

This message has been scanned for known viruses.

From: Fudinj
To: Fudinj
Subject: Fwd: Information requested by VA-OIG, Gerard Poto
Date: Fri, 15 Jul 2005 22:39:00 -0400
Files: oncstats-Poto.doc (35K) Taxol_Death.pdf (3033K)

-----Original Message-----

From: Fudin, Jeffrey
Sent: Thursday, July 14, 2005 10:07 AM
To: Poto, Gerard; Poto, Gerard, VBANWRK
Cc: 'william.pericak@usdoj.gov'
Subject: Information requested by VA-OIG, Gerard Poto
Importance: High

Jerry,

I'm glad we bumped into each other today (7/13/05) at the Stratton VA. You requested the name of the patient who allegedly died from receiving Taxol inappropriately. We also discussed some statistical information regarding certain patients that were treated by Dr. XXXXXXXXXX, and you confirmed that you were aware of the recent Times Union article dated 6/27/05, FBI Closes Inquiry at VA. Commensurate with our conversation, I dug up a number of documents.

Before proceeding, I must request that this e-mail not be forwarded outside your office (or Mr. Pericak's office) due to patient confidentiality policies. As allowable by HIPAA Guidelines, I am providing the names here for purposes of an ongoing investigation that could potentially impact on public safety.

To start, the name of the patient who died from inappropriate Taxol use was XXXX XXXXXX (XXXX). This is outlined in a memo to Dr. Walter Rivera dated February 6, 1996, which I attached for your review. As indicated in this letter, I had previously disclosed this patient death to the CQI (Continuous Quality Improvement) office. Previous to this 1996 letter, I shared this [and similar] information with XXXX-XXXXX XXXXX, who at that time was in charge of CQI. This (and other patient care disclosures) were never investigated by the CQI office for various reasons that I would be happy to discuss with you. Coincidentally, XXXX-XXXXX XXXXX is now the Stratton XXXXXXXXXX XXXXXXXXXX, and was in the XXXXXXXXXX XXXXXXXXXX while Mr. Paul Kornak and Dr. James Holland were charged with falsifying patient records to qualify them for studies.

The second attachment is a summary of patients who received the combination of 5-fluorouracil with leucovorin where 15/30 (50%) of patients received a chemotherapeutic drug that was NOT indicated for the tumor type for which it was prescribed and/or was delivered in an unconventional manner. Of those receiving an appropriate drug(s), each received chemotherapy as X XX/XX XXXXXXXXXXXX XXXXXXXXXXXX maximized ambulatory infusion by what Dr. XXXXXXX XXXXXXXXXX as standard of care, outside of standard practice guidelines. In essence, this "research" was completed prior to submitting an investigational protocol. XXXXXXXXXX then requested to do a retrospective review, which was approved by the Research and Development (R and D) Committee. The R and D Committee approved his request without questioning why he did this research in advance of seeking

approval or why he engaged in such human research to begin with. Fifty percent of these patients received a fabricated chemotherapy regimen that would not be considered acceptable by any oncology standards. It appears that Dr. XXXXXXXX simply placed patients on 5-FU in this "circadian optimized" fashion in an effort to perhaps hit upon something for which he might later request a retrospective review.

His findings were published in
XX was misstated and misleading to the readers, and was also based on research that was done on patients without informed consent, and condoned by the R and D during the years that Dr. Min Fu Tsan was Chief of Research at the Stratton VA.

Finally, I'd like to briefly discuss the article that appeared in the Times Union on 6/27/05. You indicated that you were aware of that article. When asked if you needed evidence of some of the exorbitant salaries that were provided to certain VA employees, you said that you had seen the information from 1995. One item that particularly stands out in my mind is that Dr. XXXXXXXX received over \$250,000.00 in addition to his full time VA salary. Although I am aware of certain policies that allowed for practitioners to have their salaries augmented by ARI funds, this activity was not permissible by regulation for a number of reasons. First, a federal employee is only allowed to receive additional funds from outside sources if the payment is for work done outside of federal employment hours. Since the money paid to XXXXXXXX was likely more than twice his VA salary, I'm guessing he would have had to work for greater than 24 hours per day to justify this. Secondly, policies were clear that any monies dispersed had to be voted upon by members of the Stratton VA Research and Development Committee. Since I was a member of that committee at that time, I can confirm that no such discussions ever took place, and disbursement of these funds was done behind the scenes without the knowledge of "outsiders". As you know, other exorbitant funds were dispersed to various practitioners within the Stratton VA.

Which administrators knew about specific research violations and alleged patient abuse by Dr. XXXXXXXX? I will provide some names below. In most cases I have written documentation, and in other cases I can tell you the dates that I spoke to certain officials.

XXXXXXXX, MD (Chief of Medicine, retired)

XXXXXXXX, MD (Chief of Staff, later promoted to Hospital Director, and now has a VISN level position as XXXX XXXXXXXXXXXX)

XXXX XXXXXXXX (Previous Hospital Director, promoted to Regional Manager. He is now a hospital director in the Northern Florida area.)

XXXXXXXX (Administrative Assistant, retired)

XXXXXXXX, MD (received the XXXXXXXX memo XXXXX. He was appointed to lead two separate administrative investigations against me. Coincidentally, he also was up for a promotion, which he eventually received.)

XXXXXXXX, MD (He led the investigation of my allegations that XXXXXXXX was abusing patients. He too was up for a promotion. *[According to a Times Union report on 5/25/03], he was instructed by Dale Morgan and Dr. Lawrence Flesh to edit his findings of wrongdoing, which otherwise would have substantiated my allegations)

XXX-XX XXXX, MD (He was the Associate Chief of Staff for Research.
XX, for
many years. I had many conversations with him regarding the behavior of
XXXXXXXXXX and patient abuse. XXXX acknowledged the abuse by XXXXXXXXX and
often muttered, "It's out of my hands".)

...and more!

Jerry, I have documentation for a lot of this. There is no statute of
limitations on manslaughter. I'm not sure if there is a limitation for
patient abuse. Surely, if some of these professionals can't be criminally
charged with wrongdoing, they should be removed from the VA system,
exposed to the public, and in cases of money laundering, be required to
pay the money back with interest.

Attachments:

02/06/96 letter from Fudin to Rivera
Summary of 5-FU / Leucovorin misconduct

<<oncstats-Poto.doc>> <<Taxol Death.pdf>>

Copied to William Pericak, U.S. Attorney

Jeffrey Fudin, B.S., Pharm.D., DAAPM
Clinical Pharmacy Specialist, Pain Mgmt/Primary Care (VAMC-Albany)
Diplomate, American Academy of Pain Management
Adjunct Associate Professor of Pharmacy Practice (Albany College of
Pharmacy)
CEO, American Pharmaceutical Pain Associates
VAMC Office: 518-626-5706
VAMC Fax: 518-626-6328
Digital Pager: 518-342-3084
Mobile Phone: 518-588-5651

* [According to a Times Union report on 5/25/03, Cover-up charged in VA probe, by
Brendan Lyons] This qualifier was added in to the original e-mail for clarification
and ocumentation purposes.