Title: EDWARD HINES, JR., VETERANS ADMINISTRATION MEDICAL CENTER
ALLEGED MATERIAL FALSE STATEMENTS

Licensee:

Edward Hines, Jr. Veterans
Administration Medical Center
Hines, IL 60141

Docket No. 030-01391

Reported by:

Mary Kay Fahey, Investigator
Office of Investigations
Field Office, Region III

Case Number: 3-87-003S

Report Date: March 29, 1988

Control Office: OI:RIII

Status: CLOSED

Reviewed by:

Eugene V. Pawlik, Director
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SYNOPSIS

On August 24, 1987, an NRC Order (EA 87-150) was issued affecting Edward Hines, Jr., Veterans Administration Medical Center (HMC). The order removed the authority of the Section Chief, Clinical Nuclear Medicine (SCCNM) to use or supervise the use of NRC licensed material at HMC as a result of information developed by the Office of Investigations (OI) during an investigation into allegations of unreported misadministrations.

On October 21, 1987, the NRC staff held a meeting at the request of the SCCNM. The attorney representing the SCCNM stated that the purpose of the meeting was to determine if matters between the NRC and the SCCNM could be resolved without an administrative hearing.

It has been determined by review of the meeting's transcript that during this meeting, the SCCNM made statements to the NRC staff that contradicted his previous sworn testimony to OI on June 30, 1987. During the meeting, the SCCNM also attempted to present new evidence to the NRC staff, when in fact, the SCCNM was misrepresenting previously documented evidence. The SCCNM and his attorney further attempted to convince the NRC staff that the SCCNM was not responsible for the unreported misadministrations by misrepresenting HMC policy and procedures, and by misrepresenting previous evidence. The SCCNM also failed to correct inaccurate statements made by his attorney on his behalf during this meeting.

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ACCOUNTABILITY

The following portions of this Supplemental Report of Investigation (Case No. 3-87-003S) will not be included in the material placed in the PDR. They consist of pages 2 through 17.

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APPLICABLE REGULATIONS

Atomic Energy Act, Chapter 18, Section 223, Violation of Sections Generally

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DETAILS OF SUPPLEMENTAL INVESTIGATION

Purpose of Supplemental Investigation

This supplemental investigation was conducted to determine if the Section Chief, Clinical Nuclear Medicine (SCCNM), Edward Hines, Jr., Veterans Administration Medical Center (HMC) made statements to NRC staff that contradicted his previous sworn testimony to the Office of Investigations (OI).

Background

On October 21, 1987, NRC staff held a meeting in Bethesda, Maryland, at the request of Maynard L. FREEMAN, M.D., SCCNM at HMC, through his attorney, Samuel TENENBAUM. Present at this meeting were FREEMAN, TENENBAUM, and the following NRC staff: James TAYLOR, Deputy Executive Director for Operations; James LIEBERMAN, Director, Office of Enforcement; Richard CUNNINGHAM, Director, Division of Industrial and Medical Nuclear Safety; Jack R. GOLDBERG, Deputy Assistant General Counsel for Enforcement; Lawrence CHANDLER, Assistant General Counsel for Enforcement; Susan CHIDAKEL, Office of General Counsel, Enforcement Staff Counsel; and Geoffrey CANT, Office of Enforcement. Region III (RIII) staff participating in the meeting were: Bruce BERSON, Regional Counsel; John GROBE, Director, Enforcement and Investigation Coordination Staff; and Bruce MALLETT, Chief, Nuclear Materials Safety and Safeguards Branch.

This meeting addressed an NRC Order (EA 87-150) issued August 24, 1987, for HMC and affecting FREEMAN. The order removed FREEMAN's authority to use or supervise the use of NRC licensed material at HMC as a result of information developed by OI during an investigation into allegations of unreported misadministrations. TENENBAUM indicated that the purpose of the meeting was to determine if matters between the NRC and FREEMAN could be resolved without an administrative hearing (Exhibit 1, p. 3).

It has been determined by review of the meeting's transcript that during this meeting, FREEMAN made statements to the NRC staff that contradicted his previous sworn testimony to OI on June 30, 1987. During the meeting, FREEMAN also attempted to present new evidence to the NRC staff, when in fact, he was misrepresenting previously documented evidence. FREEMAN and TENENBAUM further attempted to convince the NRC staff that FREEMAN was not responsible for the unreported misadministrations by misrepresenting HMC policy and procedures. FREEMAN also failed to correct inaccurate statements made by his attorney on his behalf during the meeting.

Chronology

During the meeting, while FREEMAN was reiterating the circumstances of the [redacted] misadministration, FREEMAN stated that he had reviewed the delay films and had discussed whether the [redacted] scan was a bone scan or a brain scan. FREEMAN stated that this discussion included Rachelle ARGUIJO, Arnold PHILLIPS, M.D., and several other unnamed HMC staff (Exhibit 1, pp. 27-28). However, on June 30, 1987, FREEMAN told OI that while PHILLIPS reviewed the films with him, FREEMAN did not tell PHILLIPS that ARGUIJO had indicated the possibility of [redacted] receiving two doses (OI Case No. 3-87-003

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Exhibit 9, p. 36). ARGUIJO stated in her April 28, 1987, interview with OI that she was not present when the [redacted] scan was read (OI Case No. 3-87-003 Exhibit 8, p. 19).

FREEMAN told the NRC staff that ARGUIJO explained to him that both [redacted] had been scheduled for gallium scans and that [redacted] had arrived in the Nuclear Medicine Service (NMS) when [redacted] was scheduled. FREEMAN stated that ARGUIJO showed him the records, "the daily planning sheet," that indicated [redacted] was scheduled on Tuesday and [redacted] was scheduled either Wednesday or Thursday (Exhibit 1, pp. 37-38). FREEMAN previously told OI that ARGUIJO advised him of the [redacted] misadministration, but the specific information regarding the circumstances and schedule had been shown to him by technologists June LEUNG and Mark NIEMIRO (OI Case No. 3-87-003 Exhibit 9, pp. 40-45).

ARGUIJO stated during her OI interview on April 28, 1987, and during a subsequent interview on July 8, 1987, that on August 4, 1986, when [redacted] was misadministered, there was nothing on the schedule to indicate that [redacted] should have received a gallium injection. She stated that there was no Consult (an HMC physician's order form for a diagnostic study) in the NMS, nor was there an order in [redacted] from the referring physician ordering a gallium scan (OI Case No. 3-87-003 Exhibit 1, Attachment BB; Exhibit 8, pp. 34; Exhibit 11).

INVESTIGATOR'S NOTE: The only time both [redacted] appeared on the daily schedule as being scheduled for gallium scans was when the data base information was corrected and entered into the computer after the misadministrations had been discovered (OI Case No. 3-87-003 Exhibit 11).

FREEMAN also told the NRC staff that upon searching [redacted] patient chart, he discovered a doctor's order for a gallium scan. "With the doctor's order for Gallium, I determined that since the doctor, referring doctor had, indeed, ordered the Gallium, that the Gallium was, indeed, ordered. There was a doctor's order" (Exhibit 1, p. 38). FREEMAN failed to indicate to the NRC staff that the order was a notation that was approximately one month old, dated July 8, 1986 (OI Case No. 3-87-003 Exhibit 1, Attachment BB, p. 1). In her OI interview, Rani CHINTAM, M.D., [redacted] referring physician, stated that she had made the notation for a gallium scan in the patient's chart on July 8, 1986, but had subsequently changed her mind, and a bone scan Consult was prepared, ordered, and was performed on July 9, 1986 (OI Case No. 3-87-003 Exhibit 19, p. 3).

FREEMAN and TENENBAUM presented to the NRC staff a copy of what they asserted was the original Consult ordering a gallium scan for [redacted] FREEMAN stated that this Consult appeared, "...and about a day later, either the next day or a day later, the original consult sheet was found on an x-ray form and was shown to me by the technologist, and I said, 'Fine. Get it in the chart along with the consult sheet that I obtained'" (Exhibit 1, pp. 41-42 and 57-60, and Attachment 2). Neither FREEMAN nor any of the technologists corroborated these statements during their OI testimony. The copy provided to

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the NRC staff by FREEMAN and TENENBAUM was, in fact, a copy of the corrected Consult that ARGUIJO had prepared when the misadministration was discovered (OI Case No. 3-87-003 Exhibit 8, pp. 32-33).

INVESTIGATOR'S NOTE: FREEMAN and TENENBAUM appeared to be presenting new evidence that they contend was available during the RIII inspection and the OI investigation, when in fact, they were misrepresenting previously documented evidence.

During the meeting, FREEMAN told the NRC staff that the NMS protocol did not require a written order by the NMS resident or NMS attending physician when a change in the type of study (scan) had been made (Exhibit 1, pp. 18 and 31-32). However, the Nuclear Medicine Procedure Manual (NMPM), which FREEMAN presented to the NRC staff as being in effect at the time of the misadministrations, contradicts FREEMAN's contentions. The procedure clearly states that, "before any radiopharmaceutical is injected, confirmation as to the procedure requested must be completed by cross checking the schedule and the requesting consultation sheet. Under no circumstances can any patient be injected without a signed consult" (Exhibit 1, Attachment 3).

INVESTIGATOR'S NOTE: When [redacted] was injected with technetium-99m (Tc-99m) diethylenetriaminepentaacetic (DTPA), a brain scanning agent, neither the Consult nor the schedule reflected that a change had been made from a bone scan to a brain scan.

FREEMAN further attempted to convince the NRC staff that he was not responsible for the unreported misadministrations by misrepresenting HMC policy and procedure. When questioned by the NRC staff, FREEMAN stated that his responsibilities were limited to determining whether there were any adverse reactions to the patient, completing the patient's chart, and notifying the referring physician (Exhibit 1, p. 72). However, FREEMAN, as SCCNM (Chief, Clinical Section), failed to fully indicate his responsibilities in the event of a misadministration, as delineated in the NMPM, wherein it indicates he must: (a) notify the Chief, NMS; (b) prepare and sign VA Form 10-2633; (c) prepare a memo to the patient's attending physician; and (d) submit a signed copy of VA Form 10-2633 to the Radiation Safety Officer (RSO) (Exhibit 1, Attachment 3).

FREEMAN explained that the RSO would be responsible for investigating a possible misadministration (Exhibit 1, pp. 72-73). However, Ervin KAPLAN, M.D., Chief NMS, provided testimony to OI stating that FREEMAN would be responsible for investigating misadministrations (OI Case No. 3-87-003 Exhibit 13, p. 7). FREEMAN also admitted that the Chief Technologist would report to the Chief of the Clinical Section (Exhibit 1, p. 83). FREEMAN failed, however, to make the NRC staff aware of his position at HMC as the Chief, Clinical Section (or SCCNM), preferring instead to be referred to only as the Assistant Chief, Nuclear Medicine Service (OI Case No. 3-87-003 Exhibit 9, p.4).

TENENBAUM, while speaking on behalf of FREEMAN, made several inaccurate statements and misrepresented evidence to the NRC staff. TENENBAUM began the meeting by stating that he felt the NRC overreacted by removing FREEMAN from NRC licensed activities when there was no harm to the patients. TENENBAUM

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also questioned the public safety basis for the Order removing FREEMAN (Exhibit 1, pp. 6-8). However, at the conclusion of the meeting, FREEMAN contradicted TENENBAUM's contention that no public safety issue was involved. FREEMAN stated that if an incorrect study (scan) was performed, it could have jeopardized the patients' lives. "These patients' lives were placed in jeopardy if there was, in fact, indeed, a misadministration and, indeed, the studies were done wrong, then these people could have died because a lot of the therapy is based on our particular reporting" (Exhibit 1, pp. 103-104).

In an apparent attempt to diffuse the responsibility of the unreported misadministrations, TENENBAUM pointed out to the NRC staff that both Lawrence F. CASE, Jr., RSO, and KAPLAN had independent responsibilities to investigate the misadministrations, and to single out FREEMAN was inappropriate (Exhibit 1, pp. 33-35). However, there was no testimony received by OI that indicated that CASE had been provided with any information regarding the misadministrations. CASE admitted that LEUNG had approached him at one time about " a problem," but that she had refused to provide any further specific information (OI Case No. 3-87-003 Exhibit 23, pp. 43-45). KAPLAN stated to OI that when ARGUIJO reported the misadministrations to him, "I told her I would discuss this with Dr. FREEMAN, who was the Clinical Chief, and ask him to investigate this further, which is his job" (OI Case No. 3-87-003 Exhibit 13, p. 7).

TENENBAUM stated that while FREEMAN did not have a discussion with the referring physician, the daily schedule indicates that the referring physician was notified by someone within the NMS that the [redacted] scan had been changed. TENENBAUM indicated that some of the notations on the schedule were scratched out and illegible (Exhibit 1, pp. 55-56).

INVESTIGATOR'S NOTE: The daily schedule that TENENBAUM submitted to the NRC staff does not corroborate FREEMAN's contention that the scan was changed to a brain scan. In fact, the daily schedule corroborates ARGUIJO's OI testimony that the schedule clearly reflects that [redacted] had originally been scheduled for a gallium scan. The notation on the schedule indicates that the gallium injection ("GM-INJ") was crossed out and changed to "bon-fid," a three phase bone scan (OI Case No. 3-87-003 Exhibit 8, pp. 22-23; Exhibit 11). There were no changes on the schedule to indicate that the scan was changed to a brain scan, nor that the referring physician was notified of a change to a brain scan.

Twice during the meeting, while the NRC staff was attempting to determine FREEMAN's responsibilities for reporting misadministrations, TENENBAUM stated that FREEMAN was not involved in the reporting chain. TENENBAUM stated that "...normally, Dr. FREEMAN is not in that loop of events. The normal loop would be, be it Dr. PHILLIPS, Dr. ROMANE (sic), Dr. XYZ, whoever the attending is, is in the loop of those events and Dr. FREEMAN really isn't involved in that" (Exhibit 1, p. 103). Earlier during the meeting, TENENBAUM stated that, "Dr. FREEMAN was not involved in that break down. Okay. In other words, he was not the attending physician..." (Exhibit 1, p. 66). During this particular discussion, FREEMAN made no attempt to correct TENENBAUM, nor did FREEMAN indicate that he was the attending physician. FREEMAN also indicated during the meeting that the attending physician is the one in charge, but failed to indicate that he, in fact, had been the attending physician (Exhibit 1, pp. 81-82).

INVESTIGATOR'S NOTE: FREEMAN defined an "attending" or "attending physician" as "...a physician who has completed his residency or fellowship in nuclear medicine, who has his boards in nuclear medicine, and then comes to our department to both supervise the residents and to teach" (OI Case No. 3-87-003 Exhibit 9, p. 6). FREEMAN did admit prior to this discussion that he was the attending physician the day [redacted] was misadministered, but he did not clarify that point to the NRC staff during the subsequent discussion (Exhibit 1, p. 31). Cheryl KRESSY, clerk-typist in NMS, told OI that FREEMAN was the attending physician the week of August 4-8, 1986 (OI Case No. 3-87-003 Exhibit 14, p. 19).

TENENBAUM stated that in the HMC Board of Investigation (BI) report, "...Mr. NUMERO (sic) advised that he gave the brain scan to cover up the bone scan, in that order. The bone was given first and then the brain" (Exhibit 1, p. 20). TENENBAUM then offered a possible explanation for NIEMIRO injecting a bone dose and then a brain dose (Exhibit 1, p. 21-22).

INVESTIGATOR'S NOTE: TENENBAUM misrepresented the facts to the NRC staff. The HMC:BI report does not indicate that NIEMIRO advised he gave two injections (OI Case No. 3-87-003 Exhibit 1, p. 5). The HMC:BI report indicates that NIEMIRO told them that he gave [redacted] a brain scan only (OI Case No. 3-87-003 Exhibit 1, p. 29). The only time NIEMIRO admitted that [redacted] had received two doses was during his OI interview (OI Case No. 3-87-003 Exhibit 7, pp. 6-7). The HMC:BI report does state that "Ms. ARGUIJO indicated in her testimony that Mark NIEMIRO, in an effort to cover up a misadministration of a bone scan agent, immediately injected [redacted] with a brain scan agent" (OI Case No. 3-87-003 Exhibit 1, p. 5). However, a review of ARGUIJO's Voluntary Witness Statement to the HMC:BI on November 7, 1986, states, "Ms. ARGUIJO indicated to the Board of Investigation that based on the remarks by Mark NIEMIRO that [redacted] was mistakenly given a brain scan agent on August 4, 1986, when a bone scan agent had been ordered" (OI Case No. 3-87-003 Exhibit 1, p. 24). The HMC:BI appears to have made some inaccurate conclusions from their investigation.

INVESTIGATOR'S NOTE: OI did not use the HMC:BI report to substantiate their findings.

TENENBAUM stated that there was corroborating evidence that FREEMAN had ordered a brain scan for [redacted] "Among those are Dr. PHILLIPS [who] signed a protocol related to the patient, and it's in the materials, that indicates that a brain scan was a test to be performed" (Exhibit 1, pp. 19-20).

INVESTIGATOR'S NOTE: FREEMAN made no attempt to correct TENENBAUM at that point during the meeting. The referenced letter from PHILLIPS dated September 2, 1987, indicates that the studies (scans) administered to [redacted] were correct and openly discussed (Exhibit 1, Attachment 1). PHILLIPS does not indicate in his letter when the nuclear medicine studies administered to this patient were openly discussed. It is not corroborating evidence, as TENENBAUM asserts, to have PHILLIPS, a resident in training, state that a brain scan was appropriate for [redacted] when FREEMAN explained it to PHILLIPS after the brain scan injection had been given.

After additional questioning by NRC staff, FREEMAN stated that he did not speak to PHILLIPS after determining that a brain scan was more appropriate and that PHILLIPS was not available when FREEMAN gave the order for the brain scan (Exhibit 1, p. 27). FREEMAN also told OI that he did not discuss the brain scan decision with PHILLIPS until after the injection for the brain scan had been given (OI Case No. 3-87-003 Exhibit 9, p. 32).

TENENBAUM also contended that the fact that NIEMIRO advised Mitchell THOMAS, a nuclear medicine technologist, to draw up a brain dose and not a bone dose further corroborates that FREEMAN gave orders for a brain scan (Exhibit 1, p. 20). However, NIEMIRO told OI that he followed the order indicated on the Consult, that being a bone scan, and he did not receive any verbal order from FREEMAN to give a brain scan (OI Case No. 3-87-003 Exhibit 7, p. 5). NIEMIRO admitted that the reason had received a brain dose was because NIEMIRO had made a mistake when the dose was requested from THOMAS (OI Case No. 3-87-003 Exhibit 7, pp. 6-7).

Willfulness/Intent

It has been established that FREEMAN made statements to the NRC staff that contradicted his previous sworn testimony to OI on June 30, 1987. FREEMAN told the NRC staff that he reviewed the delay films and discussed whether the scan was a bone scan or a brain scan. FREEMAN stated that this discussion included PHILLIPS (Exhibit 1, pp. 27-28). However, FREEMAN told OI on June 30, 1987, that while PHILLIPS reviewed the films with him, FREEMAN did not tell PHILLIPS that ARGUIJO had indicated the possibility of receiving two doses (OI Case No. 3-87-003 Exhibit 9, p. 36).

FREEMAN again contradicted his previous sworn testimony to OI when he told the NRC staff that ARGUIJO was the technologist who showed him the schedule that indicated both appeared on the schedule (Exhibit 1, pp. 37-38). However, FREEMAN stated during his OI interview that ARGUIJO advised him of the misadministration, but the specific information regarding the schedule had been shown to him by technologists LEUNG and NIEMIRO (OI Case No. 3-87-003 Exhibit 9, pp. 40-45).

It has also been established that FREEMAN attempted to misrepresent a purported new piece of evidence. This new piece of evidence supported FREEMAN's previous testimony that had been scheduled for a gallium scan and that the original Consult had been lost. FREEMAN stated to the NRC staff that a few days after the misadministration, the original Consult appeared. He further stated that the original request had mistakenly been completed on an x-ray Consult, rather than a Nuclear Medicine Consult and had, therefore, been misfiled (Exhibit 1, pp. 41-42 and 57-60, and Attachment 2).

FREEMAN showed NRC staff members a copy of this purported original Consult; however, the copy shown to the NRC staff was actually a copy of the corrected Consult that ARGUIJO had prepared after the misadministration had been discovered (Exhibit 1, Attachment 2; OI Case No. 3-87-003 Exhibit 8, pp. 32-33). During their OI interviews, neither FREEMAN nor any of the technologists corroborated the statements FREEMAN made to the NRC staff regarding the original Consult being misfiled and then being discovered.

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It has also been established that FREEMAN misrepresented HMC policy and procedure to the NRC staff in an attempt to convince the staff that he was not responsible for the [redacted] misadministration. During the meeting, FREEMAN told the NRC staff that (with respect to the [redacted] misadministration) NMS protocol did not require a written order by the NMS resident or NMS attending physician when a change in the type of study (scan) had been made (Exhibit 1, pp. 18 and 31-32). However, the NMPM presented to the NRC staff as being in effect at the time of the misadministrations, contradicts FREEMAN's statements. The procedure clearly states that, "before any radiopharmaceutical is injected, confirmation as to the procedure requested must be completed by cross checking the schedule and the requesting consultation sheet. Under no circumstances can any patient be injected without a signed consult" (Exhibit 1, Attachment 3).

FREEMAN further attempted to convince the NRC staff that he was not responsible for reporting the misadministrations. When questioned by the NRC staff, FREEMAN stated that his administrative responsibilities for misadministrations were limited. FREEMAN, as Chief, Clinical Section, failed to indicate his responsibilities in the event of a misadministration as delineated in the NMPM wherein he must: (a) notify the Chief, NMS; (b) prepare and sign VA Form 10-2633; (c) prepare a memo to the patient's attending physician; and (d) submit a signed copy of VA Form 10-2633 to the RSO (Exhibit 1, Attachment 3).

When pressed by NRC staff members, FREEMAN admitted that the Chief Technologist would report misadministrations to the Chief, Clinical Section (Exhibit 1, p. 83); he failed, however, to identify himself to the NRC staff as the Chief, Clinical Section (OI Case No. 3-87-003 Exhibit 9, p. 4).

FREEMAN also explained that the RSO would be responsible for investigating misadministrations (Exhibit 1, pp. 72-73). However, KAPLAN (FREEMAN's supervisor) provided testimony to OI stating that FREEMAN would be responsible for investigating misadministrations (OI Case No. 3-87-003 Exhibit 13, p. 7).

FREEMAN also made no attempt to correct TENENBAUM, who, while speaking on behalf of FREEMAN, made certain inaccurate statements to the NRC.

Agent's Conclusion

As a result of a review of transcripts and OI investigative evidence, it has been established that during the October 21, 1987, meeting with NRC staff, that FREEMAN made material false statements to the NRC staff that contradicted his previous OI sworn testimony on June 30, 1987. The evidence also revealed that during the October 21, 1987, meeting, FREEMAN made a conscious attempt to introduce a purported new piece of evidence which supported his previous testimony. FREEMAN made material false statements when he presented this new evidence, which in fact, was a misrepresentation of previously documented evidence. FREEMAN made additional material false statements when he further attempted to convince NRC staff members that he was not responsible for the misadministrations. He did this by misrepresenting HMC policy and procedures and by misrepresenting previous evidence to the NRC staff. FREEMAN made additional material false statements when he made no attempt to correct TENENBAUM, who, while speaking on behalf of FREEMAN, made inaccurate statements to the NRC staff.

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LIST OF EXHIBITS

1. Copy of transcript of October 21, 1987, meeting between Maynard L. FREEMAN, M.D., and NRC staff.