BEFORE THE
DEPARTMENT OF TRANSPORTATION
OFFICE OF THE SECRETARY

COMMENTS OF THE OWNER-OPERATOR INDEPENDENT DRIVERS ASSOCIATION, INC.

IN RESPONSE TO A NOTICE OF PROPOSED RULEMAKING

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INTRODUCTION

The Owner-Operator Independent Drivers Association, Inc. ("OOIDA") submits these comments in response to the February 4, 2010 notice of proposed rulemaking published by the Office of the Secretary at the Department of Transportation ("DOT"), 75 Fed. Reg. 5722, soliciting comments in Docket OST-2010-0026 on DOT's proposal to amend its drug-testing procedures governing laboratory testing of urine specimens. The proposed changes are intended to make the DOT's drug-testing rules consistent with the revised Mandatory Guidelines for Federal Workplace Drug Testing Programs ("HHS Guidelines") issued by the U.S. Department of Health and Human Services ("HHS") at the end of 2008.

DOT, which is for the most part simply parroting the HHS Guidelines, is now proposing to amend its drug-testing procedures as set forth in Part 40 to allow DOT-regulated employers to choose between a full service laboratory and an Instrumented Initial Test Facility ("IITF") for initial drug testing. An IITF is a free-standing facility comparable to the initial screening section of a full-service laboratory. Under DOT's proposal, the IITF would perform automated initial drug tests and provide test results to employers when specimens test negative or negative dilute, or are rejected for testing. All specimens producing other results, including positive, adulterated, substituted, or invalid findings (which DOT lumps together as "non-negative") would be forwarded to a full-service laboratory, which would repeat the initial drug test and then perform a confirmatory test. DOT is also proposing to expand initial and confirmatory drug testing to include screening for MDMA

(Ecstasy) and additional heroin metabolites, with confirmatory testing also expanded to include screening for amphetamines chemically related to Ecstasy. Also following HHS's lead, DOT is proposing to lower both the initial and confirmatory cutoff concentrations for amphetamines and cocaine.[1]

OOIDA is a not-for-profit trade association incorporated in 1973 in Missouri with its principal place of business located at 1 NW OOIDA Drive, Grain Valley, Missouri 64029. The nearly 157,000 members of OOIDA are independent owner-operators, small business motor carriers, and professional truck drivers located in all 50 states and Canada. These groups have a significant presence in the trucking industry: One-truck motor carriers represent nearly half of the active motor carriers operating in the United States while approximately 96 percent of active motor carriers operate 20 or fewer trucks.

OOIDA is the largest international trade association representing these small business truckers and professional drivers. The Association actively promotes the views of these groups through its interaction with state and federal government agencies, legislatures, the courts, other trade associations, and private businesses, to advance an equitable and safe environment for commercial drivers. OOIDA also actively represents the positions of these groups on all aspects of highway safety and transportation policy in numerous committees and various forums on the local, state, national, and international level.

The majority of OOIDA's members are owner-operator truck drivers who are subject to DOT's drug testing requirements and participate in testing programs as required by the motor carriers

[1] DOT is also proposing modifications to the roles and certification standards for MROs. OOIDA has not addressed those changes in these comments, leaving them to be addressed by those having greater familiarily with MRO-related issues.

to whom they are leased. A smaller group of OOIDA's members, approximately one-third, are small business motor carriers who satisfy the drug testing requirements for themselves and/or their drivers by participating in a third-party testing consortium ("TPA") such as CMCI, a TPA established by OOIDA in 1990 to offer members a comprehensive program that satisfies DOT's mandatory drug and alcohol testing requirements utilizing a nationwide network of collection and testing sites. As a TPA, CMCI currently provides drug testing services for a population of more than 7,300 drivers.

OOIDA has always taken a zero-tolerance approach to drug use, by supporting any changes to drug-testing and reporting procedures that will, in a cost-efficient manner, effectively keep drivers with substance abuse problems off the road until their problems have been successfully addressed and resolved. In this spirit, OOIDA wants to make certain that any revisions to DOT's current drug-testing program that are borrowed from the revised HHS Guidelines do just that. Having analyzed the situation from this perspective, OOIDA supports the proposed addition of MDMA (Ecstacy) and certain heroin metabolites to the list of drugs already being tested for.

However, OOIDA's research has suggested that the proposed rule changes may in other respects be counterproductive. While HHS's original proposal said that IITFs are intended to "more quickly and economically meet local testing needs," 69 Fed. Reg. 19673, 19677 (April 13, 2004), the proposed use of IITFs in the motor carrier industry may well result in higher overall testing costs for employers, which may often be passed through to drivers. The new procedures may also result in an increase in false positive results that will not only raise doubts about the accuracy of DOT's drug testing programs generally but will jeopardize the careers of responsible, non-drug using drivers who stand falsely accused of substance abuse. For these reasons, as discussed more fully below, OOIDA does not believe that IITFs should be incorporated into the DOT drug-testing program. The

pros and cons of the proposed lower cutoff concentrations should also be more carefully weighed to determine whether or not they should be adopted.

DOT recognizes in its notice that it must "consider program costs and the value added in adopting some of the new HHS Mandatory Guidelines procedures," considerations that prompted DOT to reject certain aspects of the HHS Guidelines. 75 Fed. Reg. at 5724. Keeping both program costs and value in mind, OOIDA proposes, as an alternative means of improving the efficacy of DOT's drug-testing program, that the Agency consider adopting a performance-based random drug testing program that would allow drivers who repeatedly test negative on drug tests to be removed from the pool of drivers subject to the annual 50 percent random drug testing requirement currently applicable to all drivers. These drug-free drivers would be placed in a separate pool that is subject to an annual 25 percent random testing rate. Maintaining two separate pools would decrease drug-testing costs while increasing the likelihood that drivers in the 50-percent pool will be tested and, in turn, increasing the likelihood that drug abusers remaining in that pool will be caught.

DISCUSSION

I. The accuracy of drug test results may be downgraded under the revised rules.

As noted above, DOT has decided to lower the initial and confirmatory cutoff concentrations for cocaine and amphetamines under the revised rules. In so doing, DOT has seemingly without question adopted HHS's reasoning that the estimated identification of 10 percent more amphetamine and cocaine users (approximately 3,000 from more than 5 million tests) will increase the deterrent effect of the program. 75 Fed. Reg. at 5725. The identification of even a small number of substance abusers is, of course, a laudable goal strongly supported by OOIDA. However, it appears here that some portion of these apparent drug users identified by the lowered cutoff concentrations will

actually be victims of false positives. Because of the serious adverse impact that inaccurate results ordinarily have on those wrongly accused of drug use in the DOT context, such false accusations of drug use are no more acceptable than failures to identify drug users. These mistakes can end careers. Drivers may not only lose their current jobs or find themselves denied potential job offers by motor carriers, but the false result in their record also impedes their ability to find driving jobs in the future since all commercial motor vehicle driving positions require such drug tests.[2] Thus, a false positive has a longer-lasting effect in the DOT context than it does for employees in other settings. In addition to these very serious economic consequences, drivers may experience emotional harm and their reputations may be permanently injured by dissemination of inaccurate test results. It is important to protect drivers being tested from such consequences.

It is well established that over-the-counter or legally-prescribed medications may, at lower concentration levels, inaccurately signal the presence of illegal drugs. Over-the-counter medications that have caused false positives for amphetamines are numerous and include many common sleep, cold and allergy, diet, and asthma aids,[3] as well as a variety of legally-prescribed medications. *See* www.askdocweb.com/falsepositives.html; www.netwellness.org/healthtopics/substanceabuse/drugtesting.cfm. While substances causing false positives for cocaine are smaller in number, they

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[2] The unwarranted impact of false tests will be even greater if, as proposed by certain industry groups, FMCSA establishes a national clearinghouse that retains all non-negative results, invalid as well as positive, false as well as true, and makes them available to potential employers.

[3] Over-the-counter substances that can cause false positives for amphetamines and some of the products they are contained in include ephedrine, pseudoephedrine, propylephedrine, phenylephrine, or desoxyephedrine (Nyquil, Contact, Sudafed, Allerest, Tavist-D, Dimetapp, Phenegan-D, Robitussin Cold and Flu, Vicks Nyquil), diet aids with phenylpropanolamine (Dexatrim, Accutrim), nasal sprays (Vicks inhaler, Afrin), and asthma medications (Marax, Bronkaid tablets, Primatine Tablets).

include commonly-prescribed antibiotics, such as amoxicillin and ampicillin, topical anesthetics such as xylocaine, and tonic water. *Id*.

The use of IITFs, no matter what the cutoff levels, may further add to the number of false positives. Under the proposed rules, IITFs are required to use automated immunoassay tests. These facilities do not have the option to use other available tests that often are used by trained personnel at full-service laboratories. However, OOIDA has learned in conversations with individuals actively involved in the field that the automated immunoassay equipment produces more false positives and false negatives than those other types of tests and equipment. Thus, the automated equipment being required for IITFs does not appear to be "the best available technology for ensuring the full reliability and accuracy of drug tests," as HHS was required to use in developing the drug-testing guidelines. Supplemental Appropriations Act, P.L. 100-71,§ 503(a)(1)(A)(ii)(I), 101 Stat. 391, 469 (July 1, 1987).

The accuracy of drug test results may also be downgraded by newly-created delays inherent in the proposed IITF process. Under current rules, when a specimen is received by a full-service laboratory, it will generally be tested, certified, reported to the MRO and then the employer, all within 2-3 days of collection. Under the revised procedures, if the initial screening test performed by an IITF has a non-negative result, the IITF must then ship it to a full-service lab, which will duplicate the initial test and perform additional confirmatory tests as needed. The time for initial testing, repacking the specimen, and shipping it to the full-service lab for retesting, could add at least 2 additional days to the processing time for non-negatives. Even more time might pass when a specimen is shipped from the IITF on a Friday and won't reach and be retested by the lab until the following Monday.

The extra time for processing IITF-tested specimens exacerbates a range of potential problems already implicated in the testing process. First, normal urine falls within specific pH and temperature ranges and both are checked for each sample provided, temperature at collection and pH during the specimen validity test. Since pH levels steadily increase over time once a sample is collected, the passage of several extra days between collection and final testing might cause the pH of a specimen to rise to a level where it is can no longer be retested. Likewise, because specimens en route from one facility to another are not always kept in temperature-controlled containers or vehicles, the specimen may be heated to a level that also precludes effective retesting. The handling of non-negative specimens by many parties involved in the transport and testing of non-negative specimens, even if done as quickly as possible and in a temperature-controlled environment, also increases the potential for contamination, leakage, or total loss of a specimen before a final confirmatory test can be performed.

Any of the invalidating circumstances discussed above would necessitate a repeat of the entire testing process, beginning with collection of another specimen. However, that often will not be able to happen because, as OOIDA's member drivers have often reported, employers tend to fire them or deny them a job instead of waiting for what is simply assumed to be a positive test result. Of course, the myriad of serious problems implicated when an IITF is used can be avoided by continuing to require all DOT drug-testing to take place at full-service laboratories.

Perhaps even more importantly, the delays inherent in the IITF process hinder the primary goal of DOT's drug-testing program, which is to ferret out that small group of drivers who use drugs and ***quickly*** get them off the road until their substance abuse problems can be eliminated. In fact, the use of IITFs will substantially slow down the transmission of results for individuals with non-

negative test results. Thus, the new IITF process will have precisely the opposite of the intended effect, by delaying the identification and removal from the road of those drivers who might present an actual safety risk. For all these reasons, OOIDA does not believe that the DOT drug testing program presents an appropriate context for their use.[4]

II. The revisions to DOT's drug-testing rules present significant modifications with substantial costs for the trucking industry.

DOT has determined that the proposed changes to its drug-testing rules "will not have a significant economic impact on a substantial number of small entities" because the economic effects "will be negligible for DOT regulated employers" and other involved parties. 75 Fed. Reg. at 5725. This finding, however, does not appear to be based on DOT's independent analysis of the likely impact of the rule changes. Rather, it is based upon the fact that the changes being proposed here, for the most part, mimic the HHS Guidelines in an attempt to align DOT testing procedures and processes with HHS procedures which, according to DOT, "were considered non-significant." *Id*. For the reasons discussed below, OOIDA disagrees with DOT's conclusion. Whether the changes are or are not "non-significant" in the HHS context when applied to the Federal Workplace Drug Testing Programs, they will impose significant additional costs in the motor transportation setting.

The charges levied by IITFs for initial drug tests are unlikely to be less than those charged by full-service laboratories. Initial screening drug tests are easy to perform and the volume is large, far larger than the volume of confirmatory tests performed. Accordingly, they generate the bulk of

[4] Interestingly, IITFs were not envisioned initially as substitutes for full-service laboratories operating under normal circumstances, as is now being proposed. Rather, IITFs were meant to be used by an agency like the Nuclear Regulatory Commission when it had to clear hundreds of workers at one time to perform maintenance or fuel rod replacement in a nuclear facility. The high volume of testing to be done in a short time under those circumstance was more than full-service labs could handle.

the income currently earned by full-service labs. Although IITFs will be able to perform those income-generating tests without investing in the more costly facilities and equipment associated with confirmatory tests and without hiring the well-trained "responsible persons" and "certifying scientists" that are employed by full-service laboratories, they will incur costs in establishing new facilities and getting them certified. Thus, testing costs are unlikely to drop in any meaningful way from current levels until these amounts are fully recovered by IITFs.

Also, the workload at full-service laboratories should be expected to drop substantially once IITFs assume much of the initial testing function. A majority of those labs can be expected to become unprofitable and close, leaving employers and drivers who prefer them to IITFs with fewer choices and, more generally, eliminating competition in the marketplace for repeat and confirmatory testing. Reduced competition plus fewer initial tests generating income to support the remaining full-service laboratories will undoubtedly lead to an increase in the per-test costs and therefore the charges for their testing services. Indeed, evidence has shown that amounts charged for drug tests vary significantly, and are far higher at facilities where the volume of tests performed is lower. *See, e.g.*, 75 Fed. Reg. at 5725 (data collected by DOT from 11 full-service labs shows that charges for heroin and ecstacy testing range from a low of 6 cents per test to a high of $1.27 for ecstacy and $2.27 for heroin depending in part upon volume). Higher costs for confirmatory testing of non-negatives will certainly be passed through to those being tested.

OOIDA also expects that extra tests performed due to rule changes to further increase the overall costs to industry. There will be more tests because, as discussed above, the equipment used by IITFs will generate more false positives than the immunoassay tests more commonly used by full-service laboratories. This is added to approximately 75,000-100,000 duplicate initial tests for every

non-negative result.[5] While HHS initially envisioned that the full-service laboratory would perform only the confirmatory drug test when an IITF got a non-negative result, it responded to commenters' concerns about the use of two different facilities to perform the tests on specimens from one individual, by requiring the full-service laboratory to repeat the initial test "as if the specimens had not been previously tested." 73 Fed. Reg. 71858, 71867 (Nov. 25, 2008). The result is that three tests, instead of the two ordinarily required now, will routinely be performed before a non-negative result can be confirmed. In cases where the specimen that initially tested non-negative is unusable because of overheating, increases in pH, contamination, leakage, or loss, the entire testing process will have to be repeated. Of course, someone has to pay for all of these extra tests. That someone is undoubtedly going to be the employer requesting the test who will in most cases pass through this cost, like other out-of-pocket costs attributable to a particular driver, directly to the driver in the case of owner-operators or indirectly to the employee driver through adjustments to compensation.

Another matter of concern related to the use of IITFs that might generate additional costs are inconsistent results between the IITF and laboratory. Such a result is not as improbable as it might seem at first glance, given the use of different types of immunoassay tests by IITFs and full-service laboratories. Inconsistencies are especially likely when the IITF's non-negative results are very close to the cutoff concentration or when they simply reflect a false positive. Drug tests, particularly those performed with the automated equipment used by IITFs are not at all foolproof.

As we read the rules, a full-service lab receiving a specimen from an IITF is not given the original test results. Nevertheless, in contrast to a sample that comes to the lab directly from a

[5] This is based upon positive testing rates from at least 5,000,000 tests ranging from 1.5-2 percent according to FMCSA reports between 2000 and 2005.

collection site, which is tested without any preconceived expectations, a sample sent from an IITF arrives with the presumption that there is something wrong with it, otherwise it would not have been forwarded to the lab. Given human nature, the lab technician would expect a positive or other non-negative result on the retest. This could in close cases bias the result or lead to confirmatory tests even when a negative result should have been reported. Lab personnel may be inclined to perform more complete confirmatory tests simply to ensure that they have not missed a positive specimen. Such procedures not only raise questions about the integrity of the process, but will add to the costs of testing.

In sum, it is premature for DOT to find that the costs of the proposed revisions will be "negligible." As discussed above, the already substantial costs to the trucking industry for DOT's drug-testing program will increase to reflect the higher charges for confirmatory tests by labs that are performing far fewer initial drug tests, the charges for retesting a higher number of specimens producing false positives, and the charges for duplicating the initial test when a non-negative result is obtained by an IITF. OOIDA is not in a position to calculate how much this will add to current costs. However, OOIDA firmly believes that DOT should attempt to independently quantify these and other costs before it blithely concludes that their impact is not sufficient to raise any doubts about the merits of the proposed rule changes.

III. DOT would catch more drug users by establishing a two-tier random drug-testing program that focuses more directly on those that might be using drugs.

The ultimate goal of DOT's drug-testing program is to keep drivers with substance abuse problems off the roads until their problems have been successfully addressed and eliminated. As discussed above, the proposed changes to the scope of testing under Part 40 might result in the

identification of a small additional number of drug users, but the establishment of IITFs will also increase the time required to identify them. It will also burden the system with more false positives than currently exist, at great cost to industry and the individuals who are wrongly identified. OOIDA believes that DOT could achieve greater improvements in the system, without comparable adverse side effects, by modifying the random drug-testing program imposed by Part 382 of the regulations.

DOT regulations require motor carriers to subject drivers to pre-employment drug testing before they are hired. 49 C.F.R. § 382.301. Once hired, carriers must subject at least 50 percent of their drivers to random drug testing on an annual basis. 49 C.F.R. § 382.305(b)(2). Because of the totally random manner in which driver are selected for this testing, some drivers are repeatedly tested while others are rarely or never tested. The result is that some drug users escape detection, while others who never use drugs are subjected to repeated testing that does not offer them (or their employers) any direct reward for their continued drug-free status. Adding new drugs to the list to be tested, lowering the cutoff concentrations that are deemed to reflect illegal drug use, and allowing IITFs as well as full-service laboratories to perform initial drug tests, will not eliminate or help in any way to eliminate this inequitable and wasteful allocation of resources.

OOIDA believes that DOT's drug-testing program will be far more productive if the random drug-testing component, which has a far greater deterrent effect than the more predictable forms of drug testing, is modified to focus more directly on detecting the small group of drivers who are drug users while at the same time rewarding drug-free drivers and their employers with an incentive for continued good performance. It makes no sense to continually water down a testing pool with drivers who have repeatedly produced negative tests - in many cases going back to the inception of mandatory drug testing. Accordingly, OOIDA proposes the creation of a performance-based drug-testing

program that would allow drivers who test negative on 5 consecutive qualifying drug tests (reasonable suspicion, post-accident, and random tests) and have never had what DOT considers to be a non-negative test result of any kind to be removed from the pool of drivers subject to the annual 50 percent random drug testing requirement and be placed in a separate pool that is subject to an annual 25 percent random testing rate. All other drivers – i.e., those who have not proven themselves under the 5-test criteria to be drug free either because they are relatively new drivers or simply because they have not often been randomly selected in the past – would still be subject to the 50 percent testing requirement. All testing performed in both groups would still be conducted in full compliance with the requirements of Parts 40 and 382 of DOT's regulations.

There is no direct reward at the present time for individual drivers who remain drug-free throughout their driving career or for employers whose hiring and training practices foster a drug-free group of drivers. No matter how many times drivers test negative they remain just as likely as undiscovered drug users who have never been tested to be selected again. Similarly, employers with excellent records are treated precisely the same as the poorly-performing employers in the percentage of drivers they must continue to test. The two-tier program will provide the missing reward, by recognizing the exemplary records of drivers who have shown themselves repeatedly not to be drug users with a less burdensome and costly reduced level of testing.

As proven drug-free drivers move to the lower-level testing pool, testing resources will be focused on the remaining group of drivers that is far more likely to include any unidentified drug users. The likelihood that any particular driver in the 50 percent pool will be selected for testing will increase. To the extent that there are any drug users in that group, this means they are more likely to be caught. Moreover, because the rate of positive drug test results in the overall truck driving

population is quite low, approximately 1.5 percent, a significant percentage of drivers could be expected to qualify for the 25-percent pool over time, further increasing the likelihood of detecting drivers who are safety risks because of their drug use. The ultimate result should be a drug-testing program that is far more effective than the current program in ferreting out drug users, whether or not the modifications now being proposed are adopted.

Although the proposed changes could be made through a notice and comment rulemaking, OOIDA understands that DOT might be reluctant to make such a major change to the current testing program without trying it out on a provisional basis first. This could be done through a pilot program administered by the FMCSA pursuant to 49 C.F.R. Part 381, Subpart D. Such a pilot program, if extended over several years, would allow DOT to gather statistical data on the efficacy of a two-tier testing program in identifying drug users as compared to the current regulatory regime. If, as OOIDA suspects, it results in a more effective program, it could later become the subject of a rulemaking.

CONCLUSION

The revised drug-testing rules now being proposed might catch a small number of drug users who are escaping detection under the current regulations. However, as discussed above, the incremental benefit may well be offset by the increase in tests invalidated because of the more complicated testing process when an IITF is used for initial testing and by the increase in false positives that is likely to result from both the equipment used by IITFs and by the reductions in the cutoff levels for amphetamines and cocaine.

The two-tier system proposed by OOIDA is likely to catch a greater number of drug users at an overall reduced cost, and is not measurably more difficult or costly to administer. When Congress mandated drug testing programs in the transportation industry it said that "the greatest efforts must

be expended" to eliminate the use of illegal drugs by truck drivers because of the impact such conduct has on the performance of those individuals and the increase in transportation accidents. Omnibus Transportation Employee Testing Act of 1991, Pub.Law 102-143, *supra*, Title V, § 2. "Greatest efforts" requires DOT to promote and test alternatives to the current regulatory scheme such as the two-tier system if further progress is to be made.

Respectfully submitted,

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