

From: "Beardsley, Grant" <GBeardsley@omlabs.com>

To: <wvogl@samhsa.gov>

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I want to share my comments on the HHS proposal for alternative specimens as published in the Federal Register last Tuesday, April 13, 2004 (pg 196673 to 19732). This proposal is not ready to be proposed, I strongly recommend the document be withdrawn until the work is done. When it is complete, then resubmit it. It's that simple.

I believe HHS has work to complete before offering anything to replace the "gold standard" that laboratory-based urine drug testing has provided over the years. Today, hair, oral fluid, sweat, and POCT offer only supportive information and do not meet the forensic-scientific standards needed. Clearly, the industry producing these testing techniques desire their products acceptance into federal workplace programs to gain characterization as equivalent to laboratory-based urine drug testing for the purpose to improved their market recognition and creditability for all employment drug testing. The historical "bar" of the program's standard of excellence must instead be raised and not removed as the proposal would allow. The science isn't there.

I submit the following statement inspired from testimony by Donna Smith, Ph.D. before SAMHSA and DTAB in April 1997, it still holds true today:

The federal rules, the guidelines, the science, the policy and the procedures put in place over the past 16 years, first with the Department of Defense testing programs, later with programs in the federal workplace, and then in the private sector by and large have been very successful at what they started out to do.

While the procedures may not be perfect, while the policies may need adjustments, basically the science was sound. From that science, the programs have been able to achieve their original objectives. Amidst all of our discussions about new technology, about the need for convenience, for speed, we must understand the program set out to insure that:

- 1. in drug-free workplace testing, no employee would be falsely or wrongly accused of being either an illicit drug user or to have cheated on his or her test;
- 2. these programs were to deter people from using illicit drugs, and to establish such deterrence would result in improved safety and productivity;
- 3. to insure the resulting testing programs were in fact fair and equitable for every single person who was subjected to them.

We have come along way. The DOD, HHS, DOT and other federal agencies including NRC did their homework: they waited until the NLCP was in place to provide a proficiency program and an inspection program.

Another essential and critical part of the program is we are able to medically interpret the test results knowing the science is sound. A series of checks & balances has permitted the program to endure and improve. It is forensically supportable, it must be. The end result must prevent a person's job being in jeopardy when, even though the analysis showed drugs, that individual was not an illicit user.

If we lose sight of these objectives, then I think we have done a tremendous disservice to the journey we've taken over the past 16 years.

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CC: "Erfurth, Steve" <SErfurth@omlabs.com>