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

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

Dr. Vogl:

This letter represents Publix Super Markets, Inc., with ~ 125,000 associates in five states, successfully implementing Intercept® oral fluid testing for our company's drug-free workplace program. Publix has been ranked "A great place to work" by FORTUNE Magazine for seven consecutive years. We believe our commitment to the dignity, value, and employment security of our associates has been a key factor in this accomplishment. It is our belief that oral fluid drug testing is a dignified and convenient method for ensuring a drug-free environment for Publix associates and customers. Our company utilizes Quest Diagnostics to process our Intercept oral fluid specimens. We are currently in the process of implementing Intercept testing corporate-wide. Our company has processed more than 5,000 oral fluid specimens. We have found our Intercept oral fluid testing program 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' (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 an FDA-cleared collection device is also an acceptable if not preferred collection method. We have experience with this method in the collection of over 5,000 specimens.

Spitting into a tube to obtain a "neat" specimen does not necessarily represent the "best available technology," nor do we believe this collection method would be practical. Our associates 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 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 oral specimen collection device. Specimen collection of oral fluid by an absorbent pad has been shown to be relatively consistent, and the donor is not able to control any variances by attempting to dilute or adulterate the sample.

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 adds unjustified burden and cost for employers. Scientific data demonstrates that positive oral fluid test results from any realistic exposure situation would be extremely unlikely.

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.

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.**" 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 data demonstrates that oral fluid has sensitivities comparable to urine for detection of drug use in the workplace.

We believe oral fluid testing is appropriate for all 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 soonest with oral fluid testing.

Oral fluid testing is also uniquely able to detect illicit drug use. A worker trying to cheat on an 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 tests ..."

Sincerely,

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