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#04-7984
P.C. 8400110

July 7, 2004

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Comments Re: Proposed Mandatory Guidelines for Federal Workplace Drug Testing Programs, Alterative Testing (69 CFR 19672, April 13, 2004, FR Doc #04-7984)

Dear Dr. Vogel:

Please accept and record the following comment to FR Doc #04-7984).

Although I understand that the proposed revisions to the mandatory guidelines to include alternative specimens are the result of intense congressional pressures, I sincerely believe these revisions are not ready for implementation.

There are major scientific obstacles to each of the suggested alternative methods of testing. These problems, in some cases, are admittedly areas of scientific controversy. However, there also exists clear-cut, unrefuted scientific evidence of weaknesses to these alternatives, which may render them ineffective under the combined scrutiny of defense attorneys, and scientific peer review.

HAIR

HHS reviewed 15 references on hair testing. Twelve of those references contain warnings about interpreting hair test results with respect to hair color. One of the HHS references, Handbook on Alternative Testing Matrices by Huestis and Cone, Chapter 11, presents a subsection on "racial effects and possible bias." There are 3 additional cross-references by R. Joseph, et al., in this subsection and they all allude to this problem.

The study that offers powerful evidence of racial bias is the study from the University of Utah Health Services Center, Department of Pharmacology and Toxicology. It was reported by Rollins, et al., in the Journal of Analytical Toxicology, Vol 27(8) Nov-Dec, 2003, pp 545-551. It is

number 2 in your bibliography from the Federal Register, April 13, 2004. This well-constructed study reveals very strong direct evidence of racial bias with hair testing.

I am unaware of any study, literature or evidence, which directly refutes these findings. This includes all 15 articles cited in the HHS bibliography noted above.

Below are 2 citations of legal cases that upheld the notion that there is no racial bias to hair testing. The decisions in these two cases turned on the fact that no evidence was presented to support the contention of racial bias in hair testing. Had any of the evidence in the foregoing discussion been presented, I suspect the outcome of these 2 cases might have been very different. Further, the argument that "hair testing doesn't lose racial bias cases in court" is specious, since we don't know how many of these have been settled out of court.

I believe the preponderance of currently available scientific evidence favors the concept of racial bias in hair testing. If hair testing is acceptable by HHS, the defense bar will be avidly seeking this sort of evidence for their clients' defense.

If called to testify as an MRO, I must, in good conscience, testify that there is strong scientific evidence of racial bias in hair testing. I hope you will not put the MRO's into the position of having to defend this matrix.

ORAL FLUIDS

Even HHS admits to the known inaccuracy of oral fluid testing for Marijuana, the commonest drug of abuse. At present, science cannot differentiate between oral fluid Marijuana from external contamination and that arising from actual use.

HHS appears to be attempting to solve a scientific knowledge gap with an administrative policy. This policy will require the increased cost of 2 collections. For every oral fluid collection, a concomitant urine collection must be obtained. Double collection costs and double collection error probability will ensue. If oral fluid Marijuana is found, the urine specimen must be tested. This causes double testing costs and doubles turnaround time, since the tests are run consecutively; not concurrently.

Who would be foolish enough to do this? Who is going to pay for this?

SWEAT

The sweat patch has very limited use; follow-up and return to duty. A significant number of people are allergic to the adhesives in skin patches. In fact FDA approved skin patches for drug delivery systems mention skin allergy and irritation. While these are generally mild, they can, in rare instances, be severe. Who bears the liability and medical cost for an adverse skin reaction to a mandated drug test? The employee? The employer? The collector? HHS? This is the only testing matrix with a built in possibility of an adverse reaction from the test itself.

A major limitation of sweat patch testing is that the production of sweat varies with physical activity and environmental temperature, thus the volume of sweat collected during the week it is worn is unknown.

This precludes quantitative measurement of drug concentration per mL of sweat. The report is in "amount per patch." Without concentration quantification (ng/mL sweat). Any cutoff level loses much of its value because the amount of drug per patch is a function of body activity and environmental temperature, as well as amount of drug ingested. How is a fair cutoff level established with these variables in play? Thus it's impossible to equate any positive sweat test with the positives for urine, hair or oral fluids. Without "equitable" results, sweat testing is forever relegated to follow-up and return-to-duty testing as its only value.

Furthermore, environmental contamination has been shown to pass drugs through the so called "impermeable outer membrane" of these testing patches, and are capable of causing false positives according to Kidwell et al-- #39 in the HHS bibliography published in the Federal Register April 13, 2004. However, the study by Fogerson et al-- #45 in the same bibliography, indicates the polyurethane outer layer of the sweat patch is impermeable to molecules larger than dimmer water. The focus is not simply whether a molecule must be smaller then dimmer water to traverse the polyurethane outer coating. It must also be whether or not any common substance is likely to degrade the polyurethane outer coating and render it permeable to external drug contamination. The Federal Register states:

> "Based on that information, the Department believes that external absorption of any drugs through the outer layer is not possible under normal circumstances." The operant wording here is "under normal circumstances."

There is a large array of substances, which "under normal circumstances" might come into contact with the patch and degrade its impermeability to allow passage of external drugs to contaminate the patch.

Examples include: Acetone, rubbing alcohol, ethanol, ammonia (household cleaners), nail polish remover, paint thinner, turpentine, muriatic acid (swimming pool maintenance), monosodium glutamate (food handlers), bleach, stain removers, and a number of chlorinated hydrocarbons such as benzene and carbon tetrachloride. A commonly used industrial chemical, dimethyl sulfoxide ($DMSO_4$) greatly enhances passive transfer of drugs through a very impermeable membrane—skin. In fact $DMSO_4$ has been used, off label, by physicians as a therapeutic agent, by itself, when applied directly to the skin for absorption.

These products are ubiquitous in our environment and "under normal circumstances" could very easily come into contact with the sweat test patch. I don't know of any studies testing the patches against such products, but this kind of knowledge would seem to be essential before approving this matrix.

IITF'S

I really don't understand why these are being proposed. The only positive statement in the preamble is that an ITTF is "basically the screening part of a screening and confirmatory laboratory, but established in locations to potentially (read "possibly") more quickly and economically meet special local testing needs." HHS cites the existence of fewer than 60 HHS certified labs for Federal Workplace Drug Testing. Why do we need additional laboratory sites? There currently exist hundreds (if not thousands) of collection sites all over the United States. Proximity to a location initiating the testing is not a factor. The collection sites initiate the testing process. Not the labs. This will not increase availability for testing or competition. The existing labs would most likely establish the IITF's.

Increased need for transporting the specimen and the attendant record keeping and paper handling will surely increase the costs and error rate for this paradigm. Do the laboratories want this? Do MRO's want this?

POCT'S

HHS states a POCT device only needs to be accurate on 80% of its challenges to be certified. In section 12.12 a failure is defined as:

A. For a drug POCT, the device failed to properly identify a negative or positive patient sample.

B. The device failed to identify a POCT sample that was adulterated, substituted, or dilute.
C. The device reported a false negative after confirmation by a lab.

A reliability rate of 80% is far below the standards for any other component of the Federal Workplace Drug Testing Program. POCT's should be judged by the same standards as laboratory screening testing. This would be a substantial "dumbing down" of the drug testing process if HHS embraces an 80% reliability of the entire Federal Drug Testing Program as any stronger than its least reliable component. Doesn't it seem ridiculous to mandate specific gravity testing to four decimal places, and then accept a 20% error rate for another component of the same program?

RAMIFICATIONS

The mandatory guidelines promulgated by HHS become the basis for the Department of Transportation (DOT) drug-testing program, because the Omnibus Transportation Employee Testing Act of 1990 requires DOT to incorporate the scientific and technical guidelines of HHS.

Since DOT is bound by the rules HHS puts forth it would seem wise to have DOT's input before the rules become set in stone.

The test volumes per year for the entire drug testing industry are:

Federal Workplace	DOT	Non-Regulated
200,000	7,000,000	28,000,000
.006%	20%	80%

The non-regulated programs generally attempt o model themselves after DOT regulations 49 CFR Part 40, which in turn "incorporates" the mandatory guidelines of HHS. Thus, while the HHS guidelines are intended for 1,000,000 Federal employees, they also impact 12,000,000 transportation workers and 56,000,000 non-regulated employees in the United States. This puts HHS in the strange position of writing a rule for a target population of 1,000,000, but which, in fact directly impacts 68,000,000 other workers in the United States.

It would appear reasonable to form a reconciliation committee of HHS and DOT members to promote a single unified rule for both governmental agencies. It seems so obvious:

- These are 2 agencies of the same Federal government.
- They have the same goal: to deter the use of drugs in the workplace.

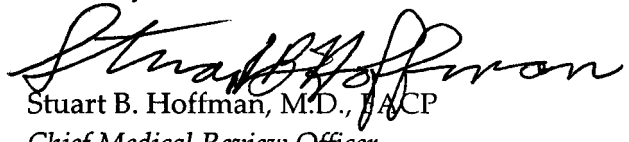
The United States Congress does exactly that when each house passes a different version of the same bill.

- If our Senators and Congressman can put aside their differences to achieve a recognized common goal, why can't 2 Federal agencies do the same thing?

FAVORABLE COMPONENTS OF THE PROPOSED REVISIONS

1. Lowering the cutoff levels for Cocaine to 150 and 100, and Amphetamines to 500 and 250 will serve to strengthen the deterrence element of the program by prolonging the window of detection for these substances. It will also make it more difficult to "dilute" a specimen by excessive water intake.
2. Inclusion of MDMA, MDA, and MDEA as testing targets is very helpful. There has been a definite increase in use of these drugs in recent years, and this would close some obvious loopholes.
3. Requiring labs to report quantitative values on all positive results will certainly help the MRO. We are frequently called by substance abuse professionals (SAP's) who request these values. If they are not included on the lab copy of the CCF or the lab report, the MRO must call the lab for the results, and then convey it to the SAP. This is extra time and work, which can easily be avoided by initially including the already available quantitative values in the lab report.

Sincerely,



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DISCLAIMER

The views and opinions expressed in these comments are solely those of Dr. Stuart B. Hoffman and do not necessarily reflect the views and opinions of ChoicePoint Services, Inc.

Disparate Impact and Statistics

Stewart v. International Truck and Engine Corp., Case No. 01 C 2756 (U.S.D.C., Northern Dist. IL, July 2, 2002)

- The United States District Court granted summary judgment in favor of International Truck and Engine Corp. and dismissed the case, finding that *"...Stewart has simply rested on his allegations that defendant's practice of using hair samples has a disparate impact. Stewart has presented no statistical evidence in support of his disparate impact claim, and this lack of statistical evidence is fatal to Stewart's disparate impact claim."*

Bias Evidence

- ***Jones et al. v. City of Chicago, Civ. Action No. 99 C 8201 (11/28/00)***
- Judge ruled in favor of the City of Chicago and dismissed the case, finding that not only was some of the evidence inadmissible, but also that *"the remaining admissible evidence would be insufficient for a tryer of fact to find that the (Psychemedics) hair test is more likely to result in false positive results for African American applicants than for white applicants..."*