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Department of
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Lakeside Hospital
Rainbow Babies & Childrens Hospital
MacDonald Hospital for Women
Leonard C. Hanna House
Howard M. Hanna Pavilion
George M. Humphrey Building
Robert H. Bishop Building
Abington House
Wearn Medical Research Laboratories
Harry J. Bolwell Health Center
University Hospitals Health Center/East
University Suburban Health Center

5-13-88
JK

Doc. 320

April 21, 1988

William **J.** Coyne & Associates
Attorney at Law
1630 Standard Building
Cleveland, Ohio 44113

Dear Mr. Coyne:

I reviewed the xeroxed medical records of Philip McIntosh which you sent me regarding a pending malpractice action. As a Neuroradiologist, **I** will confine my comments to a review of the chart information pertaining to the performance *of* the cervical myelogram on 12/9/85.

Nothing in these documents indicates any deviation from the standard care of medical practice related to St. Vincent Charity Hospital. The specific questions as I see them are as follows. 1) Was the utilization of metrizamide in December, 1985 within the standards *of* medical care at that time? 2) Was the technical performance of the myelogram e.g. injection technique position, etc. within standard care? *3)* Was there a failure to provide adequate informed consent?

The first question is the one that relates most directly to St. Vincent Charity Hospital. In December 1985 metrizamide was still considered an appropriate myelographic contrast agent and its utilization in no way violated the standard of care at that time. As I am sure you are aware, at about this time newer water soluble contrast media (in particular iopamidol and iohexol) were being introduced. Most hospital pharmacies and physicians were in the process of converting from metrizamide to these newer agents. Nevertheless, most Institutions were continuing to use metrizamide as the newer agents were being introduced. At our own Institution we continued to use metrizamide till March of 1386. The newer water soluble contrast agents did not become the exclusive agent of choice for myelography until then.

The second question relates to the technical performance of the myelogram and the utilization **of** both metrizamide and pantopaque in the same patient. Cervical myelograms are usually performed by either a lumbar puncture or a C1-2 puncture. The anatomic location chosen is usually a reflection of the experience of the myelographer as **well** as the technical equipment available. **At** our own Institution we have biplane fluoro which allows us to perform a C1-2 puncture in a very rapid safe fashion. This approach provides **a** better opportunity to collect the contrast

media in the area of interest without having to place the patient in the head down position [illegible] access to biplane fluoroscopy it nable to utilize the lumbar approach because it is technically less difficult and is not associated with the potential complication of direct spinal cord puncture. The technical difficulties encountered from this approach relate to the problems that develop when one attempts to facilitate the passage of the contrast media into the cervical region. Because of patient body habitus and cooperation it may be difficult to achieve an adequate opacification of the cervical canal. This is an accepted problem and results in the lack of adequate visualization of the cervical canal in 10-20% of patients. The decision of the radiologist to then perform a pantopaque myelogram was related to the failure to visualize the cervical region with the water soluble contrast agent. Again, the movement of pantopaque into the cervical region requires the patient to be placed in the head down position, a position that would almost certainly increase the amount of metrizamide (and potentially the pantopaque) in the subarachnoid space surrounding the brain. Nevertheless, this is a reasonable risk to take and I [illegible] there were still radiologists performing pantopaque myelography for visualization of the cervical region. The decision to do so is an individual one based on the circumstances and the patient as well as the desire to achieve an adequate examination. It has to be made in specific instances at the time of the examination and it is a decision that I will not second guess. Furthermore, to date, I am unaware of any literature which documents an adverse effect secondary to the utilization of both contrast agents in the same patient. Therefore I would again conclude that there is no violation in standards of care of medical practice in the technical performance of the myelograhic examination.

The third issue relates to informed consent. The informed consent on a xerox copy of the hospital records appears adequate.

Lastly, I would like to address an issue brought up by Dr. Tucker. The concentration of 240 mg per ml of metrizamide was customary for visualization of the cervical region, We ourselves use 300 mg/ml. The information lacking in this regard however is the total amount injected. The quantity of metrizamide provided in the single vial however is such that an overdose is unlikely.

In conclusion, I do not doubt that the patient's seizure is related to the metrizamide. However, it is an acceptable risk and I see no evidence of deviation from the standards of medical care in this case and feel that the reaction, while regrettable, in no way reflects inappropriate care.

Sincerely,

Michael T. Modic, M.D.
Head, Divisions of Magnetic Resonance
Imaging and Neuroradiology

MTM/hlk

Enclosure