FR Doc # 04-7984
Public Comment 8400029

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Dr. Walter F. Vogl
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5600 Fishers Lane, Rockwall II, Suite 815
Rockville, MD 20857

June 15, 2004

Re: Substance Abuse and Mental Health Services Administration/DHHS.
FR Doc. 04-7984.

Dear Dr. Vogl:

Attached please find a copy of our comments and recommendations in reference to the above-captioned subject.

Thank you for your attention.

Sincerely,

Anthony Wu, Ph.D.

Encls.

Re: SAMHSA/DHHS
FR Doc. 04-7984

GENERAL COMMENTS:

The proposed alternate biological media to be used in the Federal Workplace Program is premature and scientifically questionable at this time. It is a known fact that hair testing is racially bias – for a given drug, dark-haired donors will produce higher concentrations than light-haired donors due to differences in pigment concentration. There is no need to rekindle racial discrimination through federally mandated hair testing. In addition, there are serious issues related to hair contaminants which has not been satisfactorily resolved.

Limited proficiency test results for alternate biological media by participating laboratories have shown that results can vary widely, indicating the methodologies employed are not generally reproducible. The Federal Government should not allow any uncertain drug testing results in the Workplace, especially when the "Gold Standard", urine, is available and is the only biological media recognized by the Court. Administratively, depending on the type of biological media used, it is conceivable that a mixed result can be obtained from a given donor, *i.e.,* negative for urine and positive for hair, further complicates the federal mandate program. Such scenarios will generate lawsuits and will pit one laboratory against another.

The proposed POCT violates the foundation of the Drug Free Workplace Program where collection site/collector, laboratory testing and MRO review/reporting processes are distinct, separate entities. The POCT arrangement compromises the anonymity (Section 4.1) of the donor and invites the possibility for 'collaboration' between donor and collector. Since the stringent guideline rules for certified laboratories (*e.g.*, site and LIMS security, testing requirements such as $\pm$25% CO QCs, blinds, CCF documentation, adulteration, data review, *etc.*) are imposed in the name of forensic defensibility, should not this same rational, at a minimum, be required for POCT and IIFT testing?

It is not in the employer's financial best interest, especially for a pre-employment drug screen situation, to confirm their POCT screen which are presumptive positives. This may unduly compromise this donor's chance of being hired. The proposed guidelines should not be applicable to DOT-regulated industries since HHS and DOT employees are categorically different, *i.e.,* government vs. private.

RECOMMENDATIONS:

We as scientists who have been engaging continuously in the Federal Drug Free Workplace Program since the late eighties, recommend that (1) the proposed guidelines on alternate biological media (hair, oral fluids, sweat) should be withdrawn. They can be revisited in three to five years when its science and technology hopefully improves to warrant serious scientific consideration. (2) Strengthen the existing urine drug testing program by allowing only specimen validity testing (SVT) to be performed at the collection site. When an SVT is resulted as a non-negative at the collection site, an observed urine collection should immediately follow. This process will effectively stop violators at the scene – a true deterrent and will greatly improve the program as a whole, and (3) The certified laboratories can concentrate on what they do best by adopting the proposed guidelines on lowering the urine cutoff levels for benzoylecgoine (to 150 ng/mL) and amphetamine (to 500 ng/mL) including MDA, MDMA and MDEA and their corresponding confirmation cutoffs; 100 ng/mL and 250 ng/mL, respectively.