



U.S. Department of Justice

Office of the Deputy Attorney General

Associate Deputy Attorney General

Washington, D.C. 20530

November 7, 2011

The Honorable Carolyn N. Lerner
Special Counsel
Office of Special Counsel
1730 M Street, N.W., Suite 218
Washington, D.C. 20036-4505

Re: OSC File Nos. DI-11-2109 and DI-11-2110

Dear Ms. Lerner:

This responds to your July 1, 2011 correspondence wherein you refer for investigation allegations raised by employees of the United States Department of Justice, Federal Bureau of Prisons, based on your conclusion that there is a substantial likelihood that the information provided by the employees discloses a violation of law, rule, or regulation. Specifically, your letter reports that Medical Officers Pradip M. Patel, M.D., and Nicoletta A. Turner-Foster, M.D., employees at the Federal Correctional Institution Fort Dix, NJ (FCI Fort Dix), alleged that FCI Fort Dix employees did not timely collect samples for medically ordered laboratory diagnostic tests, including blood, stool, and urine samples, which in turn caused delays in receiving results that were needed for medical diagnoses.

You requested an investigation and report on the allegations. Enclosed herein is the Department's Report of Investigation submitted in accordance with 5 U.S.C. § 1213(d). The Attorney General has delegated to me authority to review and sign the report. That delegation is likewise enclosed. Please feel free to contact me at your convenience regarding this matter.

Sincerely,

A handwritten signature in blue ink, appearing to read "Scott N. Schools".

Scott N. Schools
Associate Deputy Attorney General

Enclosures

**Department of Justice
Report of Investigation**

OSC Case Nos. DI-11-2109 and DI-11-2110

I. The Predicate for the Investigation

This investigation was initiated based upon the disclosure of Medical Officers Pradip M. Patel, M.D., and Nicoletta A. Turner-Foster, M.D., (the whistleblowers), that Bureau of Prisons (BOP) employees at the Federal Correctional Institution, Fort Dix, NJ (FCI Fort Dix), did not timely collect samples for medically ordered laboratory diagnostic tests, including blood, stool, and urine samples, which in turn caused delays in receiving results that were needed for medical diagnoses.

The whistleblowers alleged that physicians and other medical professionals often receive laboratory reports several months or more after they have placed orders for medical tests, resulting in substandard care for patients. They alleged that, although they order medical tests that require the collection of blood, urine, or other samples from inmates, Carolyn Johnson, the only Laboratory Technician¹ at the facility who is responsible for collecting and shipping the samples for testing, is unable to collect the samples in a timely manner because of a backlog of such orders. The delay in the collection of samples also delays the results. According to the whistleblowers, without timely test results, they are unable to provide complete and accurate patient assessments and treatment. Patients with serious medical conditions, such as human immunodeficiency virus (HIV), diabetes, poor liver function, kidney disease, and hepatitis C, may experience complications and/or harm if they are untreated or receive inadequate medication while awaiting laboratory results. In addition, the whistleblowers emphasized that medications must be monitored through laboratory testing to establish their safety and effectiveness. They alleged that delays in the collection of laboratory samples and receipt of diagnostic test results create a substantial and specific danger to patient health and safety.

The whistleblowers assert they have raised these issues to management officials, including Donna Zickefoose, Warden; Abigail Lopez de LaSalle, M.D., Clinical Director (CD); and Michelle Baker, Health Services Administrator (HSA). However, they allege the managers have not addressed the delays in receiving medical testing results, a chronic problem ongoing for more than one year. The whistleblowers stressed that several months is an unacceptably long time to wait for laboratory testing and results for patients requiring medical evaluations.

II. The Investigation

This investigation commenced in July 2011, upon receipt of the Office of Special Counsel (OSC) letter referring the above-described whistleblower allegations to the Attorney General for investigation pursuant to 5 U.S.C. § 1213, and concludes with this report. The investigation

¹ The terms "Laboratory Technician" and "Phlebotomist" are used interchangeably in this report.

included on-site visits by the BOP Office of Internal Affairs (OIA), during the week of August 1, 2011, and the week of September 12, 2011. During the course of its investigation, the OIA conducted twelve interviews of BOP employees (including the whistleblowers); collected and examined various memoranda, email, and other records pertaining to the related events; and researched applicable agency rules and regulations.

III. Summary of Evidence Obtained from the Investigation

FCI Fort Dix was opened in September of 1992, and is located in Burlington County, NJ, on a United States Army Post. The institution occupies 333 acres which were formally utilized as Basic Training brigades.

FCI Fort Dix is made up of 64 buildings with two adjacent, separately fenced, areas known as the east and west compounds.

FCI Fort Dix is a low-security facility that houses approximately 4,850 inmates. In addition, a satellite camp was opened in January 2000 and holds approximately 450 inmates. Each compound has its own perimeter security, inmate visiting room, and outside administrative buildings. A compound consists of six housing units, Health Services, a chapel, a gymnasium, an education building, dining halls, and administrative offices to include Safety and Psychology.

The Health Services department at FCI Fort Dix is comprised of 46 staff members, and includes a CD, HSA, two Assistant HSAs, four medical doctors, ten Mid-Level Practitioners (MLPs), and nine nursing and Emergency Medical Technician (EMT) staff members. FCI Fort Dix contracted with one phlebotomist until recently. The contractor provided an additional phlebotomist on September 7, 2011, September 26, 2011, and October 4, 2011. The physicians are responsible for Chronic Care Clinics (CCC), and their caseloads range from 435 to 530 in number.

The investigation revealed that a large number of laboratory tests had been ordered but had not been conducted at FCI Fort Dix, as reported by the whistleblowers. A print-out drawn from the Bureau Electronic Medical Records (BEMR) and supplied to the OSC by the whistleblowers identified 1,199 lab tests that had not been conducted for the time period of January 2009 to April 15, 2011. A print-out requesting the same information, but run by Dr. Jeffrey Allen, Chief Physician, BOP, Central Office, for the time period of January 2008 to July 28, 2011 revealed a total of 1,141 delinquencies. It was determined that the problem with the delinquent lab tests was systemic and multi-faceted. Several factors contributed to the delinquency of ordered lab work at FCI Fort Dix:

- For more than one year, FCI Fort Dix utilized only one contract phlebotomist. The administration consistently attempted to locate another phlebotomist, but was unsuccessful for a variety of reasons. Most often the applicants could not qualify for the positions because of credit or citizenship issues.
- The one phlebotomist at FCI Fort Dix, Carolyn Johnson, receives notice from the

Health Information Technicians (HITs) of laboratory testing needing to be completed. Because of the tremendous workload and number of ordered tests at FCI Fort Dix, the tests eventually fell behind. In addition, inmates who reported for tests but were not prepared (e.g. reporting for fasting tests after eating a meal) were required to be rescheduled.

- When the HITs scheduled the requested laboratory tests they looked at a range of 30 days in the past and 30 days in the future to schedule the tests. This would allow some tests to "fall below the radar." Staff at FCI Fort Dix indicated the 30-day ranges were designed to handle all "sick leave" patients and to ensure that laboratory results were drawn from Chronic Care inmates.
- Several inmates on the list generated from BEMR were transferred to FCI Fort Dix from other institutions. If these inmates had tests ordered that did not fall within the 30-day time frames utilized by the HITs, they would not be tested. There were no safeguards in place to automatically review new inmates transferring to FCI Fort Dix from other facilities to ensure that all previously ordered tests were completed.
- The doctors did not always review lab documentation when examining patients to determine if there were outdated tests that had not been completed.
- There were a number of duplicate tests ordered for the same patients. For example, if the initial test was determined to be outdated a new test was ordered. In some cases, the initial test, no longer in the prescribed time frames, would not be cancelled and would still show as pending.

Dr. Pradip Patel said there has been a problem getting blood tests completed since "at least" the spring of 2010. Patel said the BOP implemented the use of BEMR in April of 2007. He said changing from a paper documentation system to an electronic system could account for a delay in the reporting of laboratory work dating back to 2008, but said there was still a "tremendous" backlog of tests waiting to be completed. Patel opined this delay adversely affected his ability to appropriately treat his patients.²

Patel said that he addressed this issue in writing via emails in September 2010, and orally in meetings prior to 2010. Patel said the response from the administration was always that "they were working on it" by trying to get another laboratory technician. Patel said he suggested to the administration (CD Abigail LaSalle and HSA Michelle Baker) that they utilize nurses, Physicians Assistants (PAs), and EMTs to assist in collecting these samples. Patel said he was aware that those staff members had been used in the past for specific "mass draws" (usually related to DNA

² As an example, Dr. Patel cited the following:

The patient was seen on 4/29/11 by me. I noted in my disposition for patient to be scheduled for labs due 4/4/11. They were not done till 8/1/11. This inmate's Creatinine jumped from 1.34 to 1.62. This is a decline in his measure of kidney function. If his Creatinine had gone up to 1.7 then he is at high risk for lactic acidosis from taking Metformin which is one of the medications he is on. Now I have to let him know about this and also consider discontinuation of Metformin and consider Insulin for his Diabetes. This is a time consuming process that has to be done out of pocket from the normal scheduling of patients. And when labs are not done timely it leads to delay in treatment and patient safety concerns. This is an example why patient safety is key [sic] concern to me and for the BOP.

samples). Patel said that although the collection of blood for medical diagnoses and treatment is more complex than the draw required for DNA, there could still be a significant impact on the number of pending lab collections by utilizing other staff.

During an interview on August 2, 2011, Patel said there was currently one Laboratory Technician at FCI Fort Dix and said this has been the case since another technician left "less than a year ago." However, Patel said that FCI Fort Dix experienced a significant backlog of laboratory tests even when two lab technicians were in place. Patel said he orders laboratory work for stable patients to be conducted one month prior to their next regularly scheduled visit. Patel said if the laboratory work is not done in a timely fashion he cannot effectively monitor a patient's progress. Patel said if he sees a patient and there is no evidence that the requested laboratory work has been done, he will ask the patient if he recently had blood work done. If a patient says that he has had recent blood work, Patel will call the United States Medical Center for Federal Prisoners in Springfield, MO, (where the laboratory work samples are tested) to try and obtain the results. Patel said if the patient indicates he has not had recent laboratory work done, he may cancel the previous laboratory work, depending on the circumstances, and place a new order. Patel said this is not a desirable course of action since the records would show that he canceled blood work. Patel said that FCI Fort Dix needs to get all laboratory work up to date and then maintain timely draws and collections.

Patel said he has, on occasion, taken patients to the phlebotomist to have laboratory work done when he noticed that ordered work had not been completed. Patel said these tests are completed because of the phlebotomist's willingness and said he cannot mandate the testing. Patel also added that because of time constraints, he can only take patients to the lab technician occasionally.

Patel said it is his perception that the Warden, HSA, and the CD "do not care" if the laboratory work is done in a timely manner. Patel said he feels this way because in the spring of 2011, these officials changed the assignments of all the doctors and gave them new caseloads. Patel said these changes resulted in not only having to learn and research health records for new patients, but also required them to treat new patients without adequate laboratory work.

Patel said he did not provide the Warden, HSA, or CD with the document he had retrieved from BEMR that reflected the extent of delinquent laboratory requests, but advised them orally on several occasions that the labs were not completed timely. Patel also added that the HSA and CD have access to BEMR and could have gotten the records after his numerous complaints. Patel said he also sent emails on either September 22 or September 23, 2010, detailing the delinquent labs and the need to complete these labs.³

³ On September 23, 2010, Patel sent an email to CD LaSalle, HSA Baker and Assistant Health Services Administrator (AHSA) Linda Angrisani noting, "A lot of the current CCC's that I'm seeing presently have no current labs because they are not being done on time. This makes our clinic unproductive and hence we will end up seeing the patients again for abnormal labs which should and can be avoided. We need to do something to catch up with labs. So that they are available when we see patients." On the same date HSA Baker responded, "I am aware and understanding of your frustration and unfortunately we only have 1 lab Tech and she can only do so much. I have been working in an attempt to secure another Lab Tech. Although we have had several candidates that are interested, they either cannot pass the background or are not US citizens. If you identify someone who is in need of labs with an

Dr. Nicoletta Turner-Foster said she was aware there was a problem getting laboratory results collected and submitted at FCI Fort Dix. Turner-Foster said it was her belief this problem has existed for the past six years and stemmed primarily from having only one laboratory technician. Turner-Foster said the institution previously had two laboratory technicians and said that, although the problem was not as severe, the facility still had a backlog.

Turner-Foster said most of the laboratory requests at FCI Fort Dix are driven by patients with conditions such as hypertension, diabetes, elevated cholesterol, etc. She said, "We are mandated to see these patients on a regular basis and need lab work to appropriately treat these patients." Turner-Foster opined that 50% of the patients she sees have not had ordered laboratory work completed, and approximately 15% of those scheduled for a second visit still have not had these tests completed.

Turner-Foster said she has voiced her concerns about the untimeliness of lab work to no avail. She said one idea that was put forth was to have doctors take laboratory specimens and thinks one solution would be to hire more laboratory technicians. Turner-Foster said another approach would be to utilize MLPs, EMTs, and nurses to collect samples to assist in alleviating the problem. Turner-Foster said she spoke with HSA Baker and CD LaSalle and was told that they were trying to hire someone for the laboratory technician position, but that two previous applicants were not able to be hired because of "credit issues."

Turner-Foster said that when she and Dr. Patel reported this matter to OSC, they provided OSC with a "stack" of BEMR rosters indicating over 1,000 delinquent lab tests. Turner-Foster said they did not provide this data to the Warden, Associate Warden, Health Services Administrator, or Clinical Director, but did advise these staff members on several occasions that lab work was not being done. Turner-Foster said she may have also contacted these staff members by email.

Turner-Foster said she could recall only one patient that was impacted by delinquent lab work. This patient was a Stage 4 Kidney Disease patient who could have been treated sooner if the requested blood work would have been completed. Turner-Foster said this patient had to be sent to an outside hospital for several days to be stabilized. She said the patient is now Stage 3 and is being treated at FCI Fort Dix.⁴

urgency, let Dr. Lopez or I know so that we can work with Ms. Jackson to get it done." Later that day Patel responded, "Most patients who are on CCC have previously scheduled labs usually one month prior to their next visit and there are a lot. They are not considered urgent so I can't point them out nor have time to screen all the future CCC's. They need to be done prior to their CCC. Then the CCC can be done completely. It is not a matter of what is urgent. It is a matter of what should take place in a timely manner so the CCC can be complete."

⁴ A patient was referred to an outside hospital on July 21, 2011 because of a July 5, 2011 potassium level of 7.1 mmole/L. It was noted: "He has stage 4 CKD (Chronic Kidney Disease) and...requires normalization of his potassium and stabilization of his CKD." The laboratory tests on this patient were scheduled for October 21, 2010, but were not completed until July 5, 2011. A review of this case was also conducted by Dr. Jeffery D. Allen, Chief of Health Programs in Central Office. Dr. Allen noted the inmate was seen on 10/14/10 and lab work was ordered for 10/21/10, but the work was not completed until 7/5/11. When Dr. Turner-Foster saw that patient on 4/12/11 for a routine CCC visit, she noted the labs ordered for 10/21/10 were pending collection, and ordered new labs with a due

Carolyn Johnson is a contract phlebotomist assigned to FCI Fort Dix by her employer, Interactive Medical Specialists. Johnson said she usually collects 25 to 32 laboratory specimens per day.

Johnson said she was aware there was a backlog of laboratory draws but said she was not aware there were possibly over one thousand tests not completed. Johnson said that her "call-outs" are scheduled by HITs. She said that when tests are scheduled, she "pulls up BEMR" to determine the kind of test(s) needed. Johnson said she looks at any tests scheduled for up to three months in the future, and looks back to see tests scheduled since the date of her arrival at FCI Fort Dix in February 2010. Johnson said she never looked at tests scheduled before that date because "that wasn't the way I was trained." (Johnson said she was trained by a former contract phlebotomist at FCI Fort Dix and not by any BOP staff member.)

Johnson said her patients are always scheduled for 8:00 a.m. and she collects specimens until lunch. She said that "more often than not, I am not able to complete all the patients by that time." The patients who are not completed by lunchtime are not returned in the afternoon, but have to be rescheduled for another day.

HITs Robert W. Curran, Kayle Palmisano, and Charron Smith said that approximately one year ago, the Health Services administration made the decision the HITs would do the lab scheduling and would use a range from 30 days in the past to 30 days in the future to determine the pending laboratory tests. Curran, Palmisano, and Smith agreed this system worked well for new entries, but did nothing to address the backlog. They said the doctors consistently contact the HITs in the case of any laboratory requests that need to be done immediately. Curran said this is not necessarily the case for routine laboratory work, but for more urgent situations and/or after a clinician review indicates a need for a quick return on laboratory tests.

Palmisano said that when she began her employment at FCI Fort Dix on April 5, 2010, the laboratory technician, Carolyn Johnson, chose the laboratory tests she wanted completed since she knew how long each test was going to take, whether it was fasting or non-fasting, and whether they were viral load⁵ collections. Palmisano said Johnson would pull the laboratory requests from BEMR and would email her a list of inmates from whom she was going to draw laboratory specimens. She said that her only responsibility was to enter the laboratory tests into SENTRY.⁶ Palmisano said this type of scheduling of laboratory tests was ineffective and the HITs were

date of 9/12/11. Although Turner-Foster acknowledged a long past due date, she put a 5-month due date on her lab order, suggesting no urgency.

⁵ Viral load is a measure of the severity of a viral infection and can be calculated by estimating the amount of virus in an involved body fluid. For example, viral load can be measured in RNA copies per milliliter of blood plasma. Viral load tracking is used to monitor therapy during chronic viral infections and in immuno-compromised patients such as those recovering from bone marrow or solid organ transplantation. Currently, routine testing is available for HIV-1, cytomegalovirus, hepatitis B virus, and hepatitis C virus.

