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July 9, 2004

Walter F. Vogl
Drug Testing Section, Division of Workplace Programs, CSAP
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FAX: 301-443-3031

Re: Docket # 04-7984
Comments on Proposed Revisions to Mandatory Guidelines for Federal Workplace Drug Testing Programs, 69 FR 19673 (April 13, 2004)

Dr. Vogl:

I represent MeadWestvaco Corporation, a leading global producer of packaging, coated and specialty papers, consumer and office products, and specialty chemicals. The company is headquartered in Stamford, CT and has 21,000 employees located in 41states. MeadWestvaco is committed to the responsible management and development of the human, natural, physical and financial resources entrusted to our care by our shareholders, employees and communities. An essential part of this commitment is the company's drug-free workplace program.

MeadWestvaco has successfully introduced the FDA-approved Intercept® oral fluid testing device into its drug-free workplace program at some of our major manufacturing sites and plans to expand its use throughout the company. We contract with a SAMHSA certified laboratory to process our Intercept® oral fluid specimens. Since adopting Intercept® testing, we have found this oral fluid testing to be cost-effective, convenient and reliable. In addition, our employees have expressed appreciation that the oral fluid sample collection procedure is much less invasive and embarrassing than urine sample collection.

We appreciate the opportunity to comment on the proposed revisions to the Mandatory Guidelines for Federal Workplace Drug Testing Programs, and we applaud the efforts by HHS to expand the program. We understand that HHS is making these proposed revisions to fulfill a mandate to utilize the "best available technology" for drug-free programs. We wish to comment on three recommendations in the proposed regulations addressing oral fluid testing.

Proposal for the collection of oral fluid as a "neat" specimen

In section 2.5(b), the collection of oral fluid is specified as "2mL collected as a 'neat specimen' (divided as follows: at least 1.5mL for the primary specimen and at least 0.5mL for the split specimen)." We believe that collection of oral fluid using the FDA-cleared Intercept® collection device, which utilizes an absorbent pad, is also an acceptable - if not preferred - collection method.

Spitting into a tube (to provide a "neat" specimen) does not necessarily represent the "best available technology," nor do we believe this collection method is the most practical option. The additional cost and time required for collecting "neat" specimens could be significant. The collection environment would require control and possibly sanitizing, and the allowance of 15 minutes to provide a specimen is five times longer than the collection process with the FDA-cleared Intercept® oral specimen collection device. Specimen collection of oral fluid with an absorbent pad is relatively consistent, and the donor is not able to attempt to dilution or adulteration of the sample.

Section 1.5 defines a split specimen for oral fluid as "one specimen collected that is subdivided or two specimens collected almost simultaneously." We have successfully used two FDA-cleared absorbent pads for collections, by having the donor place one unit in each side of the mouth or by having the individual collect a second specimen immediately after the first.

In section 7.1(c), the collection device for oral fluid is specified as a "single-use plastic specimen container." We propose that the collection device must be an FDA-cleared absorbent pad, which is then placed into a fixed amount of transfer buffer. The issue of an FDA-cleared collection device is also addressed in section 7.2(b). Finally, the collection device is also addressed in the specific collection procedures in section 8.3(a)(5) through 8.3(a)(10).

2. Proposal for collecting a urine specimen with each oral fluid specimen.

In section 2.3(a) and section 8.3(a)(16) addressing the specific collection procedures for an oral fluid specimen, it is specified to also collect a urine specimen, for the purpose of addressing the possibility of a positive oral fluid test result from passive exposure to cannabis smoke. We believe this additional specimen collection is unnecessary and would, practically, remove the primary benefit of oral fluid testing -- the ability to eliminate costly and inconvenient urine specimen collections. This requirement would effectively eliminate the use of laboratory-based oral fluid testing, since urine collection would be required for each sample.

We understand that recent research conducted by Dr. Edward Cone, and soon to be published in the Journal of Analytical Toxicology, shows that positive oral fluid test results from any realistic "side stream" exposure situation would be extremely unlikely. Specifically, this research demonstrates that environmental contamination is limited to only extreme exposure conditions (several joints smoked in a small, sealed room), and then for only short periods after exposure (up to 30 minutes).

3. Applicability of oral fluids testing to return-to-duty, follow-up testing.

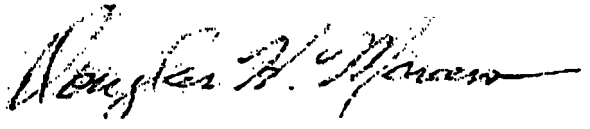
In section 2.2, oral fluid is specified for "pre-employment, random, reasonable suspicion/cause and post-accident testing." We believe that oral fluid testing is appropriate for <u>all</u> testing scenarios. It is clearly suited for Return-to-Duty and Follow-Up testing because it detects recent drug use. A worker successfully completing a substance abuse recovery program and staying clean from drugs will appropriately test clean more quickly

with oral fluid testing.

Oral fluid samples are also less vulnerable to sample adulteration or substitution than are urine specimens. It is known that some workers involved in a substance abuse recovery program will attempt to tamper with urine specimens by diluting or adulterating them, or by substituting clean urine. Oral fluid testing provides a directly observed collection that virtually eliminates the opportunity to tamper with specimens.

We again thank the Department for this opportunity to provide information to assist it in drafting and finalizing drug testing guidelines and for their careful consideration of these points.

Sincerely,



Douglas H. Marcero
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