

Subcommittee on Criminal Justice,
Drug Policy and Human Resources

Opening Statement of Chairman Mark Souder

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

July 7, 2004

Good morning and thank you all for being here.

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

At the request of the ranking Democratic member of this Subcommittee, Congressman Elijah Cummings, we held a hearing on this topic May 18, but due to time constraints we were unable to complete the questioning of our final panel. Today, we welcome back that panel of witnesses as well as Kristin Turner, a former lab worker at Maryland General Hospital who was unable to attend the May 18 hearing due to illness.

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

During this period, in July 2003, 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.

The problems at Maryland General Hospital weren't taken seriously until this year, when state inspectors investigated another warning letter, sent 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.

The College of American Pathologists 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. Yet the College of American Pathologists did not even receive the 2002 lab workers complaint until the day prior to this Subcommittee’s first hearing on this matter in May.

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.

State and federal regulators are now overseeing Maryland General’s efforts to improve its laboratory operations.

A state Medicaid fraud investigation and a federal investigation by the Department of Health and Human Services’ Office of Inspector General are also ongoing.

The purpose of this hearing, therefore, is to gain a better understanding of all of the issues that led to the deficiencies at Maryland General Hospital 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 Maryland General Hospital are identified and given proper test results.

Our first panel will be Kristin Turner, former employee at Maryland General Hospital.

The second panel will include Mr. Edmond Notebaert, President of the University of Maryland Medical System, Ms. Carol Benner, Director of the Office of Health Care Quality for the state of Maryland and Dr. Mary E. Kass, President of the College of American Pathologists.

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