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Ranking Minority Member
Subcommittee on Criminal Justice, Drug Policy and Human Resources
Committee on Government Reform
U.S. House of Representatives
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Hearing on “Part II: Ensuring Accuracy and Accountability in Laboratory Testing: Does the Experience of Maryland General Hospital Reveal Cracks in the System?”

July 7, 2004

Mr. Chairman,

Thank you for holding this second hearing to examine issues related to the release of invalid HIV and hepatitis tests to hundreds of patients at Maryland General Hospital in Baltimore City. This subject is extremely important to my constituents who, like myself, receive health care from Maryland General Hospital. I appreciate your taking an interest in this controversy and the broader oversight issues it raises for Congress.

In May, we held our initial hearing to look into allegations, first reported by the Baltimore Sun in March, that Maryland General Hospital released more than 450 invalid HIV and hepatitis test results from June 2002 to August 2003, despite error messages from the testing instrument indicating that the results might be incorrect.

On May 18th, we heard testimony from the FDA concerning the process for approving the Adaltis Labotech device that produced the invalid test results and from the Centers for Medicare and Medicaid Services concerning implementation of federal regulations to ensure accuracy and accountability in lab testing. We also heard compelling testimony from Teresa Williams, a former laboratory technician and supervisor at Maryland General, who made numerous attempts to call attention to deficiencies in laboratory operations, ultimately to no avail.

On the last of three panels, we heard statements from representatives of the parent institution of Maryland General Hospital, the private accrediting body responsible for federally certifying the Maryland General laboratory, Maryland’s Department of Health and Mental Hygiene, and the manufacturer of the Labotech testing instrument.

Because of time constraints we encountered during the final panel, our questioning was cut short. Today’s hearing provides an opportunity to continue the dialogue we began in May. We are joined today by Edmond Notebaert, President of the University of Maryland Medical System, Carol Benner, Director of the Office of Health Care Quality for the state of Maryland, and Dr. Mary Kass, President of the College of American Pathologists.

Today’s hearing also gives us an opportunity to hear from former Maryland General employee Kristin Turner, who was unable to attend the hearing in May because of poor health.

Ms. Turner is responsible for bringing the Maryland General lab testing problems to light. I salute her for her courage in coming forward, and I'm pleased that she is able to join us today to share her experiences and perspective.

Although the events that initially caught the Subcommittee's attention occurred at a single hospital in Baltimore, Maryland, they have implications for health care consumers across the nation. My goal in requesting these hearings is to ensure that nothing like what occurred at Maryland General happens again anywhere in the United States.

Fortunately, in the case of Maryland General, 99% of those who received invalid tests had their original test results confirmed. But we cannot rely on luck as a public health safety net when lives are in the balance.

The American people are entitled to have faith that the laboratory tests that help to determine the course of their medical treatment are as reliable and accurate as they can possibly be. That is the promise set forth in the Clinical Laboratory Improvement Amendments Act and we must ensure that the regulatory system established to enforce CLIA is adequate to fulfill that promise.

Sadly, the case of Maryland General appears to be one in which laboratory supervisors not only failed to ensure that proper quality controls were in place but also deliberately altered or concealed information that would have led to the discovery of invalid test results being released to patients. Moreover, employees who expressed concerns about inadequate quality controls and unreliable results were discouraged from expressing their concerns within and outside of the hospital.

It shocks the conscience that health professionals would deliberately engage in conduct that clearly places the lives of patients at unnecessary risk, but it is equally disturbing that the process for detecting deficiencies was so easily circumvented.

One would hope that such abhorrent conduct by laboratory personnel is rare, but the system of enforcement should account for the fact that there may be bad actors in hospital management positions who will seek to conceal evidence of serious lab deficiencies from inspectors. It is far from clear to me that the system in place does this adequately.

Each of our witnesses is in a position to provide an informed perspective on what gaps in the system may exist and how they can and should be addressed. I thank all of our witnesses for their appearance before the Subcommittee today and look forward to their candid testimony.