347 Madison Avenue
New York, NY 10017-3739
212 878-7000 Tel

#04-7984
P.C. 8400173

Metropolitan Transportation Authority
State of New York

BY FAX AND REGULAR MAIL

July 12, 2004

U.S. Department of Health and Human Services
5600 Fishers Lane
Rockwall II, Suite 815
Rockville, Maryland 20857

Re: Proposed Revisions to Mandatory Guidelines for Federal Workplace Drug Testing Programs, Federal Register, Vol. 69, No. 71, April 13, 2004

Dear Sir or Madam:

The Metropolitan Transportation Authority ("MTA") and its subsidiary, The Long Island Rail Road ("LIRR"), and the MTA's subsidiary and affiliated agency, New York City Transit Authority, and its subsidiary Manhattan and Bronx Surface Transportation Operating Authority ("MaBSTOA") (collectively "NYC Transit"), submit the following comments concerning the referenced proposed revised rule published in the April 13, 2004 Federal Register.

The MTA, through its subsidiaries and affiliated agencies, is engaged in, among other things, the transportation of approximately 1.7 billion commuters in the New York City metropolitan area each year. The MTA's agencies employ more than 59,000 persons. MTA itself employs approximately 1,300 employees, about 540 of which are in safety-sensitive positions covered by the drug and alcohol testing rules of the United States Department of Transportation ("DOT"), and its operating agency, the Federal Transit Administration ("FTA"). Most of those safety-sensitive employees are represented by a union. LIRR employs approximately 6,500 employees, of which approximately 2,500 are subject to drug and alcohol testing under the rules of DOT and its operating agencies, the Federal Railroad Administration ("FRA") and the Federal Motor Carrier Safety Administration ("FMCSA"). NYC Transit employs approximately 48,000 individuals in 1,100 job titles. Approximately 29,000 NYC Transit employees are employed in safety-sensitive positions subject to the drug and alcohol regulations of the FTA and all NYC Transit employees are subject to NYC Transit's own drug and alcohol testing rules. Moreover, the NYC Transit workforce is largely unionized, with collective bargaining agreements covering nearly 43,000 NYC Transit employees. MTA, LIRR, and NYC

Transit collectively conduct approximately 26,000 federally-mandated drug and alcohol tests each year, not including extensive additional testing conducted under their own authority. Our workforce is among the most diverse in the nation.

In considering the proposed rules, we understand that the proposed use of alternative drug testing methods will not at this time be applicable to DOT-regulated employers, but we note that the proposed rule provides, "The Department is well aware that these proposed changes to the Guidelines may impact the DOT and [Nuclear Regulatory Commission] regulated industries depending on their decisions to incorporate the final Guidelines into their programs under their own authorities." 69 Federal Register 19687 (April 13, 2004) (the "Proposed Rule"). Based upon this statement, we believe these changes may ultimately be adopted by the DOT. Therefore, we appreciate this opportunity to raise our concerns at this time.

We also recognize that the use of alternative testing means is intended as an employer option. We believe, however, that until more scientific data is available, the Department of Health and Human Services ("DHHS" or the "Department") should not treat them as though they are as effective and efficient in detecting drug and alcohol use as are the current testing methods. For these and several other reasons addressed below, we urge the Department to maintain the rules currently applicable without the proposed expansion. When and if the scientific evidence establishes that these alternative testing means are sufficiently reliable and their impact is non-discriminatory, we will, of course, support those means as employer options.

Current federal regulations already contemplate the use of other testing means in cases where there is an established permanent or long-term medical condition that precludes an individual from producing a urine specimen on demand. The responsibility for determining those alternative means is vested in the Medical Review Officer ("MRO"), who is empowered to certify an employee as drug-free through those alternative means. See, e.g., 49 CFR § 40.195. There is no reasonable justification to expand the use of alternative testing means beyond those already addressed in the regulations.

The Proposed Rule will have an adverse effect on labor-management relations, particularly collective bargaining. The Department's authorization of such alternative means of testing will no doubt lead labor organizations to seek in collective bargaining an employer's use of such means, which may, in the employer's view, not yet be as scientifically sound as the current testing methods. For example, a recent FTA interpretation making it optional for an employer to excuse certain individuals with bona fide child care needs from reporting for D Segment random drug testing and the last half hour of that Segment for alcohol testing has directly resulted in that interpretation becoming a mandatory practice under the collective bargaining agreement covering the majority of safety-sensitive employees at NYC Transit. The chief difference in that case was that the policy justification – sensitivity to family care needs – was coupled with carefully crafted guidance to ensure that the random nature of testing was not disturbed

overall. Should the Department proceed with its Proposed Rule here, we request that the rule provide specifically and expressly that the employer, and only the employer, has the power to determine the extent to which it wishes to use the alternative testing options.

One chief advantage of the current rules, because of the reliable scientific evidence supporting them, is the relative ease with which an employer can obtain expert and accepted testimony from a witness regarding the forensic and toxicological reliability of the testing in cases where chain of custody and laboratory procedures are at issue. A finding of an MRO-verified positive test is difficult to dispute in arbitration, and arbitrators have continually upheld employers' decisions based upon such results.

In contrast, the Department recognizes the flawed nature of using sweat patches as collection devices for the detection of drug use. The proposed regulations recognize that employee or union organizations will be able to successfully challenge determinations of positive test results in these circumstances. In the commentary to the Proposed Rule, the Department states, "Attempts to remove or tamper with the FDA-cleared sweat patch are usually visible to personnel trained to remove them. Sweat patch contamination issues continue to be a concern." Proposed Rule, p. 19676, col. 3. The commentary continues, ". . . one study suggests that sweat patches are susceptible to contamination by a drug that is on the skin before the sweat patch is applied and by absorption into the patch through the surface of the protecting membrane." Id. These known problems present a real concern that sweat testing results, to the extent they are relied upon to establish a positive drug test result, could be easily attacked in an arbitration proceeding. Moreover, these comments alone raise the possibility that an employer using such sweat patches could mistakenly seek the discipline or discharge of an employee who has not violated any policy and does not necessarily have a positive result.

Further, it does not appear that the Department itself has the necessary confidence in the performance of existing laboratories to produce reliable results from these optional testing methods. The commentary continues, ". . . it appears that valid [performance testing] PT samples can be prepared, although some further refinement is needed, and that over time some laboratories testing alternative specimens have been able to achieve performance levels approaching those levels applied to urine testing laboratories." Proposed Rule, p. 19674. The Department writes,

> Although performance in the pilot PT program has been encouraging, with individual laboratory and group performance improving over time, there are still three serious concerns. First, the data from the pilot PT program to date show that not all participants have developed the capability to test for all required drug classes, nor to perform such tests with acceptable accuracy. Second, some drug classes are more difficult to detect than others, for any given type of specimen. Third, the specific drug classes that are difficult to detect varies by the type of specimen. That means that special awareness will be required to select the most appropriate type of

specimen to be collected from a specific donor, when use of a specific drug is suspected.

Id.

We request that the Department provide further guidance to employers for selecting the appropriate testing method for a particular situation. The commentary simply states that employers will be expected to have a degree of "special awareness" to make this crucial choice. For employers with large safety-sensitive populations like MTA and NYC Transit, this "special awareness"[1] without more will likely lead to mistakes by designated personnel who must choose the testing method in a given circumstance and, more importantly, who must speculate about which drug he or she believes is at issue on any given test. Should a collector, who is usually a lay person and not a medical professional, be charged with determining which alternative test to give at a given moment? Would this type of awareness be required for all tests or only those based on reasonable suspicion or follow-up after a known positive for a specific drug? How would the decision-maker obtain immediate access to the necessary information to make an educated assessment? With the thousands of tests NYC Transit administers each year, the potential for mistakes is magnified.[2]

We also seek more guidance from Substance Abuse Professionals ("SAPs") to determine whether proposed alternative testing for a specific drug after a known positive for that drug represents a significant clinical tool. SAPs regularly discuss drug addiction as a multi-faceted disease that not only involves a "drug of choice" but often involves multi-substance abuse that existing urinalysis technology is ideally suited to detect. Since a SAP currently may recommend follow-up testing for up to five years as he or she believes appropriate, it is unclear what additional benefit hair or sweat testing represents in those circumstances.

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[1] "Special awareness" seems to presume that an employer will (1) have an adequate basis for suspecting the use of a particular drug and (2) select the right testing means at the time.

[2] DOT raised the concern about the potential for confusion and mistakes with respect to drug testing rules in connection with imposing additional training requirements on collectors. See, e.g., the DOT response to commentary on the imposition of those new requirements in 2001: "When our inspectors and program personnel visit collection sites in the field, they commonly find a wide variety of mistakes and misunderstandings in the collection process." 65 Fed. Reg. 79,471 (Dec. 19, 2000).

Hair Testing

Since the proposed regulations would permit the addition of hair testing to supplement urine testing, it is entirely conceivable that many women, in particular, would be found positive for drugs while men using the same drug may not be found positive. "The Department is proposing to permit agencies as part of their Federal workplace program to test hair with lengths of about 1.5 inches long, representing a time period of 90 days, and to use these specimens for pre-employment, random, return-to-duty and follow-up testing." Proposed Rule, p. 19675. From the outset, it appears that this provision significantly advantages individuals who choose to keep their hair length substantially shorter than 1.5 inches or those who, in anticipation of drug testing choose to cut their hair much shorter than 1.5 inches.[3] While potentially discovering more rule violations is a worthwhile goal in the interest of public safety, the potential for real or perceived discriminatory impact appears to be enormous.

> There are a number of factors that may influence the amount of drug incorporated into hair (e.g., drug dose, length of exposure, drug chemical structure, charge). Of particular concern are environmental contamination and the role of hair color.
>
> Concern has been raised about environmental contamination where a person may claim, for example, that the drug is present because the individual was in a room where others were using marijuana or cocaine. While washing the hair sample may remove some of the contamination, ultimately we can differentiate environmental contamination from actual use because of the presence of the metabolite, which is not present when environmental contamination is the source of the drug.

Proposed Rule, p. 19675. Under the existing testing rules, these "environmental defenses" are not available to employees, because reliable scientific evidence shows that drug metabolites cannot be detected at levels necessary to demonstrate a positive where the only admitted contact with the drug was environmental.

We share the Department's concern about the role of hair color. The commentary in the Proposed Rule states,

> Animal studies have shown that hair color influences drug incorporation with black hair containing the most and yellow (non-pigmented) hair the least. In vitro studies in which black, brown, and blond hair from drug-free human subjects were placed in a solution of benzoylecgonine showed the highest concentration of the drug in black hair and the least in blond.

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[3] We also note that several individuals weave human hair other than their own hair.

Proposed Rule, p. 19675. Although the proposed rule also states, "The limited population studies published in peer reviewed literature at this time do not indicate a significant association between hair color or race and drug analyte," there is no doubt that the use of hair samples could easily result in numerous claims of bias, even when there is no other evidence of such discrimination. Based upon the statements in the commentary alone, we are also concerned about the integrity of the testing program given the likelihood of potential claims of disparate impact discrimination, where a neutral test results in adversely impacting a minority group. To the extent there is an alternative to that test that is truly color-blind, we believe that the alternative should be the only acceptable method.

Current regulations permit an MRO to use alternative means of testing only to exonerate an employee or to deal with Americans with Disabilities Act concerns for individuals who are medically unable to produce urine on demand and for whom it must be demonstrated that they are drug-free prior to performing a safety sensitive function. The Department's Proposed Rule represents a major departure from that sensible approach.

Given the Department's expressed concerns about the fairness and scientific ambiguity on the current efficacy of hair testing, the Proposed Rule is subject to too much challenge to make it a useful alternative for employers. Proposed Rule, p. 19676 ("Despite these suspected limitations, the Department still proposes to go forward with incorporation of this new technology as an alternative to urine for Federal agencies who may find it useful in certain missions and tasks that only individual Federal agencies can identify.") The Proposed Rule, however, is devoid of any definition of such "missions and tasks," leaving employers in the unfortunate position of having to identify such circumstances in the face of an all-encompassing rule. We seek, at the very least, a definition limiting the "missions and tasks" that would justify resort to these admittedly flawed alternative testing means. We propose that optional testing methods be considered only after the Department reviews an applicant-employer's existing program and its specific justification for expanding testing means beyond those already approved. The DOT successfully used this process when considering whether a specific employer could have a policy whereby an employee may be taken out of service after a positive drug test but pending confirmation of the positive result from an MRO.

Oral Fluid

We believe it premature to offer oral fluid testing as an option for determining rule violations. The Department has written, "As with the other relatively new test specimens for drugs of abuse testing, less is known about the pharmacokinetics and disposition of drugs into oral fluid as compared to urine." Proposed Rule, p. 19676.

> The only way to detect marijuana use is through the presence of the parent drug (THC) in the oral fluid because the parent drug was present in the oral cavity. Unfortunately, further study is needed to be able to

> differentiate between whether the parent drug was present in a room when others smoked marijuana, for example.
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> In order to protect Federal workers from incorrect test results for marijuana, the Department proposes that a second biological specimen, a urine specimen, will need to be collected under the current Guidelines at the same time the oral fluid specimen is obtained, primarily for the purpose of testing for marijuana when the oral fluid specimen is positive for marijuana.

Proposed Rule, p. 19676.

The Department recognizes that "[m]echanical saliva stimulation (i.e., chewing gum) can also lower drug concentrations in oral fluid." Proposed Rule, p. 19676. Based upon this limitation, since federally-mandated drug testing has always included testing for the THC metabolite and has always relied on urinalysis, saliva testing appears to represent simply an additional expense without a concomitant safety benefit.

Sweat

It appears premature from a scientific standpoint to offer sweat testing as an option for determining rule violations. The Department states, "The incorporation of drugs into sweat is poorly understood but possible mechanisms appear to be passive diffusion of drugs from blood into sweat gland and transdermal migration of drugs to the skin surface, where it is dissolved in sweat." Proposed Rule, p. 19676 (emphasis added). The Department has also raised substantial concerns with regard to (1) the stigma associated with wearing a patch and (2) potentially subjecting individuals to harm by directing that they attempt to wear a patch where individuals have sensitive skin or a susceptibility to rashes. Proposed Rule, p. 19676 ("Attempts to remove or tamper with the FDA-cleared sweat patch are usually visible to personnel trained to remove them. Sweat patch contamination issues continue to be a concern); Proposed Rule, p. 19676 ("... one study suggests that sweat patches are susceptible to contamination by a drug that is on the skin before the sweat patch is applied and by absorption into the patch through the surface of the protecting membrane."); Proposed Rule, p. 19677 ("The Department knows from direct experience both at the National Institute on Drug Abuse and the Substance Abuse and Mental Health Services Administration that some individuals may not be able to wear the sweat patch for the optimal period of time. Skin sensitivity and rash are factors that can only be known after the patch is applied for the first time.")

Additionally, and dating back to the rule made effective in 1995, the Department specifically rejected blood testing because (1) it was considered too invasive and (2) urine testing had been established as eminently reliable and less invasive. Sweat patches, while not necessarily as invasive as blood testing, certainly places a burden on the employee that does not appear necessary given the current efficacy of urine testing. Of

course, it is possible that sweat testing will detect more rule violations, but if the technology is too poorly understood at this time, individuals whose drug use has been detected on the basis of that technology may not be drug positives at all, representing the deepest stigma to the employee, cost to the employer, and ultimately, little advantage to the goal of increasing public safety.

Conclusion

As set forth above, we are concerned that the alternative testing methods set forth in the Proposed Rule are premature and do not necessarily work well for employers with large workforces like NYC Transit. Given the concerns expressed here and by the Department itself about the fairness and reliability of the identified alternative testing means, we urge the Department to reconsider issuing a final rule at this time or in the alternative, to adopt an approach which would require an employer that wished to pursue optional testing to demonstrate to the Department the efficacy of the alternative means, the ability to do so fairly, as established in scientific journals and in the scientific community, and the policy justification for its proposal to go beyond urine testing in its workplace drug testing program.

Again, we appreciate this opportunity to submit comments to this proposed rule. Should you have any questions concerning these comments, please contact me.

Very truly yours,

Rhonda J. Moll

Rhonda J. Moll
Senior Employment Counsel
(212) 878-1036

cc Catherine A. Rinaldi, Deputy Executive Director,
General Counsel & Secretary, MTA
Lawrence Reuter, President, NYC Transit
James J. Dermody, President, LIRR