The Call for Deregulating Drug Testing in America

What Congress and the Next Administration Must Do to Save Drug Testing

The De-SAMHSA-fication Project

By Theodore F. Shults, JD, MS

Over a twenty-year period, **SAMHSA'**s **Division of Workplace Programs** and its **National Laboratory Certification Program** have done more to undermine drug testing in America than the drug cartels or for that matter any of the opponents of drug testing could ever have dreamed of in their wildest fantasies. The bureaucracy created to assure accuracy and reliability in urine drug testing has hobbled the entire federal drug testing program, as well as the majority of private drug testing programs which got drawn into the wake of the federal programs.[1] To a large degree this is the result of a combination of the absence of effective leadership and the intrinsic limitations of the federal bureaucracy and regulatory process.

"It is difficult to imagine how straight-jacketed American business was then."

Alan Greenspan made this statement in his current tome, *The Age of Turbulence.* Mr. Greenspan was referring to the time when government regulators oversaw the operations of airlines, trucking, railroads, buses, pipelines, telephones, television and utilities. This was the time before deregulation—when business operations *"were monitored down to the tiniest detail."* [2]

Is it really so difficult to imagine? Mr. Greenspan knows a lot about a lot of things, but he obviously knows nothing about federally regulated drug testing. The regulatory micromanagement that was ridiculed and mocked in the 1970s[3] is nothing compared to the mind-numbing micromanagement exercised today over certified laboratories in federally mandated drug testing programs. Most of it, like the regulators' activities in the 1970s, consists of ineffective make-work exercises. Laboratory micromanagement, as onerous as it may be, is nonetheless merely one small aspect of a far bigger misfortune that all have suffered.

---

[1] **SAMHSA** will state that it does not regulate private testing; it only regulates *the federal program*. If that were the case, there would only be two certified laboratories. DOT, the U.S. Coast Guard and other federal agencies mandate that private employers use certified laboratories with the constraints of the Mandatory Guidelines. The SAMHSA guidelines have been held out as the gold standard for private employers. The mandatory application of SAMHSA's rules to federal agencies and its impact on the rest of the body of drug testing is similar to injecting curare in a patient to treat restless leg syndrome. (Curare causes paralysis and death.)

[2] *The Age of Turbulence*, by Alan Greenspan. The Penguin Press, London, 2007, pg 71-72.

[3] Mr. Greenspan goes on to quote the economist Alfred Kahn, who testified to Congress in 1978 about the picayune decisions he had to make as head of the Civil Aeronautics Board. Profound decisions, such as, *May an air taxi acquire a fifty-seat plane? May a supplemental carrier carry horses from Florida to somewhere in the Northeast? May a carrier introduce a special fair for skiers but refund the cost of their ticket if there is no snow? May the employees of two financially affiliated airlines wear similar-looking uniforms?*

So what happened? There is no argument whatsoever in the toxicology community that SAMHSA's insular bureaucracy has essentially mummified the drug testing technology of the early 1980s and mandates its use today. The record reveals that there has been no substantial or even insubstantial technical development in over two decades![4] These mummified Mandatory Guidelines as adopted by DOT and other federal agencies are failing employers, the government and the public for a host of reasons.

First, there is the complete absence of any adulteration testing. The mandatory specimen validity rule adopted by SAMHSA is a fraud on the public. (See "The Day Urine Drug Testing Ended" in MRO*ALERT,* December 2005.) Second, there is an astounding number of false-negative results caused by the failure of SAMHSA to adopt lower cutoff values for cocaine, amphetamine and THC (not including the unknown number of specimens that are really substituted). The net result is that no drug user who even slightly cares is deterred by this random urine drug testing program today. The chronic stagnation and mismanagement has undermined public safety by taking the teeth out of drug testing as a deterrent and generating an unacceptably high level of false-negative results.

Failing to Protect Individual Rights

The justification for the creation of this federal bureaucracy was that it would protect the individual rights of non-drug-users who are subject to mandatory government testing. **SAMHSA** has also failed in this regard. **SAMHSA'**s incompetence and frank malfeasance resulted in issuing program guidance back in 1998 to define the criteria for what it called *"substituted specimens."* This resulted in thousands of individuals being sanctioned for "substituting" urine. SAMHSA simply did not do its homework. It guessed and it guessed incorrectly as to what was normal or what was possible.

In some cases, donors simply provided a urine specimen that was too dilute, in **SAMHSA's** infinite but apparently unsubstantiated judgment, to be physiologically possible. End of job for many, end of career for others. Further, after it was clear that they got it wrong, they did nothing. Actually, SAMHSA did more than nothing. Well beyond the time where the science demonstrated conclusively that low-level creatinine was possible, SAMHSA continued to preach to MROs and everyone else that it was still impossible. Mistakes happen, but that action was not a mistake; that was a deliberate misstatement. After the substituted specimen problem was solved in 2003 by congressional intervention, it is still not over. DOT and employers are still mopping up that mess. (See "DOT Opens Up Procedure for Reconsideration of Past Substituted Urine Test Results" in MRO*ALERT,* September 2007.)

Substituted Specimens and Now "Invalid" Results

As unbelievable as it sounds, SAMHSA is doing the same thing again now with invalid specimens: failing to do its homework, establishing a rule that results in harm to drug-free donors, and then following up with spin and cover-up.

[4] Unless you feel that SAMHSA's requirement that each laboratory purchase a $10,000 digital gizmo that reads specific gravity to four or five decimal points is a technical advancement, as opposed to just nuts.

The current mistake involves “invalid” specimens. The problem was first made public in MRO*ALERT* back in July 2005. (See the MRO Advisory “Validity Testing: Invalid Results—the 9.x pH Urine” in the July 2005 issue.) In short, just as with substituted specimens, SAMHSA has the wrong number.

It was my belief at the time that the increased temperature and the time lag between specimen collection and testing allowed for the incubation of bacteria often found in urine. I posited that the growth of bacteria led to the creation of ammonia and an elevated pH.

Following the MRO Advisory, SAMHSA commenced a number of in-house projects to study this issue. The intent, as I was informed, was to show that the MRO Advisory was wrong. Well apparently it was wrong. As it turns out, creation of elevated pH in the range of 9.0-9.5 is not limited to specimens that have bacteria—one should expect to see an elevated pH in **all** urine in the normal course of its aging. The elevated pH is simply a function of increased temperature—no bacteria needed at all! Every urine specimen will meet the current criteria for “invalid” when given a day or two in warm weather. The data indicates that it is almost abnormal for the pH not to end up between 9 and 9.5!

Since the publication of the MRO Advisory in 2005, MROs, toxicologists and the laboratories have been told by SAMHSA that the elevated pH is caused by some mysterious adulterant that has yet to be identified. They have been told that the bacteria in these specimens eats up the THC. They were told recently at the annual meeting of the Society of Forensic Toxicologists (SOFT) that some drugs and metabolites are not stable at a pH of between 9.0 and 9.5, thus validating and necessitating the 9.0 cutoff value. That is all malarkey. And even if any of it were true, how do these “facts” justify an observed urine collection, when the specimen will probably be subject to the same ambient conditions that caused an invalid in the first place?

So where did the 9.0 pH cutoff come from? My understanding is that this cutoff level comes from a 20-year-old immunoassay package insert that notes the Syva Emit immunoassay is unstable at pH above 9.0. Whose problem is that? It is my understanding that this is no longer the case. There is also some debate as to whether the SAMHSA laboratories are allowed to buffer these specimens before screening.

The science here is solid: the invalid cutoff of 9.0 is wrong. It should be 9.5. SAMHSA is telling the toxicology community that the MROs can fix this. SAMHSA states through its chief that the MRO should consider the time lag and the temperature in determining whether to require an observed collection. This is a formula for litigation.

Scope of the Problem with pH 9.x Specimens

This is not a trivial issue. Some private employers simply fire individuals with invalid specimens. SAMHSA, as it has in the past, will say that it is not their fault. They are not responsible for what private employers do. However, it is not just private employers who will be taking these types of actions. Many DOT-regulated employers will not hire applicants with invalid drug tests, and some will terminate them.

SAMHSA will also note that simply requiring observed collections on these "invalid" urines has little or no impact. So, on one hand SAMHSA has now conclusively demonstrated that there is no reasonable scientific basis to require an observed urine collection, and on the other hand says not to worry about it. Here is the legal problem: some lawyer is going to figure out that these directly observed urine collections, which are mandated by DOT regulations merely because the tested urine has a 9.x pH, is not only offensive and a violation of personal privacy but in fact constitutes an unreasonable and unconstitutional search. And odds are (at least 7 to 2 in terms of justices) that the Supreme Court would agree with them.

Following the publication of the MRO*ALERT* advisory, the military has run down a hundred of these *"abnormal"* 9.x urines. Additional testing has found all of these specimens to be drug-free, with no evidence of drug presence or adulteration. The hope is that the new round of litigation will go after the perpetrators of this rule (SAMHSA) and not the laboratories or MROs.

Potential Lawsuits Over Observed Collections for 9.x pH Results

The litigation is just starting. One case in its early stages involves a woman who has been subjected to three observed urine collections for 9.1 pH urine. Another complaint comes from a federal agency MRO who has had to subject a senior female federal official to an observed collection for the same reason—a pH 9.x. (No, it is not Condoleezza, but it could have been.) Another potential case involves the additional insult and difficulty of performing an observed urine collection with an obese donor.

This is the tip of the iceberg. All of the invalid 9.x observed urines are potential lawsuits. Think of the consequences to anyone in a safety-sensitive job who is called to the medical department for an observed urine collection—and for what? Think of the implications if the person being called in is the head of a federal agency. How stupid can this get?

After seeing the research SAMHSA presented at the SOFT annual meeting, I wrote to DOT expressing these concerns and strongly recommending that DOT's Office of Drug and Alcohol Policy and Compliance issue an **Interim Final Rule** changing the definition of an alkaline pH from "greater than or equal to 9.0" to "greater than or equal to 9.5." This step will solve the problem as effectively as DOT's proactive step in changing the creatinine cutoff for substituted specimens from 5 to 2 mg/dL ended that embarrassment. But this would be a Band-Aid (assuming it happens). It will not fix the systemic ongoing problem of mismanagement and frank deception.

The Need for *d* and *l* Testing of Methamphetamine

Another grievance is SAMHSA's failure to require *d* and *l* testing of methamphetamines. In lay terms, the GC/MS cannot distinguish between use of an over-the-counter nasal inhaler and smoking methamphetamine. A great deal of ink has been spent on this issue over the past few years, but no legal, ethical, moral or economic argument has motivated SAMHSA to change the current state of affairs. Such testing would apparently be inconvenient.

SAMHSA's Adverse Impact on Certified Laboratories

Despite all the costs and time invested with the NLCP inspections, proficiency tests, and special inspections, laboratory errors are not eliminated. A certified laboratory reported a straight-up false-positive on an NLCP proficiency test this year. What are the odds of that? Apparently a specimen was double-entered into the database, which caused all of the results following the double entry to be for the wrong bottle. Whoops. It is a law of the universe that mistakes will happen. However, the NLCP inspection program works hard, but not smart.

One aspect of the quarterly laboratory inspection is a preposterous requirement for inspectors to review every single non-negative test result reported by the lab. Sounds good, right? The NLCP could review every result five times and it would change nothing. False-positives still happen and are not found following the reviews. Working hard is not the same as working smart. Frankly, SAMHSA is not working at all. The tedious work of looking at every result is done by the dragooned laboratory inspectors who are mostly certified-laboratory directors themselves, and when the inspectors are back in their own labs they spend hours putting all their data together for when they are inspected.

The NLCP inspection process is like a big intramural game which is OK except for one issue. No one is independent. The NLCP has more power over these professionals than Saddam had over the Kurds. Most are too busy with busywork to really assess the operation. There is a real fear by the lab directors/inspectors that if they really go against the "group think" they will find their head on a stick. In fact, after 20 years of this culture I am afraid that some directors are suffering from Stockholm syndrome. In any event, how can you trust the system that has no independent oversight? Little or no information is forthcoming from the NLCP**.** There is little or no sharing with laboratories or MROs, the public or the government. This inspection process should be transparent, not opaque.

I frankly do not see how the HHS-certified laboratories can justify the appreciable cost of annual certification. I do not think it can be justified because it lowers liability exposure, or even helps them in the marketplace. A lab director recently told me that you can open a sink test lab tomorrow and claim that you are a *federally certified laboratory* if you do one CLIA-cleared dipstick test. Who knows the difference? So who needs the HHS certification for marketing?

There is a good chance that many TPAs and drug testing program administrators will begin to acknowledge that we are off the "gold standard" and that the federal program is made of painted tin. It will not take long for the sales and marketing folks to begin selling against the certified laboratory and federal drug testing protocol.

In respect to liability, it is the height of irony to realize that the only significant liability exposure for the laboratories in the last two decades has been a direct consequence of SAMHSA's negligence, not the labs. The argument can be made that today there is more liability exposure for a certified laboratory doing regulated testing than for one doing private-sector testing (which is much more profitable).

Most of the liability problems faced by the laboratories stem from SAMHSA's chronically bungled efforts to deal with adulterants, dilution and substituted specimens. It is a long story, but a good illustration of this point is the case of *Ishikawa v. Delta Airlines and LabOne, Inc.* In short, LabOne ended up with a $400,000 jury verdict against it for negligence in testing a DOT urine specimen by reporting it as "substituted." LabOne made some mistakes, but it was acting in substantive compliance with the misguided and inappropriate standard set up by SAMHSA's program document. Following this verdict, the legal environment changed overnight. Every plaintiff's lawyer who wonders if he or she can sue a service provider for involvement in a federally regulated drug test sees the *Ishikawa* case, and does not wonder anymore.

The laboratory and physician insurance companies figured it out rather quickly. One immediate consequence of the *Ishikawa* verdict was that MROs saw an increase in their liability insurance. The malpractice insurance carriers saw them in the same category as the certified laboratories and thus in a riskier "practice environment." There are millions of non-regulated urine drug tests that are done every year in non-certified laboratories with no appreciable liability exposure to the laboratory, regardless of methodology.

I know that many laboratories may feel they have a vested interest in maintaining the "certified" laboratory quasi-monopoly. But the evidence is that regulated urine drug testing is a marginally-profitable fungible commodity that needs very large volumes to make money. Those large volumes in turn beget very poor customer service. Customer service—the essential value-added element of a competent laboratory—is in general simply appalling in some of the large-volume urine factories. It is hard to understand how the large clinical laboratories do not realize that the variable (I am being polite) customer service they provide to MROs in drug testing affects their overall reputation.

The certified laboratory business is the only industry I know of where the more regulated-testing business you have, the worse it gets. It is the only industry I know of where the low-cost provider can get the lion's share of the business overnight and then realize that it is an awful business plan.[5]

If this mandatory program is just going to be about price, let's fix it now. Let employers simply outsource all of their mandatory urine drug testing. Regulated employers will be thrilled. Imagine only 50 cents for federally mandated urine drug tests! We will of course need to ship all this urine to Guangdong Province in China for testing. The good news is that for another 5 cents you could bundle MRO verification. Look at the upside: donors with positive drug tests will receive the added benefit of learning a few choice words in Mandarin.

Is it "defensible"? Well, try to sue that lab. Ship the NLCP there also. The Chinese have a rather startling way of dealing with bureaucratic malfeasance. Outsourcing this urine drug testing program will free up the U.S. labs to do something more useful, if not remunerative. I suspect most of the reagents, immunoassays and instruments will be coming from China anyway.

[5] Maybe there is one industry like this: the airlines seem to have the same business plan.

SAMHSA's Adverse Impact on Alternative Testing Technologies:
The Worst Is Yet to Come

Let's take a quick look at the impressive results of SAMHSA's 10-year, multi-million-dollar, taxpayer-financed foray into assessing and incorporating oral fluids, hair testing, sweat patch testing and on-site testing into its perfected urine drug testing program. The first clue that something was fundamentally wrong was given over five years ago when SAMHSA announced that these diverse and unique specimens and special technologies had to perform with the same precision, accuracy and reliability as urine drug testing. That on its face was a preposterous condition to set forth. Does the hair collected have to be between 90 and 100 degrees? Do you need 45 mLs of oral fluid? This is an obvious exaggeration, but it illustrates the point. These technologies need not perform with more precision than the intrinsic biological variability of the specimens tested—not to mention the variability of drug taking patterns of the donors.

The limited technical staffs of these emerging technology companies invested thousands of man-hours trying to accommodate what is an artificial, arbitrary and ephemeral standard. If the idea was to stall the development of alternative testing (and I think it was) it worked fabulously. SAMHSA torpedoed oral fluid testing, crippled on-site testing and did a general hatchet job on hair testing, all with a smile.

So, after a decade of work and the usual secret deliberation, SAMHSA produced a technically bungled alternative testing rule. It was so bungled and flawed that the Office of Management and Budget felt compelled to quietly "withdraw" (read: euthanize) the proposed rule. Here is the best part: SAMHSA continues to tell all who are interested that nothing is wrong. SAMHSA's public statement is that it is anxiously waiting to move forward on the public comments to its alternative testing rule! That is what they told the technical community at the recent SOFT annual meeting.

Maybe that is true, but it would simply be a sin to allow the SAMHSA/NLCP expert apparatchiks to suffocate and then mummify these emerging technologies as they have done with laboratory urine testing. For example, the SAMHSA proposed cutoff values for hair and oral fluids are already obsolete, but they will be chiseled in stone. Is there any credible evidence to suggest that once these cutoff levels became part of the Mandatory Guidelines they will ever be updated?

Responsibility and Integrity

Is it merely an old-fashioned notion that the government should not deceive the public? Mistakes are a part of life, they happen. SAMHSA has, however, never taken any responsibility for its mistakes, nor more importantly learned from its mistakes. SAMHSA has, however, developed an expanded inventory of excuses with the common theme that it is always someone else's fault. Here is a sample of what I have heard for 20 years:

Not enough money; not enough staff. There is political meddling; the administrators do not know what they are doing; DOT does not know what it is doing. The laboratories are at fault. It is the manufacturers; it's the lawyers; it's the doctors; it's the man-on-the-moon. No one understands this but us; no one is in charge; we get no respect. We need to regulate the MROs, the collectors, and how about the TPAs? The technology is developing. We only regulate federal testing of federal employees. Just you wait till we get our next rule out! We will look into it; we cannot look into it. We have made real progress. We need to protect the program! We are only allowed to do this; we cannot do that; we are required to do that. We are working on that; we are not working on that. We are out of money again; we will look into that.

Simon says "Stop!"

I can promise you that if they are ever put on the spot in an investigation, you can check off all of the above.

The SAMHSA/NLCP enterprise is a relatively small outfit by government standards, but it really has it all: arrogance, audacity, secrecy, absolute control over the certified laboratories, "special friends of the program," an enemies list, nepotism, impunity, employment for life for itself and threats and vindictive action against all those who raise questions or concerns. I have personally experienced all of it. Overall, it is truly something that tests one's patience and integrity, if not patriotism.[6] Few have any idea how much damage this institution has done to the prospects of managing substance abuse in America. [7]

So Why Bother with De-SAMHSA-fication?

It is a good question. SAMHSA's Division of Workplace Programs presents a classic study of the pathology of entrenched bureaucracy. I hear and read that there are loads of federal programs that do not work, so why should this be any different? Americans are great drug consumers. Talk to anyone involved in drug interdiction and you will hear the same thing. They stop tons of drugs but what is seized is only a small percentage of what is out there. So why should this be different? We still catch some folks.

Drug testing should be different because it has to be different. It needs to actually work. It needs to work because Americans are huge consumers of drugs and because the illegal drug trade is corrosive on society, and because we can only stop a small percent of illegal drugs being distributed and because we cannot arrest half the population and rehabilitate everyone else. Politically, I do not think that the public is going to be happy learning that they are paying for a ponderous, expensive, and obsolete drug testing program that simply does not work. They just do not know what is going on, and they are preoccupied with other issues.

[6] I must admit that this bureaucracy would bring tears of admiration to the eyes of Kim Jong-Il. But even I question whether North Korea would put up with this nonsense for 20 years.

[7] It is easy to target this type of bureaucracy, and although there is incompetence at some key levels in this program the majority of federal and contract employees I know personally are well-meaning, hardworking and toe the party line. The current state of affairs is demoralizing and frustrating for them as well.

Having stated that conclusion, the question remains: will it be business as usual? Shall we continue with this regulatory strangulation of drug testing? Is this what the future holds for America's last best chance for managing substance abuse? Will oral fluid testing and hair testing be compromised and mummified like urine drug testing? Will other new technologies simply suffer SIDS? Let's hope not.

Having observed both the rise and fall of federally mandated drug testing under this bureaucracy, I believe we have come to the point where completely shutting down this program as it is currently operating would have no measurable impact on public safety, demand reduction or substance abuse. (I can hear the yelling already—but it is true.) Fix it or stop it. I want to see it fixed. So does the drug testing community.

The De-SAMHSA-fication Project

Some Alternative Approaches

The laboratory directors, toxicologists and MROs with whom I have shared the concept of deregulation (de-SAMHSA-fication) strongly agree with the need to deregulate, but do not want to completely abandon mandatory testing. Most share the observations and conclusions presented here and many have more to add. They all tell me that they are not in a position to speak up, but would support the concept. (Ted, you do it and good luck.) All ask: what should we do?

There are many alternatives to the NLCP and the SAMHSA system of service. Here are just a few ideas and interim steps toward transition and de-SAMHSA-fication of drug testing.

1. Let the actual regulators (FAA, FMCSA, USCG, NRC, etc.) develop by regulation the parameters of an effective employer drug testing program. These regulations can be as specific as necessary. The employers would have to contractually require their service providers to meet these technical requirements, including ISO compliance and independent audits.

2. The change outlined above will take a legislative fix and an executive fix. Congress will need to reconsider the provisions of the Omnibus Employee Testing Act and the role of federal agencies in taking ownership of their substance abuse programs. This would, however, provide an exquisite opportunity to fix a lot of loose ends, such as:

    a. Addressing the issue of off-label use of Marinol and soon-to-be-introduced Sativex.
    b. Addressing the problem of THC levels in hemp products.
    c. Immediately lowering cutoff values for drugs in urine testing.
    d. Requiring the *d* and *l* testing of methamphetamine isomers.
    e. Immediately requiring on-site testing for adulterants and instrument-based screening.
    f. Protecting drug testing service providers from litigation by requiring arbitration or some appeals process for all contested cases.

3. SAMHSA should play an advisory role, not a quasi-regulatory role. SAMHSA can provide its technical expertise and recommendations to the ultimate regulators. So can the DEA, the FDA, and the FBI, or the Department of Labor or Department of Agriculture for that matter.

4. There needs to be competition in providing inspection performance testing (PT) and oversight of the laboratories. Laboratories should be the clients, not the slaves. This is what is done in financial institutions in respect to financial audits. Competition is good; sole-source monopolies are bad.

5. In terms of PT and quality-control specimens, the MROs could be required to retest a small percentage and random number of all routine tests and report all discrepancies to the laboratory and a regulator. Finance this by some of the millions of dollars going down the toilet in the NLCP inspection process.

6. There needs to be a breaking up of the existing "politburo" of the laboratory certification program and development of new technologies. Currently, those interested in business as usual are "developing" the competition. There is a conflict here.

De-SAMHSA-fication is going to take a great deal of cooperation, debate and general political consensus. The missing element is leadership. The good news is that you cannot further damage what is already so broken.

The Great Opportunity

Mr. Greenspan notes that the great unsung accomplishment of the Ford administration was deregulation. Politicians on both sides of the aisle were ready back in the 1970s to agree that such micromanagement by government had gone too far and that it was time for the government to do less. That time is with us again. It is time to do less—much less—and deregulate drug testing in America. Un-hobble drug testing programs, unleash competition, and harness ingenuity—do not suffocate it.

A note of optimism: there are a hundred ways to restructure a vibrant, useful and effective drug testing environment, even in the special area of federally mandated drug testing. An opportunity for a real accomplishment exists, even for the remaining time of the existing administration and Congress and certainly for the next Congress and the next administration.