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To: <wvogl@samhsa.gov>
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Subject: comment on FR Doc. 04-7984

Dear Walt: These are my comments on the Proposed Revisions to Mandatory Guidelines for Federal Workplace Drug Testing Programs. Not surprising I will comment only on hair testing and then only on the issue of drug binding to melanin.

The Proposed Revision has done a nice job of summarizing our findings with regard to drug - melanin binding and much of that does not need to be repeated. There is a substantial amount of scientific data which demonstrates that drugs that are weakly basic such as codeine, amphetamine, methamphetamine, phencyclidine, methylenedioxymethamphetamine (MDMA), morphine, and cocaine bind to melanin. Weakly acidic or neutral compounds such as THC or its metabolite carboxy-THC probably bind to melanin much less. The issue is what this means in terms of workplace drug testing.

Population studies as outlined in your history do not demonstrate a hair color effect. These studies are not controlled. There is no control or knowledge of the dose of drug ingested in fact most are self-reports of drug ingestion which are notoriously false. There is no objective measure of the hair color. Without some measure of these variables it is difficult to interpret the data. However, given the way these studies were performed I would not have expected a hair color difference. For example, the reference 12, by Kelly et.al. studied 500 positive hair samples. A positive is a positive regardless of what the hair color is. Thus, for amphetamine, a black hair concentration above 500 pg/mg would be just as positive as a red hair amphetamine concentration above 500 pg/mg. If in this same study the authors were to quantitate the amphetamine concentrations in hair, I suspect they would find the concentration greater in those persons with black hair than in those persons with red hair.

As you correctly say on page 19676 of the proposed revision, "Though there continues to be some question about the effect of hair color on the amount of a drug or its metabolite present in hair, there is not question about the fact that the drug or metabolite is present." If it is above the cutoff it will be positive regardless of the hair color.

But the real issue is in regard to the INITIAL AND CONFIRMATORY CUTOFF CONCENTRATIONS. If you look at figure 4 in our paper in JAT 27: 545-551, 2003 you will see that for the subject in our study who received therapeutic doses of codeine those with blond hair or red hair were below the 200 pg/mg cutoff. Fifty percent of those with brown hair and 100 % of those with black hair were above the cutoff concentration. Thus, this is an equality and fairness issue. If two persons are taking the same amount of codeine the one with red hair has a greater likelihood of being negative than the one with black hair. Only at the extremes of cutoff concentrations of 50 pg/mg hair or 3000 pg/mg hair were the subjects with different hair colors either all positive or nearly all negative, respectively.

can only comment on codeine because there are not similar data with

cocaine or phencyclidine although I am sure the interpretation would be the same. I am currently completing a clinical study with amphetamine, but the data will not be available for at least 3 months.

There is another possibility and that would be to measure the melanin concentrations in the hair and report the drug concentrations normalized for melanin as pg/mcg melanin instead of pg/mg hair. This considerably reduced the melanin binding effect, but did not totally eliminate it.

In summary, drug binding to melanin will not alter the interpretation of a positive hair specimen. However, it does affect the equality or fairness of a particular cutoff concentration.

I hope that these comments are of help to you as you proceed with these revised guidelines. If I can be of any further assistance please do not hesitate to contact me. As soon as the data with amphetamine are available I will send a copy to you.

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