PHARMCHEM INC.

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Dr. Walt Vogel
Drug Testing Section
Division of Workplace Programs
CSAP
5600 Fishers Lane
Rockwall II
Suite 815
Rockwall, Maryland 20857

Dear Dr. Vogel,

In response to the request by the Department of Health and Human Services regarding the proposed revisions to the Mandatory Guidelines of Federal Workplace Drug Testing Programs, PharmChem, Inc. would like to take this opportunity to submit the following comments.

PharmChem supports the Department's proposal to collect a urine sample with an oral fluid sample. However, the concept that the urine sample would be available for testing only if the oral fluid specimen was positive for THC appear to contradict the intent of this proposal. If THC is only present in oral fluid due to active exposure, what does a negative oral fluid test imply? It would seem that both the urine and oral fluid should be tested for THC to gather sufficient scientific data to address this concern.

In addition, the Department has proposed that the oral fluid be collected "non-stimulated". While this would appear to address the concern regarding dilution of the drugs from stimulated oral fluids and the concern that some drugs (THC) may adhere to the collection device, at least one individual at PharmChem has direct experience with the collection of non-stimulated oral fluids and the subsequent testing of this material for THC. Non-stimulated oral fluid is usually very viscous and can be difficult to work. It also proposes some collection challenges. There is an issue with aerosol dispersion of oral fluids during the "spitting" aspect of the sample collection that needs to be considered.

With respect to POCT testing, we submit the following comments for consideration. While POCT technology has made significant advances in recent years, PharmChem would urge the Department to adopt the same quality control and quality assurance criteria that the current certified laboratories are held to. The POCT devices must be able

to correctly identify a sample as negative when it has drugs 25% below the established cutoffs and as positive when the drugs are 25% above the established cutoffs. To hold the POCT devices to a lesser standard undermines the integrity of the entire testing program. In addition, POCT testing must utilize the same type of quality control and quality assurance testing of samples for specimen validity testing used in the certified laboratories. Otherwise, specimens that are substituted or otherwise adulterated will be reported as negative. Minimally, the POCT SVT should be able to correct detect samples at the decision points for creatinine, pH and oxidizing chemicals.

Section 11.12c indicates that: "Initial drug test kits must meet the FDA requirements for commercial distribution." PharmChem would seek clarification of this statement. Does this statement mean that the initial drugs tests kits must be FDA cleared for the specific application/matrix or does it mean that the initial drug test kits can meet the FDA requirements but not be FDA cleared? It is possible to meet the requirements in the sense of having all of the analytical data to support the claims of the application (linearity, precision, accuracy, specificity) but not be FDA cleared. Please clarify.

PharmChem would concur with the Department's proposal that the skin be cleaned with soap and water or a towelette followed by a through cleaning of the skin with two alcohol wipes prior to the application of a sweat patch. Studies conducted by D. Crouch at the Center for Human Toxicology which involved applying drugs directly to the skin, have demonstrated that this additional step facilitates the removal of more drugs than the use of alcohol wipes alone.

The proposal that a sweat patch be worn for at least three days is conservative. Controlled dosing studies conducted by Dr. Ed Cone indicated that drugs appeared in the sweat within a few hours post dose, with a majority of the drug appearing within the first 24 hours. Currently the sweat patch is worn successfully for at least two weeks. Therefore the recommendation that the patch be worn for no more than 7 days is too restrictive. PharmChem would recommend that this wording be changed to no more than 14 days.

Based on the wear times, PharmChem would concur with the Department's proposal that the sweat patch be used for return to duty and follow up testing circumstances.

With respect to SVT for sweat, PharmChem has recently conducted a study for the presence of lactate in sweat. These results from approximately 1000 sweat patches indicate that lactate (lactic acid) is present from 2 to over 500 mg/dl. Therefore while it appears to be technically feasible to test for the presence of lactate, more controlled studies are needed to determine what these lactate levels represent and what constitutes a meaningful lactate level in sweat.

Currently, sweat patches are screened using ELISA technology. The methamphetamine assay used for sweat testing has a reported cross-reactivity that is greater than 200% to MDMA. Therefore, the detection of MDMA in sweat does not appear to be a problem.

On the urine testing side, PharmChem currently uses the CEDIA amphetamine/xtc screening reagent for the testing of urine samples from clients that wish to test for the presence of MDA and MDMA. Our data has demonstrated that this particular screening product has good sensitivity for the detection of amphetamine, methamphetamine and MDMA, due to the presence of several antibodies in the screening reagent. Unfortunately, because of these multiple antibodies, this reagent also has high cross-reactivity to other sympathomimetic amphetamines.

PharmChem would support the position to allow a laboratory to report quantitative values for non-negative specimens rather than wait for the MRO to request the information. This would reduce the amount of time needed by the MRO to make a final ruling on a non-negative specimen and subsequently improve the final reporting time. Much of this is already being done, but it has required the MRO and the laboratory to maintain files for blanket quantitation letters. This change would remove this cumbersome hurdle.

PharmChem thanks you for your time and consideration and commends the Department for its efforts to incorporate alternative samples into the Federal Drug Testing Program.

Sincerely,

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Vice President Laboratory Operations
Chief Scientific Officer