



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

MAR 2 1992

Carol S. Marcus, M.D., Ph.D.
Nuclear Medicine Outpatient Clinic
Bldg. A-13 Harbor - UCLA
1000 West Carson Street
Torrance, CA 90509

Dear Dr. Marcus:

During the course of the recent Advisory Committee of the Medical Use of Isotopes (ACMUI) meeting held on November 7-8, 1991, you made several comments regarding the incident at Tripler Army Medical Center and stated that the patient had concealed her pregnancy. Specifically, the following are quotes from your statements that are part of the public record (p. 258 of the proceedings transcript):

1. "She hid her pregnancy from three physicians; her physician on the island, and the endocrinologist at Tripler, and the nuclear medicine physician."
2. "I don't know whether she hid the pregnancy because she was [REDACTED] or whether she was afraid she wouldn't be taken care of."
3. "This was a complicating thing in the whole investigation, that I think really helped in having the accident occur, that she hid it so very, very effectively."

We reviewed both your initial report dated July 4, 1990, and the Nuclear Regulatory Commission (NRC) inspection report summary dated August 3, 1990. The NRC investigation of the incident did not include any communication with the patient's personal physician on Truk, nor are we aware of any information which indicated that the patient hid her pregnancy from her physician. Also, there are several references in both these reports that the endocrinologist's secretary was aware that the patient was pregnant. In your report, you stated that "His [Dr. [REDACTED]] secretary realized that the patient was pregnant, and the secretary told the health coordinator in Truk to have the scan scheduled after the baby was born." The secretary did not inform Dr. [REDACTED] about the birth of the baby on June 1st. Although the patient did not volunteer the fact that she was nursing when she arrived at Tripler, this does not imply that she concealed that she was nursing. The patient did inform the nuclear medicine technologist that she was nursing when the scan was performed on June 21, 1990.

Because the evidence does not support the fact that she concealed her pregnancy, the NRC will submit a correction to the public record to be included with the transcript of the ACMUI meeting. If, however, you have further information

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Dr. Carol S. Marcus

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not currently available to us that would support the fact that she deliberately concealed her pregnancy, please provide us with such information by March 15, 1992, in order that we may consider it prior to correcting the record.

Sincerely,

Richard E. Cunningham, Director
Division of Industrial and
Medical Nuclear Safety, NMSS
Office of Nuclear Material Safety
and Safeguards

Distribution: IMAB-692

PKHolahan

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RECunningham

JGreeves

JEGlenn

PRathbun

LWCamper

OGC - no legal distinction
5/16/92 sent to committee
in case to Holahan
02/25/92 dated 2/25/92

DFC : IMAB	: IMAB	: IMAB	: DD/NMSS	: D/NMSS	:
NAME : PKHolahan	: LWCamper	: JEGlenn	: JGreeves	: RECunningham:	: : :
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IMAB-692



March 10, 1992

UCLA SCHOOL OF MEDICINE
HARBOR - UCLA MEDICAL CENTER
DEPARTMENT OF RADIOLOGY
1000 CARSON STREET
TORRANCE, CALIFORNIA 90509

Richard E. Cunningham
Director, Div. of Industrial and Medical
Safety, NMSS
U.S. Nuclear Regulatory Commission
Washington, DC 20555

Dear Dick:

This letter is in answer to your letter of 2 March 92 concerning the Tripler incident.

The patient, _____ is a nurse, and was told repeatedly (I think it was 5 times) before that she should not be pregnant or breast-feeding when given I-131.

I cannot prove that she hid the pregnancy from three physicians, but can only infer it. It is hard to imagine a physician dumb enough to order I-131 on a known pregnant patient, although I don't know anything about her physician on Truk or what the standards for a practitioner in that country might be.

I spoke with the health care worker from Truk who knew about the pregnancy and so informed Dr. _____ secretary the first time the request went through. I spoke to Dr. _____ also, and he was not told of the pregnancy problem. He was not involved in this first attempt at scheduling at all. I truly think that the "girls" got together and stopped this test and that probably neither physician knew; certainly _____ did not. When the second request for the procedure went through, the baby had not yet been born. I do not know if it was the same health care worker on Truk that passed it along (I think it was) but it went out anyway. I do not know if Dr. _____ secretary remembered about the pregnancy, or whether she assumed the baby had been born, or whether she thought about it at all. This is not a secretary's job, and catching the problem the first time was a lucky break. There is no way that any physician, especially a competent endocrinologist like Dr. _____ would have taken a pregnant patient off replacement synthroid, with her hypothyroidism to coincide with delivery, unless he did not know she was pregnant. No way. The patient could have talked to _____ when she got to Tripler or could have sent a message to him before when the order came through to stop the replacement synthroid and she was going into her 9th month. It is very strange to me that she did not; she could have done it through the health care worker.

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The patient could have told the Nuclear Medicine physician or a technologist that she was breast-feeding, but did not. She had a serum B-HCG drawn and did not mention she had given birth just a short time before. Of course she admitted to the nuclear medicine technologist that she was breast-feeding after the scan---it was impossible to deny. Did you see that scan? As I recall, all you saw was two extremely radioactive breasts and everything else in the image was negligible by comparison. She told the nuclear medicine physician that she knew she shouldn't be breast-feeding, but that she thought that 11 hours of waiting would be enough. Why didn't she ask? The nuclear medicine people were there, were competent, and were very nice. Yes, they were busy that day, but it would have been easy to ask the question. Someone has to be with the patient to administer the dose. It is easy to ask then.

Remember, this is a young lady who has had metastatic disease and who has been saved by excellent medical management at Tripler, despite the difficulties of dealing with another country that is very backward. She might have been very fearful of recurrent metastasis, and afraid she would not be cared for if she admitted the pregnancy/lactation. This is certainly a reasonably likely scenario.

I would also like to point out that I had at least two meetings with physicians at Tripler where no one else from NRC was with me, and I had several other meetings with physicians at Tripler in which other NRC representatives were present but we spoke briefly, technically, and professionally, and that none of the NRC people understood much of anything except [redacted] who understood some of it because [redacted] is a good nuclear medicine technologist and a pretty savvy woman and mother. In addition, I had telephone conversations with several individuals from Tripler before I left for Hawaii, and no one from NRC was in on those conversations. I therefore do not think it is of any importance what the NRC inspection report summary said. The NRC inspection team, with the exception of [redacted] and me, were not capable of doing this job. They were out of their element completely and were in the dark. The first question they asked when I arrived was, "What does the thyroid gland do?" At least they were honest. You wouldn't send me in to troubleshoot a reactor accident; why send them into a highly complex medical care delivery system? I cannot comment on the accuracy and completeness of their report, because no one from NRC ever sent me a copy to review. Why didn't you?

I disagree completely with your statement that "the evidence does not support the fact that she concealed her pregnancy"; I think

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that there is much evidence suggesting that in fact she did.

I still find it amazing that NRC had already made up its mind about wanting to "kill" Tripler before my or the NRC report was in or before this complex case was discussed. (It never has been satisfactorily discussed). The inspectors from Region V were obviously feeling this pressure throughout the inspection. Such prejudice is grossly inappropriate. I expect that things would have been quite different if it had been Bethesda Naval instead of Tripler Army Hospital.

As far as your third quotation of mine goes, it doesn't make sense as written and there probably is a transcription error in the second line. However, I still believe that she hid her pregnancy very effectively. When I left Tripler, I assumed it was because the [REDACTED]. Later I realized that I was probably applying the wrong set of cultural values, and that more likely it was fear of not being cared for.

I had no idea I would be expected to "prove" this. You sent me out as a medical consultant. I am not a detective or a public prosecutor. With [REDACTED] and her baby back on Truk, neither I nor anyone credible from NRC ever talked to her; I have had to make certain probabilistic assumptions. Why does it even matter? There is, I think, no doubt that the two Tripler physicians did not know about the pregnancy, and it is highly probable that the Trukian physician did not know, either. There is no doubt that [REDACTED] knew she shouldn't be pregnant or breast-feeding. Maybe [REDACTED] is very shy. Or very dumb. The point is that communication failed to take place despite numerous prior caveats and ample opportunity, and that is why such occurrences are so rare: the system works almost all the time.

Before NRC considers "submit(ing) a correction to the public record to be included with the transcript of the ACMUI meeting.", how has NRC "proved" that she did NOT conceal her pregnancy and lactation? You haven't. I believe she concealed her pregnancy, probably by design but possibly by being shy or dumb. Concealment nonetheless. On what basis can you dispute this? And what is your motivation to attempt to do so?

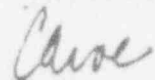
By the way, did you write this letter or did someone write it for you? I have never known you to be rude, but I received this on 9 March '92 and the "deadline" for you to receive my answer is March 15th or you intend to incorrectly "correct" the public record. Considering the fact that the ACMUI meeting was 7-8 Nov. 91, what took you so long, and why rush me? Because someone is hoping I won't make the deadline?

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You may not want to follow the advice you pay me so well(!) to produce; that is your privilege. But to try to discredit it, without any evidence whatsoever, because it does not fit the propaganda construct that your staff would like to arrange, is blatant unethical behavior. It is my opinion, and that of other professionals in the field, that NRC's behavior in the Tripler incident was contemptible. The fact that your staff is in the process of concocting a regulation about pregnancy and lactation, which is absolutely unnecessary and out of your jurisdiction anyway, appears to be the cause of this attempt to change the public record. After all, if the public record did not fit, why not change it so that it does? The same staff has performed in the same unethical manner with the Q/M Rule, the Immediately Effective Interim Final Rule, the ACNP/SNM Petition, the Syncor suit, and Abnormal Occurrences Reports to Congress.

I have known you for 22 years, Dick. I have disagreed with you numerous times, but I have never seen you stoop to this. Would you please fix this mess before it goes any further?

Sincerely,



Carol S. Marcus, Ph.D., M.D.
Director, Nuclear Med. Outpt Clinic
and
Assoc. Prof. of Radiological Sciences
UCLA

cc: Hugh Thompson, Deputy EDO
Barry Siegel, M.D., Chair, ACMUI
William Parler, Designated Agency Ethics Official

CSM:sfd