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Public Comment 8400047

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Re: Docket #04-7984

Walter F. Vogl, Drug Testing Section, Division of Workplace Programs, CSAP

Comments on Proposed Revisions to mandatory Guidelines for Federal Workplace Drug Testing Programs, 69F$ 19673 (April 13, 2004)

Dr. Vogl:

We represent approximately 700 employees in 15 states where we utilize Intercept* oral fluid testing for our company's drug-free workplace program. We are involved in plastics manufacturing at each of our locations, and are experiencing growth and the addition of new manufacturing facilities in several areas. We are committed to providing a safe workplace for our employees, as well as encouraging healthy lifestyles. Our recordable injury record is steadily declining in all facilities, as indicated by our OSHA records. We are also committed to compliance with State and Federal regulations in all areas of our business, including our Drug Free Workplace program.

Our company contracts with LabOne to process our Intercept oral fluid specimens. With 25 plants in 15 states, our pre-employment, random, and post accident testing creates the need for extensive use of this program. We have found it to be a cost-effective, convenient, and reliable way to meet our goals.

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.

1 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' (dived 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 an FDA-cleared collection device is also an acceptable if not preferred collection method. We have experience with this method in the collection of all our oral fluid specimens since we began the use of oral fluid testing procedures.

Spitting into a tube does not necessarily represent the "best available technology," no do we believe this collection method would be practical. Our applicants and employees appreciate the dignity of an oral fluid collection, which we do not believe exists for donors required to spit into a container. The additional cost and time required for collection "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 oral specimen collection device. Specimen collection of oral fluid by an absorbent pad may be shown to be relatively consistent, and the donor is not able to control any variances by attempting to dilute or adulterate the sample.

In addition, section 1.5 defines a split specimen for oral fluid as "one specimen collected that is subdivided or two specimens collected almost simultaneously." Two FDA cleared collection devices could be used. In section 7.1© 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 collection 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. Scientific data demonstrates that positive oral fluid test results from any realistic exposure situation would be extremely unlikely, especially with established cut-off limits.

The primary benefit of oral fluid testing is the ability to eliminate costly and inconvenient urine specimen collections. Requiring collection of both specimens not only negates the convenience and timesaving aspect of oral fluid testing; it adds an unreasonable additional cost and is more privacy invasive.

We would like to alert HHS that since these proposed guidelines were drafted, authoritative scientific data on the effect of environmental exposure to cannabis smoke on oral fluid tests has been developed and accepted by the Journal of Analytical Toxicology for publication (Dr. Edward Cone et al). 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).

The likelihood of environmentally caused positive test results is extremely low if not negligible. We believe this new data should allow HHS to draw the same conclusion about oral fluid testing that it did with urine testing: "The Department does not believe that passive inhalation is a reasonable defense or that significant exposure can occur through passive inhalation to cause a urine specimen to be reported positive." HHS, Mandatory Guidelines for Federal Workplace Drug Testing Programs, 59FR 29908, (1994).

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." In Draft 4 of the guidelines, oral fluid was recognized as suitable specimen for all authorized testing scenarios. However in the published Proposed Guidelines, the application of oral fluid testing to return-to-duty and follow-up testing was removed. Although the basis for this change was stated as due to the claimed short detection time for drugs in oral fluids, a review of published epidemiological data demonstrates that oral fluid has sensitivities comparable to urine for detection of drug use.

Oral fluid testing is appropriate for all testing scenarios. It is clearly suited for Return-to-Duty and Follow-up testing. Oral fluid is suited for Return-to-Duty and Follow-Up testing because it detects recent drug use. A worker successfully completing a substance abuse recover program and staying clean from drugs will appropriately test clean soonest with oral fluid testing.

Oral fluid testing is also uniquely able to detect illicit drug use. A worker trying to cheat on a SAP's program is very likely to 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. We are eager to offer whatever further information and comments that will allow

HHS to fulfill its statutory obligations to "establish comprehensive standards for all aspects of laboratory drug testing and laboratory procedures to be applied in carrying out

Executive order Numbered 12564,.. including standards which require the use of the best available technology for ensuring the full reliability and accuracy of the drug test.

Sincerely,

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