In her own words: Kristin Turner’s safety crusade

By Carren Bersch, MLO Editor

After months of maintaining her privacy — other than testifying before the Congressional Committee on Government Reform — Kristin Turner agreed to tell MLO in writing about how her exposure to HIV and HCV after an equipment malfunction at the Maryland General Hospital (MGH) laboratory has changed her life and given her a new purpose.

From the time I began working with Adaltis’ Labotechs in the MGH immunology department, I reported my every complaint with mechanical or results problems. My frustration grew as problems continued. Time after time, technical support came to fix the machines; they still never worked properly. After my infection, the reality of the depth of problems became clear; they went far beyond my department, infiltrating the entire lab. In my opinion, abuse of power and privilege by some and they went far beyond my department, infiltrating the entire lab. In my opinion, abuse of power and privilege by some and reckless disregard for safety shown by the hospital and the machine’s manufacturer placed at risk both lab employees and the community the hospital was entrusted to serve.

By my reporting the problems, MGH came into the national spotlight. Since then, Congress acted, and investigations began into how labs are run and accredited, and who is responsible for quality assurance and safety. One of the best outcomes was the empowerment of all MGH employees to speak without worry of retribution.

Problems with the FDA’s reporting system

The role of the FDA (Food and Drug Administration) is to ensure the safety and accuracy of machines used in U.S. laboratories through its medical-device reporting system. Perhaps the most frightening information I uncovered in my search into why the Labotech was allowed into use is that lab analysts are never given a thorough FDA evaluation. The FDA relies on the manufacturer’s description and comparison to classify machines and approve them for U.S. use; the FDA conducts no testing of its own. The FDA primarily relies on the manufacturers to report all mechanical issues and “incidents” involving their machines, collects this information, and places it in a database.

The FDA relies on profit-motivated manufacturers to report problems and implicate their own machinery. Are the health and safety of lab workers and the patients who rely on them not important enough to require hands-on testing and analysis before approval for use? The only reports ever made to the FDA about the Labotech were by Adaltis, according to both, more than a year after the malfunction that led to my infection. The FDA May 18 testimony before Congress indicated that the Labotech (aka Personal Lab, ETI-lab, and other names) is a Class 1 medical device — the lowest classification — requiring only the same level of surveillance and quality-assurance testing as band-aids and gauze pads. The Class 2 and 3 tests run on the Class 1 Labotech deal with life-and-death diagnostics. This machine — responsible for measuring and dispensing of all patient specimens and reagents, incubation, washing, and reading/interpreting these test results — is not watched any closer by the FDA than a refrigerator or incubator.

I encourage everybody who works or has ever worked with any unsafe or unreliable lab machine/device to report it to the FDA, the manufacturer, and his state’s worker- and consumer-safety offices. Do not give up! You have the right and the responsibility to make the report directly to the FDA. I was not aware of that option.

Counting on the silence of lab workers?

Because of the documented problems with Labotech revealed during the last year’s investigation, Adaltis has become an example of how things work in the biotech manufacturing industry. According to Adaltis [May 18 congressional testimony], out of all Labotechs distributed [2,500 currently in daily use throughout the world, including 170 in the United States], the three at Maryland General were the only ones ever to show the serious and repetitive mechanical problems resulting in dangerous situations and questionable test results. In fact, the same problems encountered with the MGH Labotechs sparked a “national” warning to its users in Europe about the problems and possible false results after only four reports about the machine.

During the time Labotechs were used at Maryland General, at least eight fully trained med techs — with a few months’ to over 20 years’ experience — reported the same errors and malfunctions, seemingly mainly system problems. Our most common errors involved missing samples and misalignment leading to false negatives and cross-contamination. People need to be aware that the machines may make these errors so they can watch for them and stop runs. The outcome with the Labotech will serve as a precedent for ensuring the safety of lab employees working with all kinds of machines. The FDA, however, is convinced that its current system is effective.

The Labotech is technologically sophisticated, but we at
Maryland General witnessed it make consistent measurement, alignment, dispensing, and reading errors. Each error independent of the others made the results unreliable. Errors were not reported by the machine itself and were completely unknown by the med techs running the machine, leading to the possibility of faulty results being reported out — a fatal flaw in which the FDA is not yet interested. Why is Adaltis not required to make the machine safe and reliable? The Labotech idea is an excellent one — fully automated immunoassays. Is Adaltis being let off the hook because, according to them, no other reports have been made in North America? Are the FDA and manufacturers counting on lab workers’ silence in order to maintain their inaction?

The FDA, aware of these reports, still has not taken action to alert workers of possible problems in order that false results are not reported and malfunctions can be avoided. In “investigating” the Labotech issues in the United States, FDA representatives talked to the manufacturer and visited the Italian manufacturing site, but never talked to people who work with the machine daily. Why did they not inquire of those most obviously familiar with the lab equipment?

With Adaltis now in the forefront, it is very important for anybody who has ever worked with the Labotech and has ever had serious mechanical/technical/program issues or problems to report them as soon as possible to the FDA, Adaltis, and his own lab-accrediting agency. I would love to hear from MLO readers about their own experiences — good and bad — with the Labotech. The malfunction leading to my exposure/infection involved the machine dropping the wash head after picking it up at the beginning of the wash cycle. Have any MLO readers seen this happen? My goal is to get the FDA and Adaltis to understand that any “incident” or exposure involving a piece of medical equipment is extremely serious and needs to be followed up.

Adaltis claims that problems with the three MGH Labotechs were not reported to the FDA for more than a year — including my exposure and infection — because they were not serious enough. I was astounded; my exposure and subsequent HIV and HCV infection was not considered “serious enough” to report. I will die at least 25 years sooner than expected from complications relating to these diseases — unless I get hit by the proverbial bus. How callous not to consider that “serious enough.” What will it take for them to think it is?

No thought about whistle-blowing

I was persistent and never backed off from going through the MGH chain of command; as long as I was in the mix, I was not going to let the huge, gaping wound that was the MGH lab be covered over. It became obvious to me that Maryland General was not going to take any measures to make the lab a safe place to work nor to protect its patients, and I wish I had acted sooner in notifying other agencies. I was on medical leave due to the side effects of prescribed HIV drugs and was informed by an MGH letter to remain on leave until I could return to work. When my dental insurance card was refused, I learned I had been terminated because I had not been able to return to work. I knew I was being swept under the rug, which actually just made me more determined. I never thought about being a whistle-blower. Ultimately, I had no choice but to blow the whistle and go outside the hospital for help.

I encourage lab workers at any level to report hazardous situations/equipment to many people. Start with your direct supervisor; commit to following up and reporting to others in the organization or beyond if necessary. Keep documentation of every report you make and every conversation and phone call you have regarding the issue. Safety and health are more important than any job, and most organizations have “no retribution” policies for “whistle-blowers.” My advice is never give up until a situation is fixed.

I believe many good things can come from the actions taken to “fix” Maryland General. The federal government is looking into the accreditation procedures for laboratories nationwide. An anonymous hotline has been set up by CAP and other agencies to allow employees to report problems without fear. I have much confidence in Congressman Elijah Cummings and the attempts to set up national standards for laboratory testing, safety, and quality assurance. Congressman Cummings’ press release at www.house.gov/cummings sounds very promising. He is standing up for lab workers all over the nation.

Do the right thing

You mentioned my being a “hero.” In reality, I only did what was right. My life has become a mess. I am having problems with the HIV drugs and with finding a doctor to care for me through worker’s comp. I think about Maryland General and the patients who were put at risk. I am haunted by the malfunction and go over it in my mind every day. I know in my soul that I did everything possible to bring about changes and to create a safe environment for MGH employees and patients. I am hopeful that MGH can regain the trust of the community it serves. I am also hopeful that labs across the nation paid very serious attention to what occurred at MGH and will take necessary action before suffering the same fate.

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Lab workers have an opportunity to join together now and speak up on the local level and on the national level to the FDA, Congress, and other government agencies about changes that need to be made. I encourage every lab worker to write down his lab experiences, safety issues with any machines, and any other problems and/or solutions. When those problems are presented to Congress, solutions can also be presented. I hope MLO can help raise awareness of the need for every lab employee to “do the right thing,” whatever the personal cost, and to make it a point to be aware of government policies that affect his safety, patients, and ultimately his life. I think it is vitally important that lab workers stay informed.

I also think lab workers need a voice. Quite by accident, I have been put in that place. I am willing to fulfill that role. I have been given the opportunities to testify before Congress and to meet with the “movers and the shakers,” whom I believe will make changes when they hear from the lab workers themselves about what needs to be done. I suggest that everybody e-mail/write the appropriate congressman and the House Government Reform Committee. I would welcome copies of such letters to track the issues raised and problems reported. I would like people to write to me regarding the current focus on Labotech and other machine-related/safety issues so that I can share the information with Congress and other agencies when given the chance. I have created a new e-mail address specifically for this purpose: medtechvoice@yahoo.com.

Together, we can work to ensure that the lab is a safe place to work and a trustworthy part of the medical system.