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The Honorable Dennis DeConcini
Chairman, Subcommittee on Treasury, Postal
Service, and General Government
Committee on Appropriations
United States Senate

Dear Mr. Chairman:

On August 2, 1989, we briefed your representative as part of our ongoing review of agency drug-testing programs that we are doing at your request. We reported that until July 18, 1989, the Department of Transportation (DOT) had not implemented a blind performance-testing program for assessing the accuracy and reliability of its drug-testing laboratory.[1] Blind performance testing is required by the quality assurance and quality control provisions of the Health and Human Services (HHS) Mandatory Guidelines for Federal Workplace Drug Testing Programs and, in accordance with Public Law 100-71, any agency drug testing its employees must be in conformance with the HHS guidelines. This report responds to your request that we summarize our briefing in a written report.

Background

As part of the Drug Free Federal Workplace program, President Reagan issued Executive Order 12564 on September 15, 1986, requiring each executive branch agency to establish drug-testing programs for employees in sensitive positions. The Executive Order authorized HHS to issue scientific and technical guidelines for the collection of specimens and laboratory analysis of the specimens. HHS issued proposed guidelines in August 1987, and the final guidelines were published on April 11, 1988.

Because of concerns over federal employee drug testing, Congress included provisions in the 1987 Supplemental Appropriations Act (Public Law 100-71, July 11, 1987) requiring, among other things, that DOT and other agencies that had ongoing drug-testing programs bring their programs into full compliance with the HHS guidelines no later than 90 days after the guidelines took effect. Since the guidelines became effective on April 11, 1988, DOT needed to be in compliance by July 10, 1988, 90 days later.

[1]In a blind performance test, a specimen containing a known quantity of the drugs being tested or known not to contain any drugs (i.e., a blank specimen) is submitted by the agency to the laboratory along with other employee specimens. The laboratory is unaware that this is a test specimen and the agency monitors the performance of the laboratory in analyzing the specimen.

Among other things, the HHS guidelines emphasize quality assurance controls over the laboratories that analyze employee urine specimens for the presence of illegal drugs. After a laboratory is authorized by HHS to do drug testing, the laboratory is subject to periodic testing as described below.

- Federal agencies must submit blind performance test specimens to each laboratory they contract with for employee drug-testing analysis. The agencies are to provide (1) at least 50 percent of the total number of samples submitted (up to a maximum of 500 samples) during the initial 90-day period of program implementation, and (2) a minimum of 10 percent of the samples (to a maximum of 250) submitted per quarter thereafter.
- Every other month, HHS or a recognized certification program must send at least 10 urine specimens that have quantities of drugs in them, or are known to be free of drugs, to the laboratory for analysis. These are open performance tests in that the laboratory knows it is being tested.
- The laboratories are required to have their own internal quality control programs whereby a minimum of 10 percent of all test samples processed shall be quality control specimens.

Results in Brief

According to DOT officials, until July 18, 1989, DOT had not complied with quality assurance and quality control provisions of the HHS guidelines requiring the agency to implement blind performance-testing procedures to monitor the accuracy and reliability of laboratory analyses results. In accordance with Public Law 100-71, DOT's performance-testing program should have been operating since July 10, 1988.

During the period July 1, 1988, through June 30, 1989, DOT collected for analysis approximately 16,000 employee urine samples, of which 99 were confirmed positive for illegal drugs. In order to comply with Public Law 100-71 and the HHS guidelines, DOT should have included 1,250 blind samples along with the real DOT employee specimens as part of the quality assurance program to assess the accuracy of the laboratory results. During this period, DOT did not comply with the blind performance-testing provision. DOT could not, therefore, assure employees subjected to urine testing that its laboratory was meeting all quality control standards provided by law and federal guidelines.

In addition to not meeting federal program requirements, DOT's noncompliance demonstrates the need for continuing oversight and independent monitoring of federal drug-testing programs. We expressed concerns in

1988 congressional testimony[2] about the absence of meaningful governmentwide oversight to ensure compliance with drug-testing program requirements. An HHS official who is primarily responsible for the HHS guidelines said his office is normally not aware of difficulties in a drug-testing program unless they are brought to his attention. This official said he was unaware of DOT's noncompliance until we briefed him, and he believed it to be a serious deviation from the HHS guidelines.

We discussed our findings with DOT officials, who agreed that they had not been in compliance. The officials provided additional details about their noncompliance, which are presented in this report along with our analysis. The officials also said that they have obtained the urine samples needed for blind performance testing and have begun to submit these samples to the laboratory in accordance with HHS guidelines.

Objective, Scope, and Methodology

As part of our broader effort to review selected agencies' ongoing employee drug-testing programs, we examined DOT's implementation of the HHS drug-testing guidelines and Public Law 100-71 provisions that pertain to agency blind performance tests of laboratories that analyze employee urine specimens. Our objective was to examine DOT's compliance with the HHS guidelines and Public Law 100-71 and document the results of its blind performance-testing program.

To meet our objective, we reviewed DOT records and documents and interviewed departmental drug-testing program officials. We also met with senior DOT officials in the Office of General Counsel and the Office of the Assistant Secretary for Administration to discuss the DOT drug-testing program. We interviewed Department of Defense (DOD) officials from the Armed Forces Institute of Pathology, the Army's Alcohol and Drug Abuse Prevention and Control Program Office, and the Army's Office of the Surgeon General. We also interviewed officials from the HHS Office of Workplace Initiatives at the National Institute on Drug Abuse, where we discussed the HHS guidelines with the HHS official responsible for their development.

[2]Federal Employee Drug Testing (GAO/T-GGD-88-40, June 16, 1988), before the Subcommittee on Human Resources and the Subcommittee on Civil Service, House Committee on Post Office and Civil Service.

We reviewed (1) the HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs, which include the provisions for blind performance testing, and (2) Public Law 100-71, the Supplemental Appropriations Act for the year ending September 30, 1987, which required that certain actions be taken before executive branch agencies use appropriations to fund drug-testing program operations.

Audit work on this assignment was done from June 1989 to August 1989 and in accordance with generally accepted government auditing standards.

DOT's Performance Testing Efforts

During the period July 1, 1988, through June 30, 1989, DOT did approximately 16,000 employee drug tests, of which 99 were confirmed positive for illegal drugs. In order to comply with Public Law 100-71 and the HHS guidelines, DOT should have included 1,250 blind performance-test samples along with the genuine DOT employee specimens as part of the quality assurance program to assess the accuracy and reliability of the laboratory results. DOT officials acknowledged that they did not implement this HHS provision. As a result, DOT could not assure employees subjected to urine testing that its laboratory was meeting all quality control standards provided by law and federal guidelines.

We discussed this condition with DOT officials responsible for the department's employee drug-testing program. They provided the following information.

- During the period July 1, 1988, through June 30, 1989, DOT estimates that it did between 74 and 79 blind performance tests.[3]
- DOT officials raised the question of whether during the 6 months ending December 1988 they needed to be in compliance with the guidelines, since HHS had not yet certified DOT's contract drug-testing laboratory. DOT officials said that during the interim, DOT could use a laboratory that was certified by DOD, which DOT's contract laboratory was.
- Delay in implementing the blind performance-testing provision resulted from the need to coordinate the program with the contractor handling DOT's employee specimen collection activities.

[3] In response to our request for documentation supporting these tests, DOT officials were able to provide us with information on 44 tests and indicated that documentation on the remaining tests could be obtained by a special search of DOT's testing files.

- During the period that the HHS requirement was not fully implemented, DOT officials believed they had some assurance of the laboratory's quality because other supplemental quality assurance provisions were taking place.

DOT's explanations and our analysis are discussed in detail below.

DOT Estimates That It Did Between 74 and 79 Blind Performance Tests

DOT officials estimated submitting between 74 and 79 blind samples to their laboratory. In seven cases where DOT drug-testing program staff said they provided their own urine samples, DOT had supporting documentation. In 30 to 35 other instances they said a former DOT drug program staff member provided his own urine specimen under a fictitious name. An additional 37 samples were provided as part of an agreement where DOT submitted blind performance samples to the laboratory for the Department of Energy (DOE) and the Office of Personnel Management (OPM). DOT officials said that the laboratory reported accurate test results in all the above cases.

The use of real urine specimens donated by an agency's drug-testing program staff for blind performance testing is questionable. These specimens do not appear to qualify under the HHS guidelines as blind samples. Provision 2.5(d)(3) of the HHS guidelines, which addresses agency blind performance tests, says that (1) approximately 80 percent of the urine specimens shall contain no drug and (2) the remaining urine shall contain one or more drugs per specimen for which the agency is testing. In the case of a staff member providing his or her own specimen the above criteria are not met, according to the Director of the National Institute on Drug Abuse's Office of Workplace Initiatives. Performance testing should, as indicated in the HHS guidelines, include samples containing a known amount of the drug or drugs for which the test is being conducted in order to fully monitor laboratory accuracy. Since the DOT employee samples contained no known quantity of drugs, there would not be any basis to assess the laboratory's accuracy.

DOT's claim of the 37 OPM and DOE blind samples as part of the DOT performance-testing program is also questionable. DOE and OPM had an agreement with DOT to provide their own blind proficiency-testing samples to the laboratory as part of DOE's and OPM's effort to meet the HHS guideline requirements. They were not part of DOT's program to test its employees.

DOT Suggested That the HHS Blind Performance Test Provisions May Not Have Been Applicable Before December 1988

DOT officials raised the question of whether the agency needed to be in compliance with the HHS blind performance-testing provision as of July 10, 1988. They pointed out that the guidelines called for HHS to certify laboratories as meeting all HHS technical and scientific standards before agencies could use them for employee drug testing. The HHS guidelines further said that during the time that HHS was certifying laboratories, agencies could use laboratories certified by DOD. The DOT laboratory was DOD certified and was later certified by HHS in December 1988. The DOT officials suggested that during the interim period July 1988 through December 1988, when HHS was in the process of certifying the laboratory used by DOT, DOT may not have needed to be in compliance with the HHS guidelines.

Our analysis of the HHS mandatory guidelines showed no reference to any exemption for agencies in adhering to any provision, other than the allowance for agencies to use DOD certified laboratories during the period that HHS was certifying laboratories or to develop interim self-certification procedures approved by HHS. The effective date of the HHS guidelines is April 11, 1988, and Public Law 100-71 required DOT to be in conformance with the guidelines 90 days later, by July 10, 1988.

Considering that the objectives of the HHS Mandatory Guidelines are, among other things, to ensure employees protection and accurate and reliable laboratory analyses, the applicability of all guideline provisions to all agencies from the effective date is reasonable. If an agency were authorized not to implement HHS guideline provisions during the interim period when HHS was certifying laboratories, key provisions could be ignored.

Negotiations With the Specimen Collection Contractor to Participate in Blind Performance Testing Took Over 15 Months

DOT officials explained that a reason for not implementing its blind performance-testing program by the effective date of July 10, 1988, was the need to work out details with the contractor who collected employee urine specimens. This included determining how to (1) prepare the blind samples with the proper written labels so that they would look like regular employee samples and (2) deliver the samples to the scheduled collection sites throughout the United States so that they could be shipped to the laboratory from the same location as the real samples.

A DOT official said the process took approximately 15 months because, among other things, it required negotiations with the headquarters unit of the company doing the collections as well as with its multiple subunits located elsewhere in the country. In addition, arrangements for

blind performance testing were not negotiated on a full-time basis. According to the official, the representative for the collection contractor and the DOT officials involved in the negotiations had other program responsibilities requiring their attention.

We asked the DOT officials if they considered handling the logistics themselves in the interim. A drug-testing program official said they did not have sufficient resources and did not want to ask for more.

We also asked the officials if they (1) brought the situation to HHS' attention and asked for written approval for a deviation from the blind performance-testing provision as required in the HHS guidelines or (2) considered suspending the entire program until the performance testing was in place. In the first instance, the officials said DOT did not consider requesting a waiver from HHS. As far as suspending the program was concerned, the officials did not think that was necessary, because the Army's drug-testing program was using the same laboratory contractor and was doing performance testing. According to DOT officials, this fact gave them some assurance that their laboratory was doing a good job.

DOT's Reliance on Other Agencies' Performance Testing Programs

We discussed with the Director of the National Institute of Drug Abuse's Office of Workplace Initiatives DOT's viewpoint that the blind performance-testing program of other agencies can provide some assurance to agencies using the same contractor. According to the official, this office prepared the HHS guidelines and carries out HHS' responsibilities for providing guidance and advice to agencies that are drug testing their employees.

The official said that DOT's noncompliance is a serious deviation from the HHS guidelines but pointed out that because some agencies, such as the Army, are using the same laboratory with which DOT has a contract, some assurance can be derived through the performance-testing programs that other agencies have implemented. He also pointed out that HHS' own performance-testing procedures and other inspections of the laboratory have indicated that the laboratory has met all HHS standards.

Nevertheless, the official said that an agency's blind performance testing is vital to ensuring laboratory quality. He added that other agency programs and HHS activities do not substitute for the requirements that each agency must do its own blind performance testing.

We agree that reliance on blind performance testing done by other agencies can provide some assurance that the laboratory is doing accurate urine specimen analyses. We also agree that it is not a substitute for an agency's own program, as two other considerations limit the assurance that DOT can derive from the blind performance testing done by other agencies. First, according to an Army official, the Army was testing for only two drugs while DOT was testing for five. Therefore, the Army's blind performance tests did not cover all the types of drug analyses required in the DOT program. Second, according to DOT officials, DOT did not attempt to coordinate its drug testing with that of any other agency. So, agency drug testing could be done on different time schedules, and performance tests provided by another agency may not be submitted during the same periods that the laboratory is processing DOT specimens. Thus, the Army samples would not reflect conditions existing at the time DOT's employee samples are being analyzed.

HHS Oversight

In previous congressional testimony[4] we voiced concerns about the absence of centralized oversight of federal drug-testing efforts to evaluate program effectiveness and ensure agency compliance with applicable statutes, regulations, and guidelines. We believe that DOT's noncompliance with blind performance-testing requirements is an important example of why continuing oversight is needed.

We discussed DOT's noncompliance with the Director of the National Institute on Drug Abuse's Office of Workplace Initiatives. This official said his office was not aware of DOT's noncompliance.

According to the official, neither HHS nor any other agency monitors the day-to-day operations of the agency drug-testing programs. He said that the developers of the HHS guidelines assumed that the employees and their unions would be watching the agencies to assure that the agencies conformed with the guidelines. But in this case, he said, since the agency did not carry out a process, there were no procedural errors for them to find. Even the laboratory would be unaware of the problem, because in blind testing the laboratory does not know it is being tested. He said he was taking steps to modify the HHS guidelines to require agencies to periodically report the results of their blind performance tests to HHS.

[4] Federal Employee Durg Testing (GAO/T-GGD-88-40, June 16, 1988), before the Subcommittee on Human Resources and the Subcommittee on Civil Service, House Committee on Post Office and Civil Service.

In accordance with the Subcommittee's request, we did not obtain written comments on a draft of this report. However, we did discuss the report with DOT officials, who acknowledged their noncompliance with the HHS guidelines and provided further details pertaining to that fact. We have incorporated DOT's views into the report where appropriate.

As agreed with the Subcommittee, we plan no further distribution of this report until 10 days from its issue date unless you publicly announce its contents earlier. At that time, we will send copies to the Secretary of Transportation, the Secretary of Health and Human Services, and congressional committees having an interest in this issue. Additionally, we will make copies available to others upon request.

The major contributors to this report are listed in the appendix. Please contact me at 275-8676 if you have any questions concerning the report.

Sincerely yours,

L. Nye Stevens
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