

Statement of Kristin S. Turner – May 18, 2004

Thank you for inviting me to testify at this very important hearing. I am sorry that I cannot attend in person but I have become ill and was unable to travel to Washington. I hope these comments are of some help to you as you consider these important matters.

In March of 2003, my life was forever changed because of the at best irresponsible conduct of a hospital and a biomedical equipment company. The focus of this hearing is not what happened to me, but rather why the hospital and company were allowed to engage in such dangerous practices.

There are 2 immediate things I hope are achieved through this hearing. First, I am not sure how much emphasis is being placed on the issues surrounding the Labotech. This is the instrument that in my view was designed poorly and dangerously, resulting in unreliability, inaccuracy, and injury. I am now aware that there have been international warnings issued regarding the lack of reliability of the results because of both mechanical and programming errors. Maryland General utilized 3 different Labotechs during the time of my employment, and all 3 consistently malfunctioned and failed runs. Adaltis, the distributor of the machines in use at Maryland General Hospital, was responsible for repairing the machines and many times each month sent people in to “fix” the machines, yet they were never able to be used for more than 2 or 3 days after each repair without having more problems.

The most frightening and consistent malfunction to occur with the Labotech was missed samples. Missed samples means that a patient’s sample was not dispensed onto the test plate, and therefore a negative result was obtained. In reality the machine never performed the test. The negative result obtained could possibly have been a “false negative”. There is no way of knowing how many “false negatives” have been reported to patients. The thought of patients being delayed prompt treatment and unknowingly spreading a disease they were just tested for because of a false negative is frightening.

The problems with the Labotech are not related to any individual instrument, the problem is in the design and the programming. Adaltis must be required (since they apparently haven’t taken the proper steps on their own) to remove every Labotech from service and hire an outside company to inspect each instrument for safety and reliability before it is allowed to be put back into use. There are over 2500 Labotechs currently in use in the US. The number of potentially inaccurate results being reported out to patients each day because of instrument malfunctions is staggering. Please take some action to protect the public from this machine. There must be more stringent requirements enforced before allowing an instrument like the Labotech to be released and put into use.

The second action I hope is taken is to make sure that better oversight is put in place for hospitals and hospital labs. The problems at Maryland General stemmed from a lack of accountability at every level in administration, and a grave disregard for the health and

safety of the people in the community. In the laboratory, one man was allowed to choose profit over patient safety and his actions were never questioned by his superiors; making them just as responsible for the multitude of problems that resulted from his decision. Patients were provided less than optimal care, and were provided results from a machine that he knew was unreliable and unable to be validated. He demanded that the results be run in house instead of sent out, even with the equipment problems, because the Labotech was the “money-maker” for the laboratory and to send out tests would have cost the hospital money. In my view his conduct was a betrayal of the communities trust which the administration allowed to continue.

He also refused to provide a safe environment for the employees in the lab. By refusing to replace a defective piece of equipment (the Labotech) and inform the employees of the seriousness and longstanding malfunctions, he knowingly placed employees in harms way. On March 12th, 2003, the instrument had a major malfunction exposing me to blood. I did everything I was instructed to do, from the protective equipment I was wearing to how I handled the malfunction, and the treatment following the exposure. However, in June, while hospitalized for a severe flu-like illness, my blood tests came back positive for both HIV and Hepatitis C (I tested negative on the day of the incident). My life has been irreversibly changed in every way imaginable. I only tell you this, because this incident could have been completely prevented. I learned only after the accident, that administrative director of the lab (James E. Stewart) was made aware of serious problems with the machine from the very first week it was brought into the lab. He also knew that the machine had never been safety tested or inspected by the hospital's own engineering staff. I later learned that on numerous occasions many of the laboratory staff requested that the machine be sent back and replaced by a different machine from a different company that was actually proven to be reliable and safe. Instead, another dysfunctional Labotech was brought in and put to use. If proper safety procedures were followed as set out by both the hospital and OSHA, after the extreme number of problems with Labotech, it should have been removed from service, long before I began my employment. Please don't let what happened to me, happen to anybody else with this or any other dangerous and defective piece of equipment.

What is particularly disappointing is Maryland General Hospital's response to this public health catastrophe. When its laboratory practices were first called into question, the hospital circled the wagons around Mr. Stewart and the other administrators who failed to do their jobs. They denied responsibility and awareness of the serious problems their lack of action caused. Also disappointing is the fact that following my complaint, the state found many more problems in the Laboratory than those I cited, yet Maryland General's Lab had passed all the accreditation and certification inspections that had recently been conducted. This flies in the face of all common sense and seriously calls into question the validity of the inspections and accreditation process established to insure public safety. The agencies responsible to insure the proper operation of hospital labs must also be held accountable and required to take responsibility for their failures and breach of the public trust. I fear the problem of lack of proper oversight is not a problem limited to Maryland General Hospital. New guidelines ought to be considered and/or the old ones enforced for the health and well being of every patient.

Thank you again for the opportunity to share my information with this congressional subcommittee. I have all of the confidence in the world that you will take whatever action is appropriate to help prevent these messes from occurring in the future in other hospitals and with other pieces of biomedical equipment. You have the power to prevent what happened in Baltimore and to me from happening anywhere else.

Sincerely,

Kristin Turner