Reference: Patient C

Jeff KXXXXXX

Date of Birth: 2/13/61

43 y.o. W male who presented on Feb 16, 2004 with c/c of Adrenal Carcinoma, initially diagnosed in September 2003, status post surgical resection in Oct 2003 with left nephrectomy, adrenalectomy and splenectomy, along with extensive lymph node dissection. Pt presented with a 59 pound weight loss. Prior to diagnosis of cancer, patient had significant hx of abdominal surgery in October 2002 with resection of greater than 4cm of sigmoid colon with placement of a colostomy. Three months later, in Feb 2003, pt had colostomy takedown.

Underwent 16 treatments of radiation, although advised to have 28. Pt stopped after becoming very sick and was unable to tolerate further treatments. Pt told by oncologist that chemotherapy would not be an option and was reportedly given less than 6 months to live. On Feb 3, 2004, the first post operative cat scan showed questionable lesion in lung (5mm), as well as a new lesion in the liver measuring 2 ½ cm. Patient presented to us with stage 4 Adrenal Cancer and was under the care of Dr. Buttar from February 16, 2004 until June 9, 2004 and was last seen in our clinic on June 11, 2004. Patient died on September 18, 2004 from a pulmonary embolus, more than three months after treatment had been completed by Dr. Buttar.

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Each numbered item below is the NCMB's expert reviewer's comments on the charts. Each bulleted item is our response, with references to the medical charts showing the facts.

## - Dr. Peterson:

- NCMB Expert's (Dr. Peterson) opinion on Treatment Below standard of practice/care
  - Natural Killer Cell activity more than doubled after treatment by Dr. Buttar
    - o Before treatment: Natural Killer Cell Activity: 8.6 LU
    - o After treatment: Natural Killer Cell Activity: 20.8 LU
      - A 150% increase in in NK Cell Activity
  - Reference: G17,G18,G19,G27
  - Clearly Above and Beyond the standard of care.
  - If Dr. Peterson does NOT understand the relevance of increasing CD 19 and CD 56 count (NK Cell) activity in cancer patients, he substantiates himself that he is NOT qualified to review this case.
- 2. "EDTA chelation therapy has no benefit in treating cancer."
  - First, we do NOT treat cancer with EDTA.
  - We DO treat heavy metal toxicity with EDTA.
  - The incidence of heavy metal toxicity with cancer is highly statistically significant.
  - If the cancer patients shows heavy metal toxicity, as they usually do, we REMOVE the metals.

- According to the conventional cancer literature, 75% to 95% of cancer patients have some type of toxicity. The etiology of most cancers stems from increase in oxidative stress due to some sort of toxicity.
- Sample References showing correlation of heavy metals in cancer patients Have more than a hundred others.
  - Metal Metabolism Of Neoplastic Cells: Alterations That Facilitate Proliferation? Critical Review Oncology & Hematology, Volume 42, No. 1, April 2002, pg 65-78
  - Iron Chelation Induced Senescence-like Growth Arrest In Hepatocyte Cell Lines: Association of TGF-beta1 Mediated p27superKip1 Expression, Biochemistry Journal, April 11, 2002
  - Antiproliferative And Apoptotic Effects Of Iron Chelators On Human Cervical Carcinoma Cells, Gynecological Oncology Volume 85, No. 1, April 2002, pg 95-102
  - Ninety Percent Reduction In Cancer Mortality After Chelation Therapy With EDTA, Journal of Advancement in Medicine, Volume 2, No. 1-2, Spring-Summer 1989
- **3.** "In addition, numerous labs drawn that are of no clinical relevance such as "urine toxic metals", "steatocrit", "Lactoferrin", "Lysozyme".
- 4. E1: Urine Toxic Metals is a urine element analysis used for the assessment of toxic element statue, monitoring detoxification therapy, and identifying or quantifying renal wasting conditions. The incidence of heavy metal toxicity with cancer is highly statistically significant.
  - If the cancer patients shows heavy metal toxicity, as they usually do, we REMOVE the metals.
  - According to the conventional cancer literature, 75% to 95% of cancer patients have some type of toxicity. The etiology of most cancers stems from increase in oxidative stress due to some sort of toxicity.
  - Sample References showing correlation of heavy metals in cancer patients Have more than a hundred others.
    - Metal Metabolism Of Neoplastic Cells: Alterations That Facilitate Proliferation? Critical Review Oncology & Hematology, Volume 42, No. 1, April 2002, pg 65-78
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    - Ninety Percent Reduction In Cancer Mortality After Chelation Therapy With EDTA, Journal of Advancement in Medicine, Volume 2, No. 1-2, Spring-Summer 1989
  - F2: Steatocrit, lactoferrin, lysozyme are part of the CDSA( Comprehensive Stool Analysis/Parasitology x1 test which is performed to assess many digestive and absorptive functions occurring within the gastrointestinal tract as well as providing an overview of the microfloral balance, intestinal ecology, immunology and general intestinal health.
  - D1 D51: Requirement for monitoring renal function, hepatic function, electrolytes, can hemoglobin counts in a cancer patient are HIGHLY

relevant, especially when they are aggressively being treated for a stage 4 cancer with multiple IV regiments daily.

- Labs HIGHLY necessary to monitor patient safety
- Labs HIGHLY necessary to assess patient response
- Labs necessary to assist in guiding treatment intensity
- G1 –G27: Cancer panels necessary to establish immune function, with detailed explanation in charts provided
  - G1, G9, G18 explanation of significance of level of uncontrolled cellular proliferation monitoring in immunocomprimised pts.
  - o Immune function CD 19, CD 56 counts
  - Immune function NKHT3 + Immunocompetent Natural Killer Cells, NK Cell activity, NK cell activity/cell
  - o G3,G4,G11, G12, G21,G22 Lymphocyte Subpopulation profile CD2, CD4, CD8, CD 3, CD 26
  - G7, G16, G24 Cell cycle Analysis and dsyregulation in oncogenesis
  - o G5, G14, G23 Apoptosis and subsequent suppression of apoptosis in cancer explained in detail
- 5. "The standard of care would be treatment with chemotherapy such as Mitotane or enrollment in a clinical trial versus palliative care alone."
  - C2a: Pt was told chemotherapy was not an option by oncologist.
  - Dr. Buttar's treatment was ABOVE and BEYOND the standard of care.
  - While under Dr. Buttar's care, pt did not require pain control.
  - Patient lived beyond expected and predicted life span by oncologist
  - Patient died of a documented pulmonary emboli, NOT cancer.
- 6. "No physician contact documented."
  - C2a: 2/16 Dr. Buttar conducted examination and wrote detailed Progress Notes
  - C4a,b: 3/24 Dr. Buttar conducted examination and wrote detailed Progress Notes
  - C5a, C5b: 4/7 Dr. Buttar conducted examination and wrote detailed Progress Notes
  - C6a, C6b: 4/7 Dr. Buttar conducted examination and wrote detailed Progress Notes
  - C9: 5/4 Dr. Buttar conducted examination and wrote detailed Progress Notes
  - C12a: 5/25 Dr. Buttar conducted examination and wrote detailed Progress Notes
  - C13: 6/9 Dr. Buttar conducted examination and wrote detailed Progress Notes
  - I1b: 3/15 Dr. Buttar performed an IRR treatment on patient. When ever IRR's done, Dr. Buttar always consults with patients and addresses any issues or questions patients have.
  - I1a: 3/23 Dr. Buttar performed an IRR treatment on patient
  - I2b: 3/30 Dr. Buttar performed an IRR treatment on patient
  - I2a: 4/6 Dr. Buttar performed an IRR treatment on patient
  - 13: 4/14 Dr. Buttar performed an IRR treatment on patient
  - I4a: 4/20 Dr. Buttar performed an IRR treatment on patient

- I4b: 4/27 Dr. Buttar performed an IRR treatment on patient
- I5a: 4/28 Dr. Buttar performed an IRR treatment on patient
- I5b: 5/4 Dr. Buttar performed an IRR treatment on patient
- I6b: 5/11 Dr. Buttar performed an IRR treatment on patient
- I6a: 5/18 Dr. Buttar performed an IRR treatment on patient
- I7b: 5/25 Dr. Buttar performed an IRR treatment on patient
- I7a: 6/1 Dr. Buttar performed an IRR treatment on patient
- 18a: 6/9 Dr. Buttar performed an IRR treatment on patient

## - Dr. Mann:

- 1. "The point of the chelation therapy is not stated in the record."
  - Failure of the reviewer, the NCMB or designated "expert witness" to be up to date on the medical literature is not Dr. Buttar's responsibility.
- 2. "Records: This is the weakest part of the care. There are no records of justification of the treatments given except for what appear to be pre-packaged paragraphs describing the rationale for testing for heavy metal toxicity and immune function. This information is not described in terms specific tests and procedures for this patient."
  - This is correct. Since the rationale is always the same, it is prepackaged to save time and effort. Metals increase oxidative stress. Oxidative stress leads to DNA mutation and Immunosuppression. DNA mutation leads to oncogenesis. Immunosuppression leads to suppression of apoptosis. All this leads to cancer.
  - C4b: Immune function, results heavy metal testing
  - C7b: Immune function(Cancer Panel)
  - C12A: Immune function (Cancer Panel)
  - E1-E7b: Urine toxic Metals
  - G1-G27: Immune function (Cancer Panel)
- 3. "There is no written assessment of the patient's response to the infusions and chelation therapy."
  - C4a, C4b: Dr. Buttar documented patient's response to all treatments under the Subjective portion of the Soap note
  - C5a: Documentation of patient's response to all treatments under the Subjective portion of the SOAP note
  - C6a: Documentation of patient's response to all treatments under the Subjective portion of the SOAP note.
  - C7a:Jane Garcia, NP documented patient's response to all treatment under the Subjective portion of the SOAP note.
  - C9: Dr. Buttar documented patient's response to all treatments under the Subjective portion of the SOAP note.
  - C10a:Jane Garcia, NP documented patient's response to all treatments under the Subjective portion of the SOAP note.
  - C11a: Jane Garcia, NP documented patient's response under the Subjective portion of the SOAP note.
  - C12a: Dr. Buttar documented patient's response under the Subjective portion of the SOAP note.

- C12b: Jane Garcia,NP documented patient's response under the Subjective Portion of the SOAP note.
- C13: Dr. Buttar documented the patient's response under the Subjective portion of the SOAP note.
- 4. "Most of the notes are written by Jane Garcia, ANP, are often out of order, are occasionally countersigned by Dr. Buttar and do not reflect ongoing examination of the patient or observed changes in his clinical status, linked to his therapy or otherwise."
  - When medical records given to NCMB, records and progress notes were in order.
  - ,C12b: Dr. Buttar either wrote or co-signed ALL but one Progress Note)
    - o C2a: Signed Progress Note
    - C4a: Signed Progress Note
    - C5b: Signed Progress Note
    - o C6b: Signed Progress Note
    - C8: Signed Progress Note
    - o C9: Signed Progress Note
    - o C10b: Signed Progress Note
    - C11b: Signed Progress Note
    - o C12a: Signed Progress Note
    - C13: Signed Progress Note
    - 0
  - C5a: Under (O) Objective of SOAP note, exam, findings documented
  - C6a: Under (O) Objective of SOAP note, exam, findings documented
  - C7b: Under (O) Objective of SOAP note, exam, findings documented
  - C9: Under (O) Objective of SOAP note, exam, findings documented.
  - C10b: Under (O) Objective of SOAP note, exam, findings documented
  - C11b: Under (O) Objective of SOAP note, exam, findings noted
  - C12a: Under (O) Objective of SOAP note, exam, findings documented
  - C12b: Under (O) Objective of SOAP note, exam, findings documented
  - C13: Under (O) Objective of SOAP note, exam, findings documented
  - C4a: Under the Subjective portion of each SOAP note, specific comments by the patient are documented
  - C5a: Under the Subjective portion of each SOAP note, specific comments by the patient are documented
  - C6a: Under the Subjective portion of each SOAP note, specific comments by the patient are documented
  - C7a: Under the Subjective portion of each SOAP note, specific comments by the patient are documented
  - C9: Under the Subjective portion of each SOAP note, specific comments by the patient are documented
  - C10a: Under the Subjective portion of each SOAP note, specific comments by the patient are documented
  - C11a: Under the Subjective portion of each SOAP note, specific comments by the patient are documented
  - C12a: Under the Subjective portion of each SOAP note, specific comments by the patient are documented
  - C12b: Under the Subjective portion of each SOAP note, specific comments by the patient are documented

- C13: Under the Subjective portion of each SOAP note, specific comments by the patient are documented
- 5. "The record does not use SOAP."
  - C2a: 2/16/04 SOAP note is CLEARLY used
  - C2b: 2/23/04 SOAP note is CLEARLY used
  - C4a C4b: 3/24/04 SOAP note is CLEARLY used
  - C5a C5b: 4/6/04 SOAP note is CLEARLY used
  - C6a-6b: 4/20/04 SOAP note is CLEARLY used
  - C7a,C7b,C8: 4/28/04 SOAP note is CLEARLY used
  - C9: 5/4/04 SOAP note is CLEARLY used
  - C10a C10b: 5/13/04 SOAP note is CLEARLY used
  - C11a C11b: 5/18/04 SOAP note is CLEARLY used
  - C12a: 5/25/04 SOAP note is CLEARLY used
  - C12b: 6/2/04 SOAP note is CLEARLY
  - C13: 6/9/04 SOAP note is CLEARLY used
- 6. "Overall: below standard of practice/care, particularly in terms of documentation of the attending awareness of patient status, justification for therapies chosen, and awareness of effects of such therapies."
  - C13: Dr. Buttar Signed all his progress notes and co-signed all of the Mid Level Provider's notes.
    - C2a: Signed Progress Note
    - o C3a: Signed Progress Note
    - o C3b: Signed Progress Note
    - C4b: Signed Progress Note
    - o C5b: Signed Progress Note
    - o C7: Signed Progress Note
    - o C8: Signed Progress Note
    - o C9b: Signed Progress Note
    - o C11b: Signed Progress Note
    - o C12a: Signed Progress Note
    - C13: Signed Progress Note
  - C4b: Under (O) Objective of SOAP note, exam, findings documented
  - C5a: Under (O) Objective of SOAP note, exam, findings documented
  - C6a: Under (O) Objective of SOAP note, exam, findings documented
  - C7b :Under (O) Objective of SOAP note, exam, findings documented
  - C9: Under (O) Objective of SOAP note, exam, findings documented
  - C10a: Under (O) Objective of SOAP note, exam, findings documented
  - C10b: Under (O) Objective of SOAP note, exam, findings documented
  - C11b: Under (O) Objective of SOAP note, exam, findings documented
  - C12a: Under (O) Objective of SOAP note, exam, findings documented
  - C12b: Under (O) Objective of SOAP note, exam, findings documented
  - C13: Under (O) Objective of SOAP note, exam, findings documented
- 9. "In addition to the above issues, there are several examples of repetitive blood sampling with questionable utility."
  - D1 D51: Requirement for monitoring renal function, hepatic function, electrolytes, can hemoglobin counts in a cancer patient are HIGHLY relevant, especially when they are aggressively being treated for a stage 4 cancer with multiple IV regiments on a daily basis.

- Labs HIGHLY necessary to monitor patient safety
- Labs HIGHLY necessary to assess patient response
- Labs necessary to assist in guiding treatment intensity
- 10. "-weekly assessment of immune function from 2/25 5/10 without written comment or interpretation of the results or adjustment of therapy."
  - Assessment of immune function was completed 3 times in this patient
    - o G1 G8: Once prior to initiation of treatment on Feb 25, 2004
    - o G9 G17: Once during the treatment on Apr 20, 2004
    - G18 G25: Once towards the end of the first phase of tx, on May 10, 2004
  - Clinical interpretation and comments are discussed in the Assessment and Plan of the OV when tests became available for review.
  - G27 is a running comparison that was given each time to the patient and reviewed in detail with the patient.
  - Copy of G27 given to patient at time of review.
- 11. "-intravenous infusions 03/03/2004 to 06/11/2004 without comment on change in clinical status or side effects or justification for further infusions."
  - IV tx are administered via a protocol established to change the underlying physiology of the patient from an acid to alkaline state with an emphasis in increasing aerobic metabolism from the predominant anaerobic metabolism characteristic in oncogenesis.
  - IV infusion given based on protocol, as per the AMESPA Course, which is an ACCME approved, AMA Category 1 CME course.
  - Pt's response to IV treatment is documented in nursing notes on a daily basis to assess any adverse clinical status or side effects of tx and per protocol, is brought to the provider immediately
  - There was no such adverse effect or clinical status change in this patient, and therefore, there is NOTHING documented. You can't document something if it did NOT occur.
  - J4 J16 documents All normal evaluations documented, with vital signs, including before and after blood pressures, weight, and pulse and respiratory rates were documented, as per our clinic protocol.
- 12. "-multiple blood draws for labs from 3/18/ to at least 6/11/2004 for electrolytes, liver and kidney functions, iron studies and lipid levels which changed very little, were not justified in the notes, were often out of order, and were ordered about once per week, again without documentation or justification."
  - D1 D51: Requirement for monitoring renal function, hepatic function, electrolytes, can hemoglobin counts in a cancer patient are HIGHLY relevant, especially when they are aggressively being treated for a stage 4 cancer with multiple IV regiments on a daily basis.
    - Labs HIGHLY necessary to monitor patient safety
    - Labs HIGHLY necessary to assess patient response
    - Labs necessary to assist in guiding treatment intensity
  - Fortunately, this patient was doing well, but often, this is not the case.
    - We monitor all patients closely.

- If we had NOT monitored, an adverse event could have occurred and the NCMB would be investigating the LACK of proper monitoring.
- All labs are kept in order and were in order when charts were given to the NCMB.
- C3: Note Documentation of Labs performed on 2/24/04, 3/17/04, 3/25/04, 4/5/04, and 4/8/04 for comparative analysis of renal, hepatic function, electrolytes, iron levels, hemoglobin/hematocrit levels.
  - As stated above labs are done to monitor patient safety, assess patient response, and assist providers in guiding treatment of patient.
- C4b: Under (O) Objective of SOAP note findings documented
- C5a: Under (O) Objective of SOAP note findings documented
- C6a: Under (O) Objective of SOAP note findings documented
- C6b: Documentation of Labs performed on 4/01/04, 4/13/04, 4/15/04, and 4/19/04 for comparative analysis
- C7a: Under (O) Objective of SOAP note findings documented
- C7b: Under (O) Objective of SOAP note findings documented
- C9: Under (O) Objective of SOAP note findings documented
- C10a: Under (O) Objective of SOAP note findings documented
- Of labs performed on 5/3/04, 5/7/04, and 5/11/04 for comparative analysis
- C10b: Under (O) Objective of SOAP note findings documented
- C11a: Under (O) Objective of SOAP note findings documented
- C11b: Continuation of documented findings
- C12b: Under (O) Objective of SOAP note findings are documented
- 13. "The main deficiencies are in the areas of documentation of justification for treatments, repetitive serum tests, and lack of a sense of management of this patient using assessment linked with rationale for treatment. The standard of care is below average in this case."
  - C2a: There is a definite plan of treatment as listed under the A/P portion of the SOAP note.
    - o This was the patient's initial visit.
    - Plan of treatment continued at each subsequent office visit as documented under the A/P of each SOAP note.
    - This is definitely within the standard of care.
  - C2b: Documentation under (A/P) Assessment / Plan of Soap note
  - C4a C4b: Documentation under (A/P) Assessment / Plan of Soap note
  - C5b: Documentation under (A/P) Assessment/Plan of Soap note
  - C6b: Documentation under (A/P) Assessment/Plan of Soap note
  - C7b,C8: Documentation under (A/P) Assessment/Plan of Soap note
  - C9: Documentation under (A/P) Assessment/Plan of Soap note
  - C10b: Documentation under (A/P) Assessment/Plan of Soap note
  - C11b: Documentation under (A/P) Assessment/Plan of Soap note
  - C12a,C12b: Documentation under (A/P) Assessment/Plan of Soap note
  - C13: Documentation under (A/P) Assessment/Plan of Soap note