

Subcommittee on Criminal Justice,  
Drug Policy and Human Resources

Opening Statement of Chairman Mark Souder

**Ensuring Accuracy and Accountability in Lab Testing:  
Does the Experience of Maryland General Hospital Expose Cracks  
in the System?**

May 18, 2004

Good morning and thank you all for being here.

Today's hearing will examine the investigation of lab deficiencies at Maryland General Hospital in Baltimore, Maryland.

Upon learning of these serious problems, Congressman Elijah Cummings, the ranking Democrat member of this Subcommittee, immediately requested the Subcommittee hold a hearing on this troubling situation.

During a 14-month period between June 2002 and August 2003, the Hospital issued more than 450 questionable HIV and hepatitis test results.

In July 2003, during this period, the hospital lab was inspected and accredited by the College of American Pathologists. CAP officials have assured the Subcommittee that their inspection standards were even more stringent than those required by the federal government. Yet, the inspection did not identify the ongoing deficiencies in lab testing.

Despite instrument readings showing that the test results might be inaccurate, managers at the hospital failed to act.

Similarly, state inspectors did not respond to a 2002 letter from lab workers who warned of serious and long-standing testing problems that put patients and employees at risk.

These problems weren't taken seriously until this year, when state inspectors investigated a similar warning letter in December from a former employee, Kristin Turner.

State officials have confirmed the existence of the 2002 letter. They said they took the allegations seriously but found them vague and did not discover the serious problems until this year.

Subsequent inspections by state officials, prompted by the whistleblower, showed that the

laboratory was in the midst of serious problems at the very time the accreditation inspection was conducted.

State inspectors concluded the lab was understaffed and “rife with equipment malfunctions” and state and federal inspectors later turned up pages and pages of violations of testing standards.

CAP has also since suspended its approval for two key laboratory divisions.

The complaint that led to these findings alleged that machinery used in HIV and hepatitis testing was not adequately maintained and that possibly erroneous test results were provided as a result. In all of these inspections, similar issues were identified concerning the management and quality assessment processes of the laboratory that were found to be deficient. Each oversight entity addressed these issues but did not inform all of the remaining involved parties of their findings. Therefore, each oversight entity did not have the benefit of the findings of the others.

Only after the December 2003 complaint to the State survey agency that pinpointed a specific problem area to investigate did the entities involved begin to communicate their findings to each other.

Fortunately, the hospital has retested many patients and found the original results were mostly accurate and steps have been taken to ensure patients are now receiving reliable test results.

Yet many questions remain about the full scope of this particular situation as well as the potential for similar problems to occur elsewhere.

The purpose of this hearing, therefore, is to gain a better understanding of all of the issues that led to the deficiencies at MGH and how these problems went undetected and not addressed for such a long period of time despite inspections and warnings from lab personnel.

Our goal is to make sure that a similar situation never happens again at other hospitals and that patients can be assured that when they visit a hospital and have tests taken that the results they receive are accurate and reliable.

We also want to be sure that all those adversely impacted by the problems at MGH are identified and given proper test results.

Our first panel will include Dr. Steven I. Gutman, the Director of the Office of In Vitro Diagnostics Device Evaluation and Safety of the Food and Drug Administration, and Dr. Sean Tunis, the Chief Clinical Officer and Director of the Office of Clinical Standards and Quality at the Centers for Medicare and Medicaid Services.

Our second panel will be Ms. Teresa Williams, a former employee of Maryland General Hospital. Ms. Kristin Turner, another former employee of Maryland General Hospital, was also invited to attend but is unable to attend today’s hearing due to illness.

And our final panel will feature Mr. Richard Eckloff, of Adaltis US Inc., Dr. Ronald B. Lepoff, Chair of the Commission on Laboratory Accreditation at the College of American Pathologists, Mr. Edward Notebaert, President of the University of Maryland Medical System, and the Honorable Nelson Sabatini, Secretary of the Maryland Department of Health and Mental Hygiene.

Thank you all for being here today. We look forward to your testimony and insights on this very important issue.