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July 26, 2006

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Re: Response to Remarkable Testimony Website

Dear Dr. Blumstein:

In early January of 2006, I appeared in Harrisburg, PA as an expert witness in Emergency Medicine at a trial for a patient in a Civil Lawsuit against York Hospital and Lynn S. Jensen, M.D. At that time, as I do now, I felt strongly about the medical issues involved in the case, namely the approach to an acute cerebrovascular accident. Ultimately, the decision of the jury in this case was that Lynn Jensen, M.D. of York Hospital in York, PA did not commit medical malpractice. I remain quite convinced, however, that Dr. Jensen departed from accepted standards of care in treating this patient on 10/26/02 and I intend to explain why based on credible and accepted science.

First, however, I must question why on 6/29/06 the American Academy of Emergency Medicine (AAEM) published on its website a number of remarks called "Remarkable Testimony" which misrepresents the medicine, misrepresents my views and tries to make light of them, hardly mentions the physician who was accused of departing from the standards of care, yet mentions my name many times clearly. Is it an attempt to intimidate me and other physicians who might be willing to stand up for patients and the responsible practice of medicine? It greatly concerns me, as it should all responsible physicians, that the AAEM chose to publish their remarks without contacting me in any way, and only after posting their very subjective opinions, offered me the opportunity, which I now take, to correctly represent the medicine and the situation of the case at hand.

On 10/26/02 at approximately 8 a.m., this patient was sitting in the front of a bus next to her brother on the way to a religious retreat. At the time, the patient, sitting next to her brother, was singing along with other members of the group. Suddenly, she stopped singing and slumped

over on her brother. The bus immediately stopped, pulled off the road and the Emergency Medicine Services, namely the Pennsylvania EMS, was contacted for help. The incident was clearly defined and no time was wasted in contacting the EMS for their services. The EMS report, which all who practice emergency medicine are certainly aware of and use in our daily practice in addressing patient care, clearly notes that the EMS was dispatched at 8:14 a.m. for a chief complaint of a possible CVA.

The patient was brought by EMS to York Hospital in York, PA. They arrived at the facility at 9:03 a.m. York Hospital is a tertiary care medical center with many training programs. The patient arrived and was logged into the York Hospital Emergency Department by 9:14 a.m., and the care was taken over by the resident in training, staffed by Dr. Jensen, the staff emergency medicine physician responsible for the patient's care. Laboratory tests and a CAT scan of the head were ordered. The patient had left-sided weakness and left-sided findings and clearly had a cerebrovascular accident.

From Dr. Jensen's deposition, taken under oath on 8/23/04, it is apparent that the primary physician caring for this patient was a second year resident and because this occurred in October, it was a new second year (junior) resident. In his deposition on page 78, Dr. Jensen clearly states that his understanding of the time of occurrence of the stroke, namely 7 a.m., was taken from the resident's history and that he did not recall getting it directly from the patient. There is no question in my mind that the medical resident, in the beginning of his second year did not get the correct time, which in my mind is unquestionably sometime shortly after 8 a.m., not 7 a.m.. The patient was not on the bus for over an hour from the time of occurrence until the time EMS was dispatched (recorded as 8:14 a.m.) and the patient was at the hospital shortly after 9 a.m. It appears from Dr. Jensen's statements, the junior resident was the primary care provider. The staff physician, namely, Dr. Jensen, should have been very involved in determining the absolute history and times in this serious patient, or if prejudiced in some way, called a neurologist.

Once the patient was at the hospital, Dr. Jensen clearly states on page 93 of his deposition that he ordered the CAT scan "high priority". However, from testimony by Dr. Jensen and from the medical records reviewed at York Hospital, there is no evidence that phone calls were made to the radiology department to obtain results of the CAT scan as rapidly as possible, nor were calls made to the laboratory to obtain the necessary laboratory tests. On page 126 of Dr. Jensen's deposition, he was asked if there was anything special one could do to get results and CAT scans back for a patient being considered for tPA. He said, "No, there was nothing special other than ordering it at a high priority." Technically, the standard of care for physicians considering tPA is to alert, by telephone, radiology and the lab that thrombolytics (tPA) is being considered and then these tests are prioritized over all other tests and results can be obtained typically within 45 minutes. According to Dr. Jensen's deposition on page 133, the CAT scan was noted to have been performed at 10:06 a.m. Thus, the patient was clearly within the window of three hours and should have been considered for tPA therapy.

Nevertheless, despite having a two hour window remaining when the patient arrived at York Hospital, (incident occurred shortly before EMS was dispatched at 8:14 a.m., patient

arrives at hospital 9:03 a.m.), Dr. Jensen states on page 91 of his deposition that he felt that this patient was not in the three hour time window for tPA treatment, and that, "we had lingering concerns about the possibility of false negative CAT scan for intracranial bleeding." If, indeed, Dr. Jensen were truly concerned about a bleed, then ***the appropriate action would have been to perform a lumbar puncture,*** which is ***the standard of care for pursuing the possibility of a bleed if a physician suspects bleeding in the face of a negative CAT scan.*** Neither Dr. Jensen nor his second year resident performed a lumbar puncture. Therefore, it is disingenuous for Dr. Jensen to suggest that he was truly worried about an intracranial bleed. In addition, Dr. Jensen did not call a neurologist or any of the other professionals who would have fairly considered the possibilities of what should have been done for this patient. It might also be noted here, that when the patient was ultimately admitted, it was noted by the physicians attending her that she was at that point outside the three hour thrombolytic window, and thus, no longer a candidate for tPA. This suggests that even if Dr. Jensen and the ED department at York Hospital might not have believed in tPA therapy, certainly the rest of the hospital probably did; unfortunately for this patient, they were not promptly called to participate in her early care.

Dr. Jensen also suggests that it was felt that the patient could have been on coumadin and therefore tPA would not be an option. However, the patient was ***not*** on coumadin, the patient's clotting panel was normal, and so was the patient's CAT scan. In sum, it is my medical opinion that the new second year resident in the emergency department probably did not correctly get the time of onset of the patient's stroke, nor the medications being taken, and Dr. Jensen did not fulfill his responsibilities as the staff attending supervising the junior resident.

Yet despite the erroneous times and patient history, the patient was still within a three hour window to be considered for thrombolytic therapy with tPA. It is abundantly clear why Dr. Jensen did not consider thrombolytic therapy with tPA. In his deposition, Dr. Jensen was asked, "Had you received the results within the three hour time window, would she have been a candidate for tPA?" Dr. Jensen answered, "That would be highly controversial. In my judgment, no." On page 94 of his deposition, Dr. Jensen was asked why would it have been controversial and he replied, ***"Even the use of tPA for stroke, period, is highly controversial."*** It is apparent that Dr. Jensen was not going to give tPA to a patient, regardless of the times and therefore had no reason for supervising the care of this patient to make sure that the times were correct and that the procedures were done urgently. It was, and is, my opinion that when this patient presented to York Hospital, she was about one hour from onset of her stroke and clearly within enough time to actually deliver tPA to her by two hours if the doctors treating her truly had such an inclination. She was a clear-cut candidate for tPA without contraindications. Dr. Jensen's failure to allow her the opportunity to receive tPA denied her the possibility of greater recovery and possibly a complete recovery.

Clearly Dr. Jensen, the AAEM, and I disagree on the efficacy of tPA. It is important to note that tPA has been used for a long time, initially as one of the first drugs in cardiac patients with infarcts and ischemia, and after the NINDS studies at the NIH, for patients appropriately screened and selected with stroke; it has been used for more than ten years now.

I urge anyone who has read the remarks by the AAEM to look at the Google website for stroke and tPA. I have reviewed articles and abstracts from over 40 pages on Google for tPA and stroke, as well as peer reviewed articles in the leading medical journals. The results of that review shows that the following centers use tPA for appropriately selected candidates with stroke:

Centers using tPA

Harvard University Medical Centers
Johns Hopkins Medical Center
University of Rochester Medical Center
University of Pittsburgh Medical Center
Thomas Jefferson University Hospital
Mayo Clinic Medical Center
Stanford University Stroke Center
University of Texas Health Science Center at Houston
Massachusetts General Hospital
University of Cincinnati Health Center
Stony Brook Medical Center
Memorial Herman-Texas Medical Center
Robert Wood Johnson Medical Center
Beth Israel Deaconess Medical Center
UCLA Medical Center
Washington University School of Medicine
University of Iowa Hospitals
Medical Centers in Canada, Australia, and Europe
And more….

Several months ago, a pertinent review from the case records of the Massachusetts General Hospital as published in the New England Journal of Medicine in volume 354, 21 on May 25, 2006, pages 2263-2271, reported an excellent case review of a woman presenting with a stroke who advantageously was treated with tPA. My position is that tPA is appropriate therapy in selected patients without contraindications for treatment, who fit in the appropriate place for the NIH stroke scale, and who can be treated within three hours. This patient fit this profile. I recommend all who read this to look at the above recent NEJM report.

As a statistical group reported in the accepted literature, these appropriately selected and treated tPA patients have a better outcome overall than the untreated patients, and even when including the risk of bleeding, they still have, as a group, a better outcome and a lower mortality than the untreated group. This is what I stated in my testimony and your website inappropriately misrepresented. Additionally, tPA is also the only opportunity to reverse the natural outcome of patients with early stroke. It is possibly the only opportunity to prevent a patient from an outcome of diminished potential and a life of increased dependency. Some patients do improve

without this therapy, but the statistical evidence is that thrombolytic therapy, in appropriately chosen patients, improves outcome, decreases mortality, and is the accepted standard of care by the large, well-known, academic centers of excellence that I have previously noted. And speaking of other therapies, I must comment on the erroneous, misleading and out of context remarks published by the AAEM about page 50 of my testimony as it relates to my opinions regarding stroke therapies. ***Nowhere did I comment that aspirin or other platelet agents, medications, or occupational and physical therapy for stroke patients should not be used.*** These modalities of treatment are also what one expects as a part of good and comprehensive medical care for stroke patients. However, there is no question, that these modalities do not reverse or have the capacity to reverse ischemic compromised brain tissue at the molecular and histological level.

tPA is the only acute therapy accepted and approved for stroke patients if used correctly. The American Heart Association and the Neurology Associations in this country support it and tPA is considered the standard of care to the extent that neurologists using it do not require informed consent.

Much to my dismay, Dr. Jensen and the AAEM misrepresent my remarks from page 42 of my testimony, which in total represents the fact that tPA is the only therapy we have for stroke that may reverse the molecular and histological outcome. I stand by my testimony from page 48, and I urge all readers to research tPA and stroke and to particularly note all the academic centers of excellence where tPA is used. In fact, as a director for two emergency medicine departments, I have helped lead them to stroke certification, which includes the use of tPA; in both the State of New York and in the State of Maryland. I have treated a significant number of stroke patients with tPA. On the other hand, Dr. Jensen stated, under oath, that he had never treated a patient with tPA. I have seen some patients have a dramatic response with tPA, and have had only one patient who had a bleed, which was gastrointestinal, and the patient did well despite that.

tPA has been used for many years. It has risks like many other medications in use today. It should be used appropriately, but there is no question in my mind that at York Hospital, a tertiary care center, it could have been used appropriately for this patient.

Having served in the U.S. Army for 23 years, retiring as a full Colonel and former Chief of Emergency Medicine at Walter Reed Army Hospital, I take my responsibilities as a physician very seriously. As an expert witness, I have testified for patients that have not received, in my opinion, the appropriate standard of care, as well as defended physicians involved in unfortunate, but not negligent, bad outcomes.

What deeply distresses me is the AAEM's apparent attempt at character assassination of a physician who stands up for patients and does not automatically side with the physician. I do not understand the motivation of a "professional scientific organization" that takes testimony out of context and posts completely subjective comments on a website. For example, quoting me as stating "water is more dangerous than tPA," when in fact I said, "Too much water can also be dangerous," is nothing more than an attempt to divert attention from the real issue at hand. I said

nothing to diminish the potential adverse effects from tPA like any other drug or substance misused. Many other remarks that the AAEM chose to publish were also taken out of context from my statements and intent, misrepresenting what my beliefs are in an unfortunate attempt to make light of something that is serious.

Finally, again, I urge the people who read your initial "remarkable testimony statements" and then my response, to search out the data on tPA and understand the reason why the best medical centers of excellence and academic rigor in this country support the use of tPA in carefully selected, well chosen patients.

In closing, I assume that you will, as you said in your letter to me, post my response in its entirety.

Sincerely,

Ira Mehlman, M.D., FACEP, FACP