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Docket Number ~~#####~~ 99-D1020
Dockets Management Branch
Division of Management Systems and Policy
Office of Human Resources and Management Services
Food and Drug Administration
5630 Fishers Lane, Room 1061 (HFA-305)
Rockville, Maryland 20852

**RE: Guidance for Industry, Over the Counter (OTC) Screening Tests for Drugs of Abuse: Guidance for Premarket Notifications**

Please accept this document in the context of public comment being offered in reference to the above-mentioned subject.

I am a well-recognized independent consultant with well over 20 years in healthcare and possess a history of success and expertise in the field of drugs of abuse testing. Specifically, I spent 7 years with Roche Diagnostic Systems, Inc., as director of global marketing for the Roche drug-testing portfolio of products. In addition, I am a former board of director member of The Institute for a Drug Free Workplace, current board of director member of The Hunterdon Drug Awareness Program and current board of director member for The Police Foundation. I have been interviewed frequently in the past by major news media and have appeared on a UPN 9 television special on teenage drug use, and have hosted a public radio program on WDVR 89.7 FM. In addition I've been a guest on WCBS Radio, 101.1 FM for a special segment on workplace drug testing programs.

My time with Roche has afforded me great opportunity to come before the FDA a number of times on behalf of critical drug testing legislation. In fact, I have authored several pieces of key drug testing legislation that have been passed into law in states that previously would not allow onsite drug testing in a workplace setting. A great

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majority of my background in drug testing is focused to onsite, rapid drug testing devices across just about every market segment including; workplace, criminal justice, drug treatment, schools and clinical testing arena's. I've had the opportunity first hand to observe this Country's rapid transition to accepting rapid, onsite drug tests as a viable alternative to lab based testing. Clearly I am uniquely qualified to provide valid public comment to the FDA on key issues relative to the draft guidelines for premarket notifications of over the counter drugs of abuse tests.

I also intend to provide detailed rebuttal clarification to several items presented by members of the Clinical Chemistry and Clinical Devices Panel of the Medical Advisory Committee during the open hearing session on Monday, November 13, 2000. It is my opinion and the consensus of many of the audience participants that several comments made by the Panel members are grossly inaccurate and require detailed clarification in order for the FDA to make an informed decision.

My testimony presented on Monday, November 13, 2000 contained compelling arguments and justifications to modify and/or eliminate major components of the over the counter draft guidance for premarket notifications in order to continue to permit the commercial sale of onsite drug tests ***(which have already been cleared by the FDA for professional use)*** to the workplace testing market. At present, although only an initial draft, the guidance document clearly appears constructed in a fashion that would have a chilling effect throughout the onsite drug testing industry and would impose unfair and counterproductive administrative and financial burdens on any entity that would even attempt to market an onsite (POCT) drug-testing product to the workplace.

**The Food and Drug Administration is making three stretch assumptions relative to the OTC issue of a drug test:**

1. **The FDA assumes that concerns related to OTC use of a drug test are similar in workplace, insurance and sports settings.**

2. **The FDA assumes there should be consistency in its regulation of drugs of abuse screening tests used in the home, workplace, insurance and sports setting**
3. **The FDA assumes they have legal oversight and jurisdiction to regulate drug testing performed in the workplace, insurance and sports settings, even though drug tests performed in these settings are not for medical purposes**

Prior to the introduction of onsite, rapid tests for drugs of abuse, employers were limited to having the test performed in a commercial laboratory setting, where results typically were not available for several days. The delay in test results along with logistic and administrative burdens imposed on employers forced technological innovation.

This innovation today allows us to observe first hand the rapid transition and acceptance of onsite, rapid drug tests from lab-based testing. The workplace setting has realized significant gains in productively and long-term, sustainable growth by taking advantage of this simple technology. For example, negative test results can be resolved immediately without further consideration in an extremely cost-effective manner. The hiring of qualified personnel can be achieved immediately. Chain of custody issues are virtually eliminated since greater than 90% of the samples tested are negative and do not require the administrative burden as seen with lab based testing. Onsite drug testing would prevent operation of machinery under the influence immediately. It would uncover illegal and unsafe behavior immediately.

I am making an appeal to the FDA to seriously consider deferring oversight for workplace, insurance and sports settings under the scope of this proposed guidance document. A point of care, onsite drug test that has already been cleared by the US Food and Drug Administration for professional use is more than sufficient to ensure sample integrity, test accuracy, and reliability. The FDA must be aware of the grave consequence of its position to implement oversight of workplace drug testing specifically, when in fact a drug test performed in the context of a workplace setting falls well outside

any pure diagnostic definition. In a workplace setting, a drug test is used **exclusively** to assess compliance to a corporate drug-free workplace program, it is not used for medical treatment purposes or disease management. Corporate entities utilizing drug testing simply do so to ensure they recruit and hire only those candidates that are drug free.

In fact, several State Attorney Generals have ruled, Florida being one, that a drug test conducted onsite, within a workplace environment does not fall under their laboratory statute regulating drug testing, therefore compliance to the Florida laboratory statute is not required. Additional states such as Pennsylvania, California and Kansas have also ruled in this same fashion when an Attorney General ruling was requested.

When performed in the management of probation, parole, prison, drug and alcohol rehabilitation, compliance to school policies, clearance for a life insurance policy or management of workplace policies, drug abuse screening **only** provides detection of drug or alcohol use; **it does not assess disease, immediate impairment or other health-related diagnosis requiring medical judgment or treatment.** Drug abuse testing is also qualitatively different from testing for purposes of treatment or diagnosis. This is because the individual being tested is fully aware of what the outcome of the test should be. The principles of diagnosis are then irrelevant for this type of testing. As such the FDA must defer oversight of workplace testing settings since they have absolutely no legal jurisdiction.

In a **workplace setting** for example, a drug test is used **exclusively** to assess compliance to a corporate drug-free workplace program, it is not used for medical treatment purposes or disease management, or diagnosis of disease. Corporate entities and businesses in general utilizing drug testing simply do so to ensure they recruit and hire only those candidates that are drug free, which is very consistent with any drug-free workplace program. In fact, the US Government implemented such a drug-free workplace program in the late 1980's under then President Reagan, and that program still in existence today has absolutely nothing to do with the diagnosing of neither disease, nor the management and treatment of disease. It is simply a

program that drug tests eligible employee candidates intended for hire---nothing more.

In an **insurance setting**, a drug test is also simply a means by which an underwriter excludes or includes an individual from subscribing to some form of an insurance policy. In fact, the Supreme Court of the State of New York has previously ruled overwhelmingly that insurance type testing is not considered a medical test for diagnostic purposes and as such would be exempt from the New York State laboratory statute.

In a sports setting, again we have a situation whereby as an example the NCAA will drug test athletes to assess compliance and/or drug use status to determine whether or not a policy has been violated---nothing more. As another example, Hunterdon Central High School, in New Jersey implemented onsite random drug testing of student athletes simply to assess compliance to the schools anti-drug policy.

Furthermore, the FDA cannot assume a role of selective oversight relative to the workplace setting, simply because the test format in question is that of a point of care platform and not lab-based. Currently, a number of drug testing reference labs in the US, running millions of drug tests utilize generic home brew assays made from FDA cleared products, and absolutely no oversight is enforced or even considered. To even consider oversight of an onsite, point of care drug test in a workplace setting, while completely ignoring the practice of diluting drug testing reagents is blatant prejudice and bias in favor of lab-based testing. This would be viewed clearly as a means to position manufacturers of point of care drug tests at a competitive disadvantage.

## Social-Economic Effects of Substance Abuse

Substance abuse affects each and every one of us in one way or another. Businesses in particular have a high exposure to substance abuse. Drug use in the workplace cause's high absenteeism, accidents and injuries, low productivity, high employee turnover, crime, reduced profits, and low employee morale.

It is estimated that the *cost of employee substance abuse to businesses is $75 billion*, and contrary to everyone's belief, over 70% of the 11.5 million users of illicit drugs are gainfully employed. As it stands now, greater than 90% of the Fortune 500 companies in the US, drug test their job applicants. According to the Bureau of Labor Statistics, 80% of the workforce in the US is employed by small to medium size businesses and only 3-5% of these employers drug test. The US Department of Transportation indicates that of the 300,000 employers in the trucking industry, 88% have 8 or fewer drivers, and about 50% of employers in the maritime industry qualify as small businesses. Public opinion supports drug testing and cold hard data indicates drug-testing employees is an effective business management tool.

## Workplace Drug Testing Legislation

**Currently, 40 plus states permit onsite drug testing, utilizing products FDA cleared for professional use to be used in a workplace setting**. In this regard, *the FDA's proposed guidance document is at odds with the laws in the overwhelming majority of states nationwide*, and is prohibitive of an industry practice which is increasingly common, useful, and appropriate for screening purposes, and essential for many safety-sensitive positions. Several years ago the State of Oregon revised legislation to specifically permit onsite drug testing in a workplace setting, and in 1995, the State of North Carolina passed a similar bill to permit onsite preliminary drug screening in the workplace. *To this date there has been no evidence of employers misusing the application of onsite testing* in the State of North Carolina. In fact, more small to medium employers who previously could not afford to drug test, now test their job applicants.

According to the Bureau of Labor Statistics, 80% of the workforce in the US is employed by small to medium size businesses and only 3-5% of these employers drug test. Onsite drug testing is more cost-effective for these employers and would allow them to maintain a safe working environment to the same standards as Fortune 500

companies. Employers must have the option of how and where their preliminary drug testing is to be conducted.

Businesses which have an acute need to hire casual, short-term labor while ensuring a safe workplace for all employees benefit greatly from on-site drug abuse testing. There were 6,101,924 small businesses (1 to 999 employees) in the Unites States in the last available census of 1989. Of these, 1,494,820 were engaged in retail trade, 546,848 were engaged in construction, 28,248 in textiles, 6,864 in the maritime industry, 8,893 in security services, and 12,381 were in the temporary help industry. These small businesses are examples of facilities unlikely to include occupational health laboratories and which must typically hire casual labor immediately, often for a shorter time period than the turn-around-time necessary for laboratory results.

On-site drug abuse testing is also performed on a "random" basis to ensure a safe workplace by providing a means to immediately identify high-risk individuals and to immediately return safe individuals to their ongoing activities. It is interesting to note that a recent American Management Association survey on Workplace Drug Testing showed that nearly 28% of companies said they used periodic or "random" testing, an increase of 435% compared to 1989. On-site "for cause" drug abuse testing provides protection to the workplace by allowing immediate assessment where drug abuse is suspected in cases of unsafe behavior or accidents. Individuals under the influence of illegal substances can be identified and prevented from operating machinery or vehicles immediately, thus eliminating exposure and risk to others. This would be of particular relevance in non-DOT regulated, intrastate transportation settings, such as school bus drivers, or in other areas where heavy equipment is in use, such as forestry, manufacturing, construction and maritime settings.

On-site drug abuse testing provides the most effective means of uncovering illegal and unsafe behavior because the testing takes place in the presence of the individual being tested. This minimizes denial, provides immediate feedback, and eliminates the cost, delay and "chain-of-custody" problems that accompany referral of all urine samples to off-site laboratories. Thus, for effective on-site testing to

take place where substance abuse takes place, **the FDA must absolutely defer oversight of workplace drug testing.** In short, effective drug abuse testing and management should and does begin in places where no laboratory typically exists.

In the past, an attempt to regulate workplace drug testing under CLIA 88 met with immediate industry-wide objections and ultimately was exempted and placed in moratorium by then US Health and Human Services Secretary Sullivan. Thus, in permitting this exemption, HCFA recognized the need for testing that has as its **purpose** the uncovering of **behavior** that the United States Congress and every state legislature recognizes to be sufficiently dangerous to society and its members to warrant such conduct being deemed illegal. The **purpose** of drug abuse testing in the workplace is to identify behavior that unquestionably is illegal and clearly constitutes a danger to the work force collectively and its individual members.

I would like to point out to the FDA that the mission of the FDA according to the FDA Modernization Act of 1997 is to:

- Promptly and efficiently review clinical research
- Protect the public by ensuring foods are safe
- Ensure reasonable safety and effectiveness of devices intended for human use

And according to the FDA growing responsibilities for year 2000 and beyond, FDA ***"reviewers scrutinize products that are designed to treat human conditions or diseases".***

Nowhere is it to be interpreted or stated that the FDA must now render oversight to 1) corporate hiring practices and business management, 2) criteria that effects inclusion and exclusion of insurance policy applicants, and 3) criteria for participation in structured sports. Absolutely nowhere can it even be implied that FDA has any authority over these not medically related areas.

Furthermore, FDA regulations clearly define in vitro diagnostic products as:

[those reagents, instruments, and systems intended for use in the diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or its sequelae..... 21 C.F.R. § 809.3]

By definition and admission, the FDA has no lawful jurisdiction or oversight relative to drug testing of any intended purpose unless the test is clearly intended to be used for the diagnosis of disease. Although the definition of the term "device" in the Federal Food, Drug, and Cosmetic Act (the "Act") is broad, it can only apply to products or devices intended for the "diagnosis of disease or other conditions." Explicit in the definition of device is that the seller must **intend** that the product be used for medicinal use. See, U.S. v. An Article of Drug ...Ova II, 414 F.Supp. 660, (D.N.J. 1975), *affirmed without opinion,* 535 F.2d 1248 (3rd Cir. 1976). The intended use determines whether these products are medical "devices" (21 C.F.R. § 801.4)

It should be noted that the FDA recently attempted, unsuccessfully, I might add, to regulate cigarettes as devices and was soundly rejected by the courts. The United States Court of Appeals for the Fourth Circuit stated, "[b] y its ultra vires action, the FDA has exceeded the authority granted to it by Congress, and its rulemaking action cannot stand." Brown & Williamson Tobacco Co. v. FDA, 153 F.3d 155, 176 (CA 4 1998). This was clearly and undeniably upheld by the U.S. Supreme Court earlier this year in FDA v. Brown and Williamson Tobacco Corp., et al., 120 S.Ct. 1291 (March 21, 2000).

**The U.S. Supreme Court held that:**

> *No matter how important, conspicuous, and controversial the issue, and regardless of how likely the public is to hold the Executive Branch politically accountable,* ***an administrative agency's power to regulate in the public interest must always be grounded in a valid grant of authority from Congress. (p. 1294) (emphasis added)***

Furthermore, the **United States Congress and many Courts across the country agree overwhelmingly that a drug test specifically does not under any conditions, diagnose disease.** There have been numerous legal claims made by individuals who tested positive on employment drug tests, that the drug test "diagnoses" them as drug abusers and thereby entitles them to protection as handicapped or disabled persons under the American With Disabilities Act. The courts have carefully and cautiously reviewed numerous claims such as these, and do not agree that drug tests provide any basis for a medical evaluation of disability or illness. Copeland v. Philadelphia Police Dept., 840 F2d 1139 (3rd Cir. 1988), cert denied 109 S.Ct. 1636 (1989); Mccleod v. Detroit, 39 FEP Cases (BNA) 225 (E.D. Mich. 1985).

The United States Congress has been outspoken on this issue and has been very explicit in its view and opinion on this matter in the language of the Americans With Disabilities Act of 1990 where it states that ***"a test to determine the illegal use of drugs shall not be considered a medical examination."*** 42 U.S.C. 12114(d)(1).

The Courts in this country have unanimously upheld the following legitimate and valid reasons for employment drug testing:

1. Promoting workplace efficiency and reducing employer costs associated with drug abuse
2. Ensuring the integrity of employees by prohibiting off-duty conduct which is inconsistent with duty representations
3. Promoting public confidence in the safety or integrity of a particular job
4. Prevention of theft
5. Prevention of blackmail
6. Promoting co-worker morale
7. To corroborate evidence of misconduct
8. To prevent embarrassment to the employer
9. Discouraging illegal or immoral conduct by employees
10. To promote a drug free society
11. To gather facts about employee drug use and operational efficiency

Not one of the above reasons includes a medical diagnosis or could even be construed as being closely related to a medical situation. It is a distortion of the lawful definition of the term "device" to claim that the FDA is permitted to regulate drug and alcohol tests that are clearly and unequivocally intended to be used for compliance for societal and law enforcement purposes, as well as inclusion and/or exclusion criteria for insurance underwriting. It appears that the FDA is engaged in an arbitrary effort to interfere with or complicate access to the clear benefits associated with these products and it will thwart consumer efforts to reduce and eliminate illegal use of drugs and alcohol.

***Rebuttal to November 13, 2000 Panel Comments***

As stated earlier, many comments were made by several Panel members that clearly were grossly out of context, lacked any supporting clarification, and misleading to an uninformed public citizen. Several comments specifically were mentioned with absolutely no scientific evidence what so ever, or were made to appear biased against onsite, point of care testing devices.

**Below are several of the Panel comments with my rebuttals:**

**Comment**: "Prescription Use notification is a logical progression"

**Rebuttal**: Hearing this language from several of the Panel members lead me to believe, ramifications of FDA oversight have no been thoroughly examined. Consider the logical process a consumer would have to undertake simply to obtain a drug test result. First, a visit to the physician will be required to secure a valid prescription, if the consumer lacks medical benefits this may cost the person an estimated $35 - $50. Once the prescription is secured, the consumer must then purchase the drug test at an estimated cost of $20 - $30. The total cost to the consumer to purchase a simple drug test is now an estimated $55 - $80.

The FDA is being ignorant to the financial burden being passed to the consumer, while at the same time being insensitive to the basic

needs of a desperate consumer that may have a drug-related problem. As an example, in the US today, general prescription drug use has at best a compliance of an estimated 50%, primarily because the consumer cannot afford to have their prescription filled. The only thing the FDA can expect to accomplish by requiring "Prescription Use" compliance for a drugs of abuse test is placing undue burden and costs on manufacturer's, and potentially restricting the purchase of such tests to wealthy individuals.

**Comment**: "Visual point of care drug tests should contain a statement to caution reading results under certain light sources"

**Rebuttal**: Drugs of abuse point of care tests utilize the identical immunoassay technology as seen in just about every OTC pregnancy test. A review of a UniPath, Clear Blue Easy OTC pregnancy test package insert reveals absolutely no mention of such a caution. In fact, the Clear Blue Easy package insert simply instructs the consumer to look for specific line formations. In addition, a caution statement to have consumers read results under different light intensity will only result in "cognitive dissonance" thereby leading the user to second and third guess at the initial result.

**Comment**: "FDA certainly has oversight to workplace, insurance and sports settings since it would be a preventative action, for example, to reduce Cholesterol and prevent heart attacks, the FDA regulates the drug Lipitor"

**Rebuttal**: This is really a stretch comparison of regulating a prescription drug such as Lipitor, and exercising oversight of a drug test utilized outside of any medical diagnostic definition. The FDA is required under law and by the US Congress to ensure prescription drugs safety and effectiveness. The FDA is duly authorized and obligated to regulate a drug such as Lipitor, where a disease is diagnosed and ethical treatment is rendered for cure.

**Comment**: "The FDA regulates latex gloves"

**Rebuttal**: While this may be true, the FDA exercises oversight simply due to the latex content of the rubber gloves coming in contact with human skin.

**Comment**: "In a clinical setting, people are complaining a POCT test is more expensive than a batch lab-test"

**Rebuttal**: I am certain this statement was made by Dr. Donna Bush, and I would agree with her. However, a lab-based batch drugs of abuse test will be less expensive given that both the FDA and SAMHSA permit labs to "water-down" FDA cleared drugs of abuse reagents. In some cases for example, THC reagents are diluted down 10-15 times simply to reduce cost. Yet both the FDA and SAMHSA completely ignore this issue even after numerous industry complaints have been made.

At the same time, I would further question FDA's oversight of drugs of abuse tests used in non-medical situations would do nothing more than keep the costs of a POCT test high.

**Comment**: "POCT tests for drugs of abuse should be further tested against cross reactants such as nicotine"

**Rebuttal**: Laboratory drugs of abuse tests were not and are not required to be tested against Nicotine as a cross reactant---what is next ???? Chewing gum, life savers, tic tacs ????? As previously mentioned, millions of drug tests are performed each day by SAMHSA certified labs that are "watering down" testing reagents. These home brew, watered down reagents lack certificates of analysis, stability data, and cross reactivity data. In addition, these labs are not required to manufacture 3 production lots, nor are they required to perform clinical trials on their home brew reagents. In fact one particular manufacturer has stated that they make no guarantee about the performance of their reagents when they are diluted or watered down. How could the FDA possibly hold POCT tests to higher standards without appearing to be biased and prejudicial.

**Comment**: "A wet chemistry drugs of abuse test is more accurate than an onsite POCT test"

**Rebuttal**: There are currently several dozen studies, including one specific study commissioned by SAMHSA in 1999, that has clearly established well beyond a doubt, a level of performance of onsite drug tests comparable to lab-based wet chemistry drug tests. In another study commissioned by the Administrative Office of the United States Courts in 1997, well over 15 different onsite drug tests were evaluated against the Syva EMIT drugs of abuse, instrument-based system. One analyte in particular, amphetamines demonstrated at 27% false positive rate in the Syva EMIT system, versus a 0% false positive rate in several of the onsite, POCT assays.

**Comment**: "Negative POCT tests should be confirmed"

**Rebuttal**: It must be noted that approximately 95% or so of all drug tests performed in the US (both lab-based and POCT) yield negative test results. Currently, no federal law or agency mandates testing each and every negative lab-based drug test result. In addition, it would be virtually impossible for the drug testing labs in the US to handle the workload of confirming all negative drug tests. Furthermore, the FDA must realize the significant cost of confirming all negative results, and the FDA must realize the delay in reporting results due to confirmation testing. This suggestion is completely unreasonable and further proof of bias and prejudice against POCT drug test devices. Lastly, all current methods of drugs of abuse confirmation tests are not FDA cleared, nor are they in any standardized kit form.

**Comment**: "Workplace positive screen tests must be confirmed"

**Rebuttal**: I believe this is the only instance that 100% agreement exists among all the key stake holders and special interest groups. However, the FDA must understand that safeguards are already in

place to ensure such precautions are implemented. For example, the State of North Carolina revised its drug testing law in 1995 to permit the use of onsite, POCT drug tests in the workplace. The North Carolina law further requires all pre-employment positive drug tests to be confirmed prior to rejecting a job candidate, and in the case of for-cause positive results, confirmation must be performed prior to any action taken against the employee. On the other hand, most states designate "work at will", and therefore pre-employment positive drug screens do not require confirmation since the job candidate has no relationship to the perspective employer. A potential job candidate in this instance is seeking employment solely at will, and not under obligation, force or requirement.

As another example, in 1997 the State of Oregon revised its drug testing law to permit the use of onsite, POCT drug tests in a workplace setting. Under the current Oregon law, confirmation testing is only required in situations for post accident, random, for cause and reasonable suspicion drug testing situations.

In addition, just about every collective bargaining agreement/contract for organized labor absolutely requires confirmation testing of all preliminary positive screen results. In the federally regulated drug testing market such as DOT, confirmation testing of preliminary positive results is required under federal law.

In conclusion, the FDA must and should limit its oversight authority specifically in those areas where a drug test is utilized for diagnosis of disease for treatment and/or cure, and in those situations where medical treatment is required. Those situations could be defined as drug treatment, clinical and analytical settings where the drug test result will be used as a means to render immediate medical care and treatment, with the expectation of cure.

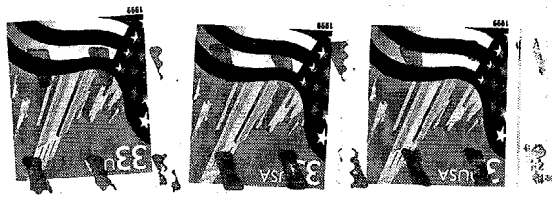
Within the confines of workplace, insurance, and sports settings that **only utilize a drug test to assess compliance to policy**, the FDA is definitely and unequivocally outside the parameters of its legislative charge and clearly outside its jurisdictional reach and authorization. Any attempt on the part of the FDA to pursue oversight to these

areas specifically is likely to result in potential litigation and public scrutiny at a time when FDA does not need such attention.

I hope the information I have provided is helpful in understanding the true utility of a drug test, and I would look forward to the opportunity to discuss my testimony in detail if necessary.

Sincerely,

Robert L. Aromando, Jr.
Independent Industry Consultant
Drugs of Abuse Testing
(908) 996-3137



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5630 Fishers Lane, Room 1061
Rockville, Maryland 20852