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VIA FACSIMILE (202) 395-6102

Susan Dudley, Administrator
Office of Information and Regulatory Affairs
Office of Management and Budget
Room 262 EEOB
1650 Pennsylvania Avenue, NW
Washington, D.C. 20503

Re: ***Mandatory Guidelines for the Federal Workplace Drug Testing Program***

Dear Ms. Dudley:

Thank you for meeting to discuss the HHS-SAMHSA final regulation on the federal drug testing program. I am writing to follow up on issues raised in the meeting.

First, you asked representatives from J.B. Hunt whether their records indicated that there were more refusals to test when administering a hair test than when administering a urine test. Here is what I am told. Of the 22,000 individuals tested or who refused to be tested the percentage of those who refused to take the urine test was .46 percent while the comparable number for refusals of hair testing was .68 percent. J. B. Hunt concluded that the disparity of those who refused one test but not the other looked at with the number who refused to take either test and the overall large number of the sample is of no real significance.

Additionally, it is difficult to explain why so many Fortune 500 companies would choose to use hair testing even incurring duplicate expenses for so long now without seeming to be deterred by any administrative difficulties. The safety reasons set forth in the meeting for using hair testing should be compelling.

Secondly, a question was asked again about "false positives" and Psychemedics has provided additional information. While I believe this question was addressed in the meeting, I am setting forth in the following paragraphs the further detailed information provided here and attaching an informative study they have provided.

A forensic "false positive" in drug testing occurs when a sample is reported to contain a certain drug and such presence cannot be confirmed through mass spectrometry. The term is often incorrectly applied when the medical use of a substance that is identified in a drug test is reported as a positive when a prescription for the drug exists or when some inadvertent ingestion takes place. These are "true positives"... the drug is actually there. There may be reasons for the drug to be there, however, when a drug is confirmed as present through mass spectrometry—the result is not a "false positive."

In the forensic arena of drug testing, accurate laboratory-based drug testing must be performed in a two-tiered fashion using two different scientific principles for detection. The first is commonly referred to as the screening test, and this technique is applied to all samples that go through the laboratory. Samples screening at or above the administration cutoff are then called "presumptive positive" and are structurally confirmed by a second, separate scientific principle called mass spectrometry (MS). Thus, in a typical forensic drug test, the initial screening test is followed by a mass spectrometry confirmation test thereby providing the benefit of two testing techniques verifying the presence of the same drug type.

Inherent in the process of evaluating screening methods generally accepted in the scientific community, is clearance by The Food and Drug Administration ("FDA") either by pre-market clearance submission or a 510(k) application under the U.S. Food Drug and Cosmetic Act. In this clearance process the screening assay is reviewed under regulations designed to ensure accuracy and reliability. Such clearance is granted by the FDA after reviewing the screening test for safety and reliability and subsequently finding the scientific methods as precise and accurate for the purpose. There is no higher authority in scientific peer review than the FDA and both urine and hair assays have been cleared by the FDA.

Screening tests are generally performed using immunoassay (EMIT, ELISA, and RIA being the most commonly cleared by FDA). These screening tests typically allow some amount of false positives and false negatives because of cross reactivity with related compounds, use of certain prescription drugs and adulteration. The screening test, however, is only a preliminary determination.

The confirmation test in most laboratories is performed using various types of mass spectrometry in combination with chromatography, either gas (GC) or liquid (LC). This combination of two physical properties for molecular structure identification (such as GC/MS, LC/MS/MS and GC/MS/MS) guarantees unambiguous identification of the drug moiety and its metabolites at the molecular level. The confirmation test phase involves testing for the molecular sub-structures and their characteristics by chromatography and mass spectrometry equipment and comparing these to known references. In common terms, this molecular identification is akin to the uniqueness of finger printing.

Therefore, a "false positive" sample from the screening test will result in a negative result on the confirmation test and be reported "Negative." Samples testing positive during both screening and confirmation tests are reported as "Positive" as the drug is confirmed as present (regardless of whether or not a medical or other explanation exists for the presence of the drug).

The two tiered scientific identification process is not subject to a false positive result based on three recognized and accepted applied principles: screening, chromatographic behavior and tandem mass spectrometry. The confirmation with mass spectrometry identifies the specific compound present and does not produce "false positives" since the sample is not reported "positive" unless the particular molecular components of a substance is established as present.

The attached paper is typical of the studies undertaken in this area with hair. The study, peer-reviewed and published in Forensic Science International, demonstrates that proven non-users (denying any use and testing negative on 10 consecutive urine tests over a 5 week period) in no instance tested positive on the hair test. (100% accuracy in avoiding false positives) Over 97%

of the "user" population (persons admitting use and testing positive on at least one out of several urine tests) had positive results in the screening test and 95% of those were confirmed positive by mass spectrometry above the cutoff.

Akin to the claim of "false positive" (but not actual false positives because the drug is confirmed as present) are the claims that positive results were generated by external sources of drug. This could include passive ingestion, dermal absorption or some contamination scenario.

Because of the higher threshold levels in hair compared to urine (it requires ingestion of significantly more drug to generate a positive result in hair compared to urine) as well as the extensive wash procedures that have been demonstrated to account for external drug contact, hair testing is capable of providing increased safeguards in this area compared to urine testing. When proper procedures are followed, these are unlikely sources of positive results with urine tests and even more unlikely with hair testing.

Finally, Psychemedics wishes to reiterate its position that they are not suggesting that urine testing should be replaced by alternate tests or that alternate tests should be mandated. Rather, the agency should address alternate tests as it began to in the proposed rulemaking. If the agency were to disregard alternate tests altogether, Psychemedics urges that SAMHSA should re-promulgate the rule as a notice of proposed rulemaking. It has taken years for the agency to address alternate matrices in a proposed rule and four more years for the proposal to reach the final rule stage. To abandon alternate matrices now would be to ignore many years of technological advances, guidance sought by the agency from its advisory group, and rounds of public comment. Such a final rule would be a tremendous setback for both the public and private sectors.

Again, thank you for your time and consideration. If we can provide additional information, please do not hesitate to contact me.

Sincerely,

Harriet Miers