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Mr. Mark Snider
Senior Policy Advisor
Department of Transportation
Office of Drug and Alcohol Policy and Compliance
1200 New Jersey Avenue SE
Washington, DC 20590

RE: *Notice of Proposed Rulemaking*
[Docket OST-2010-0026] RIN 2105- AD95
Comments on DOT NPRM – Specimen Validity Rules,
IITF Laboratory & New CCF, and Following HHS Guidelines

Submitted via *www.regulations.gov*

Dear Mr. Snider:

This is my second submission in response to the issues DOT has raised in the above-referenced NPRM. It concerns the overall efficacy and management of the DOT drug and alcohol testing program.

I have played an integral role in the development of these programs over the past 20 years. I am deeply concerned about the technical direction, management and continuing loss of efficacy of the program to deter drug abuse and identify drug abusers and protect the rights, privacy and interests of the overwhelming majority of employees and applicants who are subject to these programs.

1. HHS (SAMHSA) Specimen Validity Rules

SAMHSA's specimen validity rule has profoundly failed to do what the employers and the public expect the rule to accomplish. Further, the public has been misled. I recently read in a human resources magazine that the new rules by HHS have eliminated adulterated specimens—citing the Quest Drug Testing Index! The DTI data is indeed correct—there are no more "adulterated" specimens—they are all now "invalids."

The HHS Mandatory Guidelines require laboratories to screen for the major classes of adulterants, but do not require the labs to confirm them. The result is that specimens that screen positive for adulterants are reported to the MRO and employer as "invalid." This simply requires a new drug test, which is typically done two to three days later. The second test is almost always negative.

The laboratory pricing structure for mandated drug testing is based on one price for all, where profits are made on negative results. That is a powerful incentive for the laboratories. This appears to be the primary reason why adulteration testing was completely abandoned by HHS; properly confirming adulteration results was too expensive.

This decision was a fundamental error that undermined the overall integrity of the program and the deterrence effect of drug testing for motivated users. SAMHSA's actions have not substantially changed incidence of substance abuse but have created and fostered a multi-million-dollar adulteration industry that enables most drug users to easily beat the drug test.

On the other hand, the specimen validity rules do a good job of identifying specimens that are more than one or two days old. They all screen as "invalid" because of the universal increase in the pH of these specimens. This has resulted in thousands of individuals being subjected to a rather humiliating observed urine collection for no good reason. It has also resulted in many employers terminating employees for providing "invalid" specimens.

This has fundamentally hurt the DOT program. I know this is old news for DOT, but the public needs to know what this is all about. The problem is the increased level of false-negatives combined with the fundamental loss of deterrence of a motivated drug user to change behavior. It is simply too easy to beat the urine test with an adulterant.

Recommendations:

1. DOT should require all laboratories performing DOT tests to confirm for all adulterants that screen positive. Other regulators have taken this step.
2. DOT should change the pH cutoff for an alkaline invalid result from 9.0 to 9.5. (This is analogous to what DOT did to correct the incorrect creatinine level established by SAMHSA for "substituted" specimens.)

2. The Instrumented Initial Test Facility (IITF)

The IITF proposal by SAMHSA is without any technical merit. The idea that we set up "screen only" laboratories and then send everything that is not a negative to a second screen-and-confirm laboratory will do nothing to speed up results reporting to employers. In fact, it will cause a universal delay of two to ten days for all non-negative results. The use of IITFs will result in innocent people losing their jobs by again increasing the number of "invalids" because the specimen is several days old and the pH has become too high.

It will make tracking non-negative specimens between two laboratories extremely difficult for the MRO (and the laboratories). It will add to the complexity of the process and increase the probability of breaks in the custody and control for every positive result that is subjected to this treatment.

The idea that all custody and control forms must be changed to facilitate the implementation of IITFs is idiotic and will cost employers millions of dollars just for the new forms, not to mention the time wasted in retraining collectors and fixing the millions of mistakes that are going to come along with implementing this scheme.

I have also raised concerns that this will not increase the number of laboratories but will instead do just the opposite. It will provide the opportunity for some of the larger laboratory chains to close their confirmation facilities and send all non-negatives to one central confirmation "factory." The resulting price advantage will run out the remaining independent laboratories from regulated testing.

Recommendation:

1. DOT should prohibit the use of Instrumented Initial Test Facilities in its program.

3. Is the way in which these rules are promulgated legally defensible?

I know this is not a question that DOT has raised (and I do not anticipate an answer), but this whole process has an ***Alice in Wonderland*** quality to it, and I want to bring some of my legal concerns to the administration's attention.

My comments here and the public comments are in response to DOT's proposed rules that are in turn based on SAMHSA rules that have been "finalized" on paper but which are not really final. Not only has SAMHSA not finished digesting and/or responding to the public comments it received, but more and more serious technical problems are being recognized every day. Once again, SAMHSA has not done its homework and its "final rules" (which are supposed to be DOT's "final rules") have a high likelihood of being scuttled or delayed indefinitely.

The unfortunate nature of administrative rulemaking is that only those with vested interests take the time to study proposed rules and formally or even informally comment on them. Under normal circumstances, it is not an easy process for either the agency or the public. The frustration and shortcomings in the administrative process are not unique to drug testing. It takes lobbying, influence, political leadership and/or an agency agenda to get rules into the administrative process and actually implemented.

The process here is strikingly more difficult if not perverse in the two-stage kabuki dance that goes on between DOT and SAMHSA. A historical review of what should be the "parallel" program developments between SAMHSA and DOT looks like a skit that Monty Python would put on (except it is not funny). The end result is a difficult or impossible rulemaking process for stakeholders, the public and even the regulators to get a handle on.

A federal agency that does not actually have regulatory authority and does not regulate anyone (SAMHSA) develops technical standards (mostly in private), goes through what appears to be a full public comment period, and then basically implements final rules based on what it calls the "science." Unfortunately, their "science" is often clearly wrong and indefensible. In addition, the

rulemaking process is often violated. For example, there was no public support for "approving" MRO certification boards, and a number of commenters opposed it. Nevertheless, we now have SAMHSA approving MRO certification boards—and it appears this will be incorporated into DOT rules as well.

The record is that most of SAMHSA's rules, even the useful ones, are frequently delayed and more commonly simply do not get implemented. (One example is the ill-conceived "alternative testing rule"—remnants of which have been recycled into the current rule.) What was initially a model for efficiency and uniformity has devolved into a model on how not to run a government program.

DOT takes the position in the NPRM that Congress has mandated it must adopt whatever SAMHSA comes up with. However, if DOT is simply copying SAMHSA rules into the Code of Federal Regulations because it has no choice, this raises a threshold question: why ask for public comments at all? The suspicion is that the request for public comments is to make it look like DOT is in compliance with the Administrative Procedure Act, when in fact the substantive rulemaking is a backroom operation outside of the Act.

The major stakeholders in the DOT program are the public, regulated employers, employees and unions. They are focused on lobbying and influencing DOT—not some office at SAMHSA. By the time they are given the chance to comment on fundamental DOT technical issues, it is too late. DOT states that it must follow SAMHSA. It is even more attenuated when you consider that the actual regulator is an operating administration (FRA, FAA, etc.) which must follow the rules of DOT's Office of Drug and Alcohol Policy and Compliance. Again, this was a model for uniformity that does not appear to work anymore.

So the next legal question is this: was it the intent of Congress to short-circuit the Administrative Procedure Act and expressly exempt DOT and drug testing, or merely to require DOT to use certified laboratories? I personally think it was the latter. Even if it was the intent of Congress to have SAMHSA regulate DOT and all of federal drug and alcohol policy, the actual historical record reveals quite a different picture.

The record shows that DOT does not follow the Mandatory Guidelines when it decides there is a good reason not to do so. DOT had to "fix" the definition of a substituted specimen (lowering the level of creatinine from 5 mg/dL to 2 mg/dL) after being misled by SAMHSA for years that 5 was the right number. This took leadership at DOT (leadership that retired a few years ago). It was a technical step that added to the safeguards and the protection of individual rights and put a stop to the litigation over the matter. DOT also had to address shy bladder issues that fell within the scope of the Americans with Disabilities Act. DOT has also allowed MROs to cancel the "invalid" that is caused by testing a two-day-old urine which will have an alkaline pH, even while SAMHSA was (and apparently still is) busy denying there was a problem. These important steps deviated from the Mandatory Guidelines, and yet there was never a peep or public discussion of the need to adhere to them.

On the other hand, DOT unilaterally changed how a direct observation of a urine specimen is to be done (raising and lowering of clothing and then turning around in front of an "observer"—who can be recruited off the street or the clinic's waiting room). This was not such a great idea, and it caused a lot of legal fallout. This was a fundamental procedural change and deviation from the Mandatory Guidelines that SAMHSA to its credit did not endorse or follow when it "updated" its Mandatory Guidelines.

In the most recent changes to the Mandatory Guidelines, SAMHSA now requires federal agencies to inspect 5% of the collection sites and requires the users of certified laboratories to increase the number of blinds that are sent to the labs. This is a core technical aspect of the Mandatory Guidelines that DOT states it is required to follow—yet in its most recent proposal, DOT essentially states that it does not intend to follow it. (DOT is on good grounds not to require this, but how does it comport with its policy of having to follow the Mandatory Guidelines?)

And now SAMHSA, as stated above, is going to "approve" MRO certification boards—in the absence of any public support and over the public objections made during the SAMHSA's public comment period. There are reasons for this, which has to do with "gagging" the MRO and with SAMHSA's regulating for the sake of self-justification, and which have nothing to do with MRO competence. In fact, it is going to lead to a dumbing down of MRO credentials.

A core requirement of all medical certification boards is to have a proctored, closed-book exam. AAMRO has this requirement, but a few years ago MROCC did away with a proctored exam for their certification. Is SAMHSA going to approve MROCC-certified MROs who were not subject to a proctored exam? This will essentially destroy the MRO credentialing process for the government. (AAMRO will not follow suit.)

Obviously, the government is entitled to do any and all of this. As damaging as it looks and is, it is a symptom and not the root of the legal problem.

Arbitrary and Capricious Process

Just because the process is somewhat inelegant, abusive and ham-handed does not make the final rules unenforceable. The potential legal problem comes when the two-step, quasi-rulemaking process in place here is combined with the backroom, mistake-ridden rules—then the whole thing begins to sound like an "*arbitrary and capricious"* process. *Arbitrary and capricious* is the Achilles heel of Administrative law. Arbitrary and capricious rulemaking can be challenged in court, and the rules can be struck down.

This is a difficult rulemaking process for stakeholders, the public and even the regulators. I have noted many times over the years that the tail is wagging the dog. A federal office that does not actually regulate anyone (SAMHSA) develops these technical standards with the occasional public meeting to announce what great things they have done. DOT publicly announces what a fabulous job is being done, and then goes through what appears to be a full public comment

period. DOT then implements SAMHSA's rules where it wants to under the rubric of *"Congress made me do it."*

The perversion of the regulatory process and short-circuiting of the Administrative Procedure Act is not the core reason for the continuing breakdown of federally mandated drug testing programs, but it is a fundamental reason why it is not going to self-correct. In the absence of strong leadership and with the apparent shortage of technical and legal competence, the program continues to lose efficacy and direction. That is the real shame here, and ultimately the cause of another legal problem.

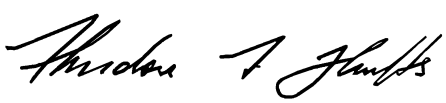
Is the overall program legally justifiable?

A separate legal threat to the rules and the overall program is the continuing march toward 100% false-negative results due to implementation of such boneheaded ideas as the IITF laboratories. Federal urine drug testing is in danger of becoming so ineffective as to become legally unjustifiable. Remember, the federal drug testing program operates as an exception to the Fourth Amendment prohibition on warrantless searches. A fundamental requirement is that the program which is legally a "search" has to be an effective search. As someone who was intimately involved in framing the technical issues of the program in anticipation of the initial Supreme Court challenge back in the 1980s, I would tell you that if you presented the current SAMHSA/DOT program to the Court today it would probably not pass muster. (Fortunately, the NRC and DOE got off the SAMHSA/DOT Titanic years ago.)

I am personally not interested in seeing this program sink, but I am convinced it is headed for the ice field. I have been characterized by some at SAMHSA and DOT as an enemy of the program and a crank, and they refer to my comments as "ranting." Just like the SEC was tired of that fellow Mr. Markopolos that kept telling them Mr. Madoff off was running a Ponzi scheme. Mr. Markopolos did that for 10 years. That is about how long I have been raising issues with SAMHSA and DOT. Madoff and Markopolos agree on two things: it was a Ponzi scheme, and the people at the SEC were basically stupid. (I prefer to think of it as core competence.)

A more open and collaborative process with the MROs, labs, manufacturers, employers and TPAs is overdue. The good news is this process is so out of whack that even I believe the administration can get bipartisan support to fix it, before the courts and the public do it for them.

Sincerely,



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