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Jon Smith, J.D.
Law Offices of Jon Smith & Associates, P.C.
1234 Mountain Street
Denver, CO 80208

Re: RM

Dear Mr. Smith,

As you know, RM is a 44-year-old man who was diagnosed by John Watson, M.D. with Malignant Melanoma after a biopsy of a right-sided neck lymph node on January 22, 2017. Very briefly, records indicate RM was seen on May 3, 2016 at Methodist Medical Center Emergency Department wanting examination of a right-sided neck lesion. The attending physician, Holden Caulfield, M.D. was concerned enough about the lesion to have your client wait in the ER until the doctor could make an appropriate referral to University Hospital Dermatology. According to the doctor's ER note RM did not wait for an appointment to be made on his behalf and stated he would follow up on his own. As you know, RM has only had health insurance off and on over the past couple years and may have not followed through with the doctor's recommendations due to lack of health insurance and/or a lack of funds to pay for medical treatment.

RM was next seen in the University Hospital Emergency Department on June 26, 2016 with complaints of right-sided neck pain. RM was primarily seen by a Physician Assistant, however, the attending physician, Eliza Doolittle, M.D. indicated in a note that she thought the neck lesion was most likely benign, however Dr. Doolittle makes it very clear in her notes that the lesion looked suspicious enough to advise RM to follow up with his primary care doctor, have the lesion removed and have a biopsy performed. As you know, RM did not follow up with the recommendation. Again, I suspect the reason for his lack of follow up was financial in nature.

RM was next seen for dental work on August 18, 2016 by Jay Gatsby, D.D.S. In Dr. Gatsby's handwritten notes he states, "lesion right neck 'skin tag' removed with laser." Apparently Dr. Gatsby disposed of the removed specimen and did not send it for evaluation by a pathologist.

Next RM was seen by John Watson, M.D. on January 22, 2017 who did make the correct diagnosis. After performing a lymph node biopsy, the specimen was sent to Very Accurate Pathology Consultants who made the definitive diagnosis of Malignant Melanoma.

Dr. Watson then, appropriately according to protocol, had the melanoma staged. Widely accepted staging protocol is done by visual examination of the lesion, examination of the biopsy

itself using the accepted TNM (tumor, node, metastasis) criteria in combination with a Whole-Body PET/CT Scan which was done on January 28, 2017. This scan along with additional CT scans, if medically indicated, completes the TNM criteria looking for metastatic disease. Because of the findings in the testing, RM also had chest, abdomen and pelvic CT scans done with contrast on January 31, 2017 at Methodist Medical Center. Based on all the diagnostic testing RM was diagnosed with Stage IV Malignant Melanoma. The consensus of the treating doctors was that RM's prognosis was poor. As you know, RM died some months later.

After the definitive diagnosis RM received chemotherapy. Based on the medical records I reviewed, it is not clear to me if RM also had surgical removal of some of the involved lymph nodes and surrounding tissue or if he had any palliative radiation. It is important for you to know there is a procedure for identification of sentinel lymph nodes and surgical removal of the most affected tissue areas. Sentinel lymph node(s) are identified by a test that very specifically maps the patient's unique lymph drainage system using radioisotopes and dye. The sentinel lymph node(s) would be the closest node(s) to the primary cancer site. There may be more than one sentinel node. According to the 7th Edition (2013) of Grabb & Smith's Plastic Surgery textbook, "because of the high success rate at identification and excision of the sentinel node(s) and the minimal morbidity (my addition: low risk of side effects) of the procedure, it has become a de facto standard of care for patients at high risk of nodal metastasis thus giving the patient a much better opportunity for improved longer term survival." The text goes on to state "Nodal status is the single most important prognostic factor in melanoma staging, and sentinel node status can guide further treatment decisions." Indications for SNB (sentinel node biopsy) are based on the examination of the primary lesion, which in RM's case was most likely the lesion on his neck. Further in the text the author, Christopher J. Hussussian, M.D., states "No systemic (whole body) treatment has convincingly demonstrated a survival benefit for patients with stage IV melanoma."

Here is an explanation of staging: **(this degree of staging may be "overkill" for your current purposes, there are simpler staging tables. I have included one.)**

- Stage IA: Lesions less than or equal to 1 mm thick with no evidence of ulceration or metastases (T1aN0M0) are associated with a 5-year survival rate of 95%.
- Stage IB: Lesions less than or equal to 1 mm thick with ulceration noted but without lymph node involvement (T1bN0M0) or lesions 1.01-2 mm thick without ulceration or lymph node involvement (T2aN0M0) are associated with a 5-year survival rate of approximately 91%.
- Stage IIA: Melanomas greater than 1 mm but less than 2.01 mm in thickness with no evidence of metastases but with evidence of ulceration (T2bN0M0) or lesions 2.01-4.0 mm without ulceration or lymph node involvement (T3aN0M0) are associated with an overall 5-year survival rate of 77-79%.
- Stage IIB: Melanomas 2.01-4 mm thick with ulceration but no lymph node involvement (T3bN0M0) or lesions greater than 4 mm without ulceration or lymph node involvement (T4aN0M0) are associated with a 5-year survival rate of 63-67%.

- Stage IIC: Lesions greater than 4 mm with ulceration but no lymph node involvement (T4bN0M0) are associated with a 5-year survival rate of 45%.
- Stage IIIA: Patients with any depth lesion, no ulceration and 1 positive (micrometastatic) lymph node (T1-4a, N1a, M0) have a 5-year survival rate of 70%. T1-4a, N2a, M0 lesions (any depth lesion, no ulceration but 2-3 nodes positive for micrometastasis) are associated with a 5-year survival rate of 63%.
- Stage IIIB: Patients with any depth lesion, positive ulceration and 1 lymph node positive for micrometastasis (T1-4b,N1a,M0) or 2-3 nodes positive for micrometastasis (T1-4b,N2a,M0) have a 5-year survival rate of 50-53%. Patients with any depth lesion, no ulceration and 1 lymph node positive for macrometastasis (T1-4a,N1b,M0) or 2-3 nodes positive for macrometastasis (T1-4a,N2b,M0) have a 5-year survival rate of 46-59%.
- Stage IIIC: Patients with any depth lesion, positive ulceration and 1 lymph node positive for macrometastasis (T1-4b,N1b,M0) or 2-3 nodes positive for macrometastasis (T1-4b,N2b,M0) or 4 or more metastatic lymph nodes, matted lymph nodes, or in transit met(s)/satellite(s) have a 5-year survival rate of 24-29%.
- Stage IV: Melanoma metastatic to skin, subcutaneous tissue, or lymph nodes with normal LDH (M1a) is associated with a 5-year survival rate of 19%. M1b disease (metastatic disease to lungs with normal LDH) has a 5-year survival rate of 7%. M1c disease (metastatic disease to all other visceral organs and normal LDH or any distant disease with elevated LDH) is associated with a 5-year survival rate of 10%.

Please note carefully: The text referenced above also states "the 5 year survival rates by stage are stage I, 92%; stage II, 68%; stage III, 45%; and stage IV, 10%."

You noted one of the most important factors for litigation purposes is determining the stage of RM's condition when Dr. Gatsby removed the "skin tag" which, in fact, was melanoma.

Other key litigation factors are, of course, that Dr. Gatsby was practicing outside of his scope of expertise by removing the melanoma and that Dr. Gatsby threw out the removed specimen and did not send it to diagnostic pathology. I will outline my opinions on these matters.

The first issue is determining staging at the time of excision. It is critical to note that examination of the suspicious lesion by the physician removing the lesion and testing by a qualified pathologist is of the utmost importance with regard to treatment options and survival rates. Obviously, by the time RM was initially examined by Dr. Watson, who did an excellent job, it was too late for RM to expect a favorable treatment outcome. The time lag between the inappropriate excision by Dr. Gatsby and the initial examination by Dr. Watson was approximately 5 months.

In the text mentioned above it states that the appropriate technique for removal of a suspicious lesion of this nature is to do a wide excision and I will come back to this point.

The issue here is that there is now absolutely no way to accurately determine the stage of RM's melanoma when the lesion was excised. Based on the available data it is my opinion to a reasonable degree of medical probability there was an extremely high probability that the cancer was at worst an early stage III when it was excised giving RM a 45% chance of 5-year survival as opposed to the 10% chance of a 5-year survival with a stage IV malignant melanoma.

In fact, it is entirely possible, the cancer could have likely been a late-stage II type when the lesion was excised giving RM a 68% chance of a 5-year survival. None of the doctors at University Hospital or Methodist Medical Center noted enlarged lymph nodes on physical exam. Dr. Gatsby did not comment on enlarged lymph nodes either, indicating there is a very good possibility the disease had not spread to the lymph nodes at the time of the excision.

Wendy Bright, M.D. and her group wrote in a 2012 paper "Approximately 70% of cutaneous (on the skin) malignant melanomas are the superficial spreading melanoma (SSM) type and often arise from a pigmented dysplastic (abnormal but not cancerous) nevus (mole). SSMs typically develop after a *long-standing stable nevus changes* (my italics); typical changes include ulceration, enlargement, or color changes. A SSM may be found on any body surface, especially the head, neck, and trunk of males and the lower extremities of females." This paper clearly indicates that a melanoma, even though it can turn cancerous, **can remain limited to the skin for a "long-standing" period of time.** Given the 5-month lag time between excision and proper diagnosis it is my opinion that it is likely the lesion was limited to the skin when excised. If the cancer was limited to the skin and appropriate treatment had been started RM's prognosis would have vastly improved.

The next important issue is the way the lesion was removed. The text I have been referring to states "Guidelines for recognition of a high-risk lesion have been codified as the well-known ABCDE criteria: *A*symmetry, *B*order irregularity, *C*olor variegation, *D*iameter >6 mm, and *E*volution." In addition the text states **"Shave biopsies should never be performed on lesions suspected of being melanoma"** (author's bolding). The reason for this warning is that shaving the lesion off can actually lead to spreading the melanoma through the lymph system. **It is highly likely that Dr. Gatsby spread the cancer by removing it with a laser (**my bolding**).**

There are very specific recommendations with regard to how wide the margin of normal skin around the lesion should be when excised. Obviously, this issue was not addressed with the laser removal.

Finally, it is my opinion to a reasonable degree of medical probability that you should expect to encounter no reasonable argument to the fact that the dentist was performing outside his scope of accepted practice. The medical literature clearly states that before removal, the patient should have a total body examination and a careful skin examination which, of course, were not done. Also in this regard the literature states that suspicious lesions should be examined by a qualified dermatologist.

In summary, there is no question that you should have a very substantial theory regarding substandard care and it would be worth the time and expense at this time to bring in a nationally known medical expert to confirm my findings. I can assist you in finding a medical expert willing to further review the case and testify as an expert.

Please let me know if I can answer any questions for you.

Sincerely,

Armin Feldman, M.D.
MD Consulting Services LLC

References

Text Books:

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Malignant Melanoma Staging

Also of importance are the "Clark level" and "Breslow depth" which refer to the microscopic depth of tumor invasion.

Melanoma Stages:

Stage 0: Melanoma in Situ (Clark Level I), 99.9% Survival

Stage I/II: Invasive Melanoma, 85-95% Survival

- T1a: Less than 1.00 mm primary, w/o Ulceration, Clark Level II-III
- T1b: Less than 1.00 mm primary, w/Ulceration or Clark Level IV-V
- T2a: 1.00-2.00 mm primary, w/o Ulceration

Stage II: High Risk Melanoma, 40-85% Survival

- T2b: 1.00-2.00 mm primary, w/ Ulceration
- T3a: 2.00-4.00 mm primary, w/o Ulceration
- T3b: 2.00-4.00 mm primary, w/ Ulceration
- T4a: 4.00 mm or greater primary w/o Ulceration
- T4b: 4.00 mm or greater primary w/ Ulceration

Stage III: Regional Metastasis, 25-60% Survival

- N1: Single Positive Lymph Node
- N2: 2-3 Positive Lymph Nodes OR Regional Skin/In-Transit Metastasis
- N3: 4 Positive Lymph Nodes OR Lymph Node and Regional Skin/In Transit Metastases

Stage IV: Distant Metastasis, 9-15% Survival

- M1a: Distant Skin Metastasis, Normal LDH
- M1b: Lung Metastasis, Normal LDH

M1c: Other Distant Metastasis OR Any Distant Metastasis