July 9, 2015

Rosemary Schnall, Esquire
White and Williams LLP
1650 Market Street
Philadelphia, PA 19103

Sarah Pulaski v.The Children's Hospital of Philadelphia

Dear Ms. Schnall:

I have had the opportunity to review this case in depth, the medical records, the depositions, the emails, and the blog postings of the parents. I have read in depth the report by Jean Sanders, M.D. I disagree with Dr. Sanders' opinion that this child did not receive good care.

There are very few givens when it comes to the world of Pediatric Oncology. We currently cure over 80% of these children diagnosed with cancer but that is not nearly enough. One thing for certain is there is no definitive treatment for these kids. It is still an art and a science to their therapy – there is not only one way that is correct to treat them, if there were there would be no clinical trials and we would all be treating them the same way. For all of us, our sole goal is to cure these young people of these devastating diseases.

The things I can tell you for certain are:

-T cell disease is a difficult entity and there is not a consensus on how to treat.
-It is more rare and more difficult to treat than B cell disease.
-When T cell disease recurs it is very difficult to cure.
-Most Pediatric Oncologist would consider clinical trials, especially sponsored through the Children's Oncology Group, comprised of the world's childhood cancer experts, and vetted through the NIH, as standard of care treatment.

The care this unfortunate child received conformed to the standard of care. The protocol was adhered to and chemotherapy was appropriately administered, with thought given to this being an individual and not just a number. There were times when Sarah's chemotherapy was appropriately held until her counts recovered.

The end of induction MRD allowed Sarah to stay on study. This fact however was not blindly accepted, but a further MRD study was done at the end of consolidation that was negative that was not required. A potential bone marrow donor was

sought in case this avenue was to be pursued, again not a requirement. Of note and not really discussed is that is child presented with a life threatening presentation of leukemia, hyperleukocytosis (white count around 500,000) – she was treated with the absolute best care and very cautiously, with leukopheresis, and survived her initial induction therapy without consequences of renal failure or other complications that can occur.

To address some specific issues:

Dr Rheingold is the Institutional PI for the 0434 protocol. This is a common position that each institution has for each protocol. She is not a member of the COG AALL0434 committee. She has nothing to gain by enrolling patients on this protocol. Although there is a small per case reimbursement, it usually does not cover the cost of data management. I see no conflict of interest.

The family feels they did not have enough time to review and read the consents. However, the consents were properly signed and dated. There were consent conferences noted and the chart reflects multiple discussions with the parents. The signature represents the parents' acknowledgement that all information contained in the consent was explained to the parents' satisfaction.

The family feels they asked for a bone marrow consult. Given that the treatment for Sarah was appropriate and within the standard of care, I do not believe such a consult was mandated under the circumstances. Although it may have been more comfortable for the family to have met with the transplant service, from reading the parents' blogs , the family appeared comfortable with the decision making .

It is always important that decisions are made with the knowledge of the entire team. It appears that the case was discussed multiple times at the proper Hematologic Malignancy Group conferences and the team was in agreement with the plan of care.

Sarah's translocation is a very rare translocation. There are case reports of this being a bad actor. Some of these are quite old and it is hard to say what the outcomes would be with more current/aggressive therapies. This translocation has not been pulled out by COG as a translocation that should be treated differently or more aggressively.

Published data on MRD is sometimes hard to interpret as most studies include patient with both T and B cell disease.

There are new clinical COG trials for T cell disease. I can tell you that in the current COG trial the treatment that Sarah received is very similar and would still be considered good care.. In the current trial if there is positive MRD at the end of induction, MRD is checked again at the end of consolidation (as was done with Sarah) – if it is less than 0.1% (Sarah's was <0.01%) the patient proceeds with

chemo, if greater than this they get intensified chemotherapy and the MRD rechecked yet again. By the current schema, even today, 5 years later, therapy would be similar to what she received. The care she received to me seems to be very good and compatible with the standard of care.

In summary, it is my opinion with a reasonable degree of medical certainty the care and treatment provided to Sarah Pulaski at CHOP met the standard of care. Sarah's death was the unfortunate outcome of her leukemia.

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