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To: "'wvogl@samhsa.gov'" <wvogl@samhsa.gov>
Date: 7/12/04 5:54PM
Subject: Proposed Guidelines for Drug Testing

I am responding to the SAMHSA solicitation for comments concerning the new proposed guidelines for drug testing. I would like to address several issues:

1) The new proposed cutoffs for urine methamphetamine testing include a requirement for the presence of amphetamine. The rationale stated is that the presence of high concentrations of pseudoephedrine may produce false positives if confirmation relies on detection of methamphetamine alone. I would argue that many of the specimens collected within 24 h of methamphetamine use, though containing methamphetamine levels well above the cutoff, will contain very little or no amphetamine. At least two controlled clinical studies demonstrate this rather conclusively. This regulation will seriously limit the ability to detect recent methamphetamine use. It may also limit the ability to detect use when specimens are collected at the end of the excretion curve. I would recommend that requirements be made to employ methodology that has no potential for pseudoephedrine induced false positives or the use of a second method in those cases reporting presence of methamphetamine without concurrent amphetamine detection.

2)The new proposals do not include oral fluid sampling devices as accepted means for collection of oral fluid specimens. The rationale stated in the new proposal indicated that this was due to the possibility of causing increased oral fluid pH with the increased flows that these devices induce. It was then postulated that this could result in reduced drug elimination in oral fluid. However, increased pH would only affect the elimination of base drugs adversely if it's due to an ion trapping mechanism and would increase the disposition of acidic drugs and metabolites in oral fluid. The mechanism(s) of drug disposition in oral fluid have not been adequately described to make this kind of judgement. While a research chemist at the IRP, NIDA, I participated in several studies comparing oral fluid collection methods and we found no statistically significant differences in the elimination of drugs of in oral fluid collected by nonstimulated versus stimulated expectoration. Oral fluid collection devices would actually be very easy to standardize and would be much more convenient than the expectoration in a tube method as described in the proposal.

3)The requirements for the collection of a urine specimen in addition to oral fluid will result in lack of oral testing use by the testing community. The fact that oral fluid levels from contamination clear within the first 30 min means that samples collected after this time period should be valid. A requirement that oral fluid be collected at least 30 min following suspected use should alleviate any concern about oropharyngeal contamination therefore alleviating the need for urine collection.

4)The new proposals do not list oral fluid as a test matrix for follow-up and return to duty testing. The rational is the short detection time for oral fluid. This is precisely the time when oral fluid testing can used most effectively to detect recent drug use and not be confused with carry-over from previous use. Further, a report authored by Cone et.al. (JAT, 26: 541-546, 2002) found that oral fluid testing of over 77,000 specimens produced nearly identical, and in some cases better detection

rates compared to urine testing.

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