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Public Comment 8400097

July 8, 2004

Office of Information and Regulatory Affairs,
OMB, Executive Office Building
725 17th Street, NW
Washington, DC 20502
Attn: Desk Officer for SAMHSA

RE: FR Doc. 04-7985

Dear Sirs/Madam:

My name is Stan Gerlich. I am the Chief Operations Officer at Forward Edge, Inc.. Forward Edge, Inc. provides Substance Abuse Program Management Services for Federal Workplace Drug and Alcohol Testing Programs and Non-Mandated Programs. Forward Edge, Inc. was established in 1986 and manages approximately 500 test results per day. I have been involved with substance abuse programs and testing services since 1984. Based upon this history, I would like to comment on the proposed revisions to mandatory guidelines for Federal Workplace Drug Testing Programs.

I. General Concerns Regarding the Proposed Alternative Specimen Guidelines.

1) Many Department of Transportation employers oppose drug and alcohol testing. The proposed new rules will allow employers the ability to control the collection, testing, and record keeping of their companies substance abuse program. The proposed quality control/quality assurance and inspection requirements as outlined are insufficient to assure the accuracy, fairness, due process and a reasonable testing program.

2) Permanent and temporary personnel placement firms that supply Federal employees or D.O.T. workers may begin a testing laboratory. This practice of on-site testing is currently a **significant problem** for the non Federal workplace programs. Our experience with placement companies indicates an extremely low positive rate when compared to the industry standard. Several hiring companies have discontinued their laboratory accounts and stopped GC/MS confirmation testing of presumptive positive samples.

3) Alternative specimen testing (hair, oral fluids, sweat) in the past has produced conflicting test results when compared to urine testing at D.O.T. cutoff levels. Historically, analyzing hair and urine samples for cocaine and marijuana produce negative results for hair and positive in urine. The legal liabilities when this comparative testing is challenged will be expensive and damaging

to any substance abuse program.

4) A program that utilizes on-site testing will jeopardize the process and program by allowing one person **total autonomy**. One technician may collect, analyze, interpret the result, report the result, store the specimen and test records. A process without checks and balances is easily corrupted.

5) The difference in the units of measurement for alternate specimens will cause significant confusion for employers and employees. Furthermore, the variables between the specimens pharmacokinetics and pharmacodynamics will establish suitable grounds for legal challenge.

6) All specimens are susceptible to alteration. Several alteration products are readily available via the Internet or head shops. The most common and 100% fool proof adulterant for hair is to wear a short hair style. Oral fluids are adulterated by dilution, the saliva flow rates and specimen pH levels are greatly increased when a bicarbonate is added in vitro. Forward Edge collects specimens for several court ordered drug tests, these adulteration methods have become common place and many courts have chosen urine as the preferred specimen.

7) Delta-9-tetrahydrocannabinol (THC) does not enter oral fluids through passive diffusion. Marijuana is the most abused drug in the workplace. **Why should anyone consider this testing method?**

8) Differences in the detection time for alternate specimens will be challenged. Example:

Specimen	Detection Time
Urine	3-5 Days
Hair	10-90 Days
Oral Fluid	1-5 Hours
Sweat Patch	Accumulative measurement often 3-7 days.

It is **unfair and unreasonable** to test individuals with a variable detection.

9) On-site testing devices that utilized a detector, which transmits an image via telephone or data communication lines cannot be validated electrically. Interruptions or electrical interferences will affect data interpretations.

10) Maintaining a statistical database with several testing methods will add a further hardship on employers. Accurate record keeping for one testing method is difficult, but adding several methods will be very complicated.

11) The majority of errors identified in the current drug and alcohol program begin at the time of specimen collection. Adding alternate specimens will certainly produce a greater burden on an already stressed system. It's common in this industry to have a very high turnover of collection personnel, therefore, increasing the cost of hiring and training personnel while decreasing accuracy.

12) Validity testing at SAMHSA laboratories is well defined and may be extreme. Validity testing guidelines for alternate specimens and testing facilities appear to be chaotic or desultory.

13) Alternative testing procedures do not meet the constitutional requirements to assure fairness to the individual, accuracy, due process, and reasonableness. Over the past several years there has been a case by case, jurisdiction by jurisdiction expansion of what is essentially the scope of legal liability to include various drug test providers. Specimen collections, laboratories, Medical Review Officers, third party administrations are no longer protected from litigation, alternate testing will produce a flood of lawsuits and ultimately **destroy any public trust** in the Federal testing program.

II. HHS – Certified Instrumented Initial Test Facilities

Instrumented initial test facilities at a glance appear to be a great idea. However, as the Chief Operation/Business Development Officer for Drug Labs of Texas, we attempted to expand our operations into Louisiana. Drug Labs of Texas established a lab in Lake Charles, Louisiana as a screening facility. Drug labs of Louisiana operated under the same standard operation procedure manual as the parent laboratory. Maintaining the Quality Control/Quality Assurance program was extremely difficult. The high cost of a screen only lab soon became impractical, we decided to discontinue. If a screen only lab follows the proposed guidelines, the cost of sales and operations will most likely exceed budget. Drug labs of Louisiana was established to service a unique marketplace, but this venture wasn't economically feasible to continue considering the high cost and potential liability.

III. Salvia Testing

Salvia testing as an alternate specimen seems impractical because the test methods failure to detect tetra-hydrocannabinol-9-carboxylic acid. Passive contamination has not been ruled out as a excuse for a positive test. Laboratory testing procedures and long term storage of the positive samples haven't been tested by the legal system. Adulteration is possible by taking a

bicarbonate tablet prior to testing. Salvia testing can't detect the most abused drug in the workplace, therefore it shouldn't be considered for Federal workplace testing program.

IV. On-Site Non-instrumental Testing Devices

On-site testing devices should not be allowed as a testing method under this program. The SAMHSA evaluation of non-instrumental drug test devices demonstrated an unacceptable accuracy rate. In the field, opposed to laboratory studies, on-site testing is subject to many variables that often reduce the accuracy rate to levels less than the SAMHSA reported results. For convenience, I have listed many variables involved with on-site devices and a brief description of our field experiences.

1. Forward Edge, Inc. has returned complete orders of on-site devices because of manufacturer errors.

2. Temperature changes during **transit** and **storage** will affect the test result.

3. If devices are stored in a cool location and removed to normalize at ambient temperature prior to use, many devices will condense water and this variable will affect the result.

4. No quality control of the product's production, delivery or performance.

5. Quality control from the manufacturer does not address the drug testing result of each device.

6. False negative results pose a serious risk for employees in a drug free workplace.

7. Common adulterants can produce negative test results.
8. Ambient temperature may affect the test results. (Speed of the reaction).
9. Many of the test systems do not test for methamphetamine specifically.
10. Most test devices are not optimized for sensitivity and specificity resulting in accuracy rates of 55% to 80%.

11 The optimized result window diminishes with time.

12. Temperature extremes during storage of devices will reduce the ability to produce results.

13. Reduces the privacy/confidentiality of donor test results.

14. Individuals who perform tests require little to no training or educational requirements.

15. Reduces due process by not involving MRO.

16. Increases the opportunity for **cheating** and **corruption**.

17. Reduces dependable forensic chain of custody documentation.

18. Reduces accurate record keeping.

19. Increases liability exposure.

V. Hair Testing Technical Inconsistencies

1. Proficiency testing trials governed by SAMHSA and numerous European studies clearly demonstrate poor lab to lab test result reproducibility. Many labs failed to analyze all challenge samples and several test values were reported at greater than 2 S/D of the mean value.

2. Split sampling by the proposed method is inconsistent based on the varied absorption rates of each hair. The primary specimen is uniform and after analysis the sample can't be sent to another lab for reanalysis.

2. The length of hair is not a dependable measurement tool to determine a time frame of drug use. A United States Naval research lab study demonstrated that drugs move within the main shaft to gain equilibrium.

3. External contamination is a major problem for cocaine and marijuana.

4. The growth rate for hair varies greatly. Depending on the growth rate and regular haircuts this method of testing appears unbalanced.

5. Drug absorption rates into the hair may vary depending on hair color. Although mentioned in the proposed rules, this variable is a genuine concern.

6. Hair testing remains susceptible to alteration by a treatment of Hydroxide peroxide prior to collection. The best and 100% fool proof adulteration method for hair testing is short or no hair.

7. A lack of high quality reagents requires each laboratory to prepare and QC/QA it's reagents. The variation in reagents and laboratory methods will produce different results.

8. Problems in preparing **true** blind samples.

9. How will SAMHSA inspection teams validate hair digestion, dye tests, microscopic identification and solvability method procedures?

III. E-Screen Evaluation/Electronic Transmission of Data

Forward Edge, Inc. was approached by E-Screen to participate as one of the first companies to evaluate this system of drug testing. Forward Edge, Inc. declined this invitation based on these observations.

1 Limited or no quality control for the test.

2. No regularly scheduled **maintenance** or record keeping of testing equipment.

3. Company management did not offer technical support or training.

4. No control of the qualification or training of personnel performing the test.

5. System did not detect adulterants.

6. When analyzing challenge specimens the test result erred toward a negative result.

7. This system does not provide the user any information other than send specimen to lab.

8. Limited or no detection method to identify interfering substances.

9. Test method uses a monoclonal enzyme system which does not react well with amphetamines, ecstasy, or opiate variances i.e., Hydromorphone, or Oxycodone.

10. No back-up litigation support.

11 The practical use is very limited because of the time requirements per collection and test.

12. One technician has **total control** of the system, no built in checks and balances.

VII. Sweat Patch

1 Just not practical for workplace testing.

2. Methods are still in developing stages.

In conclusion, the alternate specimen/testing methods have not demonstrated a dependable, reproducible, or legally defensible testing program. If special interest groups are successful in this attempt to include these methods, the Federal program will lose public support and confidence. Furthermore, the decisions that govern the scientific principles/method utilized for forensic testing will be diminished. The legal challenges that will arise if these proposed rules are approved for Federal testing will establish the new guidelines, which will be based on legal proceedings rather than sound scientific principles.

Thank you,

Stan Gerlich
COO

SG/jnw