigmented human hair samples. J. Toxicol Clin Toxicol, 32:405; R.E. Joseph, W-J Tsao, T-P Su, and E.J. Cone. (1997) In vivo characterization of cocaine binding sites in human hair, J. Pharmacology and Experimental Therapeutics, 282:1248-1241.)

Most importantly, it is not possible to distinguish a false positive hair drug test result due to mere environmental exposure from a positive due to intentional ingestion of drugs. (see Romano, Barbera, Lombardo (2001) Hair Testing for Drugs of Abuse: evaluation of external cocaine contamination and risk of false positives. Forensic Science International, 123:119.) I must respectfully dispute the statement in the proposed guidelines that with hair testing, "we can differentiate environmental contamination from actual use because of the presence of the metabolite, which is not present when environmental contamination is the source of the drug." [5] In fact, the cocaine "metabolite", benzoylecgonine, is produced *not only* during internal metabolism of cocaine *but also* as an analytical by-product in some hair testing dissolution

---

Proposed Revisions to Mandatory Guidelines for Federal Workplace Drug Testing Programs, 69 Fed. Reg. 19677 (April 13, 2004).

4. Id.

5. Proposed Revisions to Mandatory Guidelines for Federal Workplace Drug Testing Programs, 69 Fed. Reg. 19675 (April 13, 2004).

protocols. Moreover, benzoylecgonine can also be produced when cocaine contaminants break down on or in the hair itself, after environmental deposition. For these reasons, it is not yet possible to distinguish true positive hair drug tests from false positives due to environmental exposure of hair to drugs.

Finally, there is no scientifically validated method to clean drug-contaminated hair. As a result, it is not possible to reliably prevent false positive results due to environmental contamination.

SAMHSA has acknowledged these rather serious "limitations" of hair testing yet proposes to go forward with this new technology without explaining the reasons why reliable workplace testing should be compromised to include hair as a sample source. [6]

Oral Fluid Testing

SAMSHA proposes to include oral fluid as an alternative specimen while acknowledging that, as to marijuana, "further scientific study is needed to be able to differentiate between whether the parent drug was present in the oral cavity due to drug use or environmental contamination." [7] I submit that such studies are also necessary to determine whether or not other drugs of abuse are present in the mouth as contaminants. Oral fluid is particularly prone to contamination as individuals are constantly exposed to environmental contaminants through kissing and other intimate contacts as well as activities such as eating, smoking, fingernail biting, pencil chewing, and casual contact of the hands with the lips. Even though oral contamination goes away from saliva within a few minutes, fingernail biting and casual contact of the hands with lips could continue around the time of a saliva test.

Thus, while I approve of SAMSHA's proposal to require a urine specimen for confirmation of oral fluid results positive for marijuana, I believe urine should also be collected and required to confirm positive oral fluid tests for other drugs. Given these issues, I question the wisdom of adding oral fluid as an alternative specimen when it has not been scientifically validated as a stand-alone test.

Point of Collection Testing

SAMSHA's new regulations for federal agency Point of Collection Testing are not sufficiently rigorous to ensure reliable drug testing results. The POCT regulations would permit trained lay people to conduct work place drug testing without adequate scientific oversight. While I recognize SAMSHA's stated concern that scientific supervision of remote and overseas POCT drug testing would present "logistical" difficulties, [8] I believe that SAMSHA's proposal to allow federal agencies to create and oversee POCT drug testing programs is unwise. Federal

---

6. Proposed Revisions to Mandatory Guidelines for Federal Workplace Drug Testing Programs, 69 Fed. Reg. 19676 (April 13, 204).
7. Proposed Revisions to Mandatory Guidelines for Federal Workplace Drug Testing Programs, 69 Fed. Reg. 19676 (April 13, 204).
8. Proposed Revisions to Mandatory Guidelines for Federal Workplace Drug Testing Programs, 69 Fed. Reg. 19684 (April 13, 204).

agencies without SAMSHA's depth of scientific expertise will be hard-pressed to create accurate and reliable POCT drug testing programs, train and certify testers, and create quality control and inspection programs. Moreover, SAMSHA has failed to articulate protocols for identifying test kit failures and for identifying and controlling contamination in the POCT sites.

Finally, the proposed guidelines for POCT are so vague that they virtually ensure a lack of uniformity in such testing programs throughout the United States and abroad. It will be difficult if not impossible to design reliable studies for assessing the performance and reliability of very diverse POCT programs. For these reasons, I believe SAMSHA's proposal to create POCT programs for federal agencies is premature and should be set aside pending further study and protocol development.

Addition of GC/MS/MS and LC/MS/MS Testing

The existing guidelines, Section 2.4(f), provide that confirmatory drug testing analysis shall be by mass spectrometry (MS). Subpart K, Section 11.15 of the proposed guidelines adds three new analytical methods to the existing guidelines, GC/MS/MS, LC/MS and LC/MS/MS.

I am concerned that the addition of tandem mass spectrometry as a confirmatory detection method will degrade the reliability of drug testing results because of the possibility that laboratories will employ single ion monitoring. Minimal standards for confirmatory testing currently require triple ion monitoring to produce confirmatory test results that identify controlled substance analytes with acceptable reliability. While a single ion monitoring system is more sensitive and therefore capable of detecting analytes at lower levels than a triple ion system, the results are less specific and therefore less reliable. (see Smith F.P., Kidwell D.A. (2000). Commentary on Minimal Standards for the Performance and Interpretation of Toxicology Tests in Legal Proceedings, J Forensic Sci 45(1):237.) GC/MS is a reliable confirmatory test method under the existing guidelines and I believe that the addition of tandem mass spectrometry as a detection system is risky, unnecessary, and unwise.

Sincerely yours.

Frederick P. Smith, Ph.D.
Professor
Graduate Program in Forensic Science
Department of Justice Sciences
The University of Alabama at Birmingham