

**WRITTEN TESTIMONY  
BEFORE THE HOUSE  
GOVERNMENT REFORM  
SUBCOMMITTEE ON CRIMINAL JUSTICE,  
DRUG POLICY AND HUMAN RESOURCES  
REGARDING MARYLAND GENERAL HOSPITAL**

**BY**

**Edmond F. Notebaert  
President and Chief Executive Officer  
University of Maryland Medical System  
May 18, 2004**

Good morning Chairman Souder, Congressman Cummings, Members of the House Government Reform Subcommittee on Criminal Justice, Drug Policy and Human Resources, and other distinguished government officials.

Thank you for allowing me to speak with you today. My name is Edmond F. Notebaert. I am the President and Chief Executive Officer of the University of Maryland Medical System, which is the parent organization of Maryland General Hospital. I have been the President and CEO of University of Maryland Medical System, which I will refer to as "UMMS," since September 1, 2003. Prior to joining UMMS, I served as President and CEO at Children's Hospital of Philadelphia Health System for 13 years. During my tenure, The Children's Hospital of Philadelphia was transformed from a small, regional inpatient facility into the number one ranked Children's Hospital in the world. Together with my management team, the hospital developed a first-class reputation for quality and expanded its patient base and its research funding, while operating in a fiscally sound manner. I have more than thirty years of health care management experience in urban hospitals.

I would like to address the issues currently surrounding Maryland General Hospital. Specifically, I have come here today to discuss with you what we at UMMS have learned about what happened at Maryland General Hospital's laboratory, what the response has been to what happened, and what has been done to ensure that it does not happen again.

When UMMS first became aware of the issues at Maryland General Hospital in early March, the response was immediate, decisive and comprehensive. On March 8<sup>th</sup>, the very first day Maryland General Hospital executives revealed the problems, Mike Mullane, UMMS' Vice President, Strategy & Corporate Operations, one of the System's top executives, was assigned the responsibility to lead the System's team in understanding and addressing all of the issues

identified by the regulatory agencies at Maryland General Hospital. Mike met with Maryland General Hospital's management daily and remained on site well into the evening for the first six weeks in an effort to identify and remedy problems in the laboratory's operations and processes. He continues to be involved on a daily basis.

Within 5 days of learning about the situation at Maryland General Hospital, UMMS decided to bring in a lab management company, and within 10 days, we identified and hired Park City Solutions ("PCS"), the leading laboratory consulting and management services provider in the United States and Canada, to provide lab management services to Maryland General Hospital. Recognized for its innovative vision and ability to execute business solutions in the healthcare industry, PCS has supported more than 850 healthcare systems in the United States and Canada, provided services to over 1000 laboratories, conducted more than 85 compliance audits for hospitals and independent laboratories, and provided compliance training for more than 3,000 laboratories and internal auditors. PCS took over the operation of the lab on March 19th, just 16 days after the state issued its report citing deficiencies in the laboratory. As part of the System's comprehensive approach, we hired PCS to not only fix the identified deficiencies, but to conduct a top to bottom review of the laboratory and fast-track the implementation of any necessary changes. We rejected taking any sort of band-aid incremental approach.

During their first week at Maryland General Hospital, PCS brought in a lab administrator and two technical experts. Shortly thereafter, they recommended additional people be brought in and in fact, we told them to bring in whomever they needed. We gave PCS broad authority to take all necessary action to understand and address Maryland General Hospital's laboratory issues. In addition to providing an initial assessment of the situation and addressing problems as

they are identified, PCS administers the laboratory operations on a day to day basis, which includes placing specialists to oversee each and every section of the laboratory, implementing new policies and procedures, putting in place a system of quality, and providing training to the laboratory personnel to ensure their competency. As issues are resolved and tasks completed, their presence will decrease. However, for the indefinite future, PCS will be retained as the laboratory administrator until all issues are resolved and Maryland General Hospital has the lab staff and management that embody the culture of quality that we stand for.

Quality is the single most important goal of University of Maryland Medical System. Our own review has shown that there were insufficient quality controls and quality improvement processes in the Maryland General Hospital laboratory. Retesting has confirmed that the original test results were overwhelmingly accurate. Rather, it was that the quality processes that validate the tests' accuracy and provide integrity to the results that were below the standards we would expect.

Over the last few weeks of the investigation, we have learned a great deal. First and foremost, there was a breakdown in Maryland General Hospital's policies and procedures, adherence to those policies and procedures, and management reporting systems. Moreover, apparently, even when problems were brought to the attention of management, they were not sufficiently addressed. That response is not acceptable.

UMMS also found that the supervisory structure was poorly defined, certain laboratory supervisory staff did not take responsibility, hospital management was not sufficiently involved, salaries were not competitive and staff was not as well trained in quality assurance processes.

The various steps that are being taken, including working with PCS, are bringing immediate and positive change to Maryland General Hospital. Sometimes, bad things happen at good hospitals. Maryland General Hospital is, and will continue to be, a good hospital providing services to members of the surrounding community who need and deserve quality health care. Indeed, our objective for Maryland General Hospital is to provide first class lab services that will be a model not only to our other hospitals, but also to labs elsewhere.

I can and want to assure you that the Maryland General Hospital lab is fully operational today, that its results are accurate and its personnel are competent. PCS is finalizing the documentation and quality improvement processes that will make this lab a model for others.

Let me give you one example of the quality improvements that we are instituting. Federal and state regulations require quality controls to be reviewed on a periodic basis. I understand that most labs interpret this periodic requirement to mean on a weekly, monthly or even a quarterly basis. We have taken it a step further. Our lab director is conducting these reviews every single day and will continue to do so until we have absolute assurance of accountability and responsibility at all levels.

Maryland General Hospital voluntarily implemented a patient notification and retesting process to locate, notify and retest every patient and employee who had been tested on the Labotech machines at Maryland General Hospital. Maryland General Hospital, in an effort to be comprehensive, responsive and sensitive to the community, expanded its testing well beyond anything that was required by any regulatory agency. There were two “phases” in which patients were identified for retesting. Phase I began with the identification of all individuals who may have received testing on a Labotech machine on which the proper quality control measures were

not followed and who were the focus of suspected invalid runs by the state. Based on that criteria, approximately 460 patients were identified. Later in March, when PCS determined the extent of the Labotech quality control issues, Maryland General Hospital implemented Phase II and identified all individuals tested for HIV and Hepatitis during June 2002 – August 2003 on any Labotech machine. During Phase II, again in an effort to be comprehensive, approximately twenty two hundred individuals were identified, although many of those patients had test results where quality controls were not at issue.

Maryland General Hospital continues to go to great lengths to locate and contact all patients who were identified as having been tested on the Labotech machine. Specifically, for all patients identified, the Hospital sent 2 letters to these patients, one by regular mail and one by certified mail to the patient's last known address. These letters informed the patients to contact a toll free number (which was established to receive calls from anyone who had questions about a test they received at the Hospital, or from anyone who received the letters) for instructions on how to receive free testing. In addition, letters were sent to all ordering physicians and many physicians were personally contacted to explain the retesting program. The Hospital also engaged Hospital Support Services, a Medicaid eligibility service, and private investigators to assist in locating patients and to offer these patients the opportunity to be retested. Numerous newspaper and radio ads were placed in a variety of newspapers and on a number of radio stations on multiple occasions. Finally, a Community Outreach Manager was hired in March, and has made contact with many community organizations, including HealthCare for the Homeless, Total Health Care, Our Daily Bread, and Chase Brexton Health Center, to assist the Hospital in locating and notifying patients of the retesting program. We will, however, not rest until all individuals originally tested have had the opportunity to be retested.

As of May 13, Maryland General Hospital has successfully contacted the vast majority of all Phase I patients and a significant number of Phase II patients. The vast majority of tests have been reconfirmed. In particular, 99.6 % of HIV test results have been reconfirmed to be consistent with the original tests. What this means is that while the quality control processes within Maryland General Hospital's laboratory were not up to our standards, this circumstance did not result in significant mistakes in the actual testing or the test results thus far. In fact, we are fairly confident that external factors, such as subsequent exposures, account for the different results in the few cases where there has been a difference. In addition, it is important to keep in mind that there is a margin of error rate for all laboratory tests that is generally accepted by the industry and regulatory agencies.

Our comprehensive approach to change at Maryland General Hospital goes far beyond the laboratory. It includes changing the existing culture and instituting a new management philosophy there and throughout the System overall. While we still support the important principle of keeping community orientation at each of our community hospitals, the individual hospitals will now operate more as an integral part of a larger System, creating more collaborative relationships and instituting greater accountability. This will require hospital executives to report certain identified issues to the appropriate individuals within their organization and to the System and to follow up and monitor the results to assure that issues are resolved properly within a reasonable period of time.

More specifically, we also have implemented specific changes in reporting mechanisms at the System level, Maryland General Hospital level, and the laboratory level. Specifically, at the System level we have created new reporting systems so that the System's management is

made aware of certain issues identified at a facility. For example, we now require that all surveys and reports issued by third parties, including regulators and accrediting agencies, be submitted to the corporate office for our review. We also have created and are publicizing an e-mail address that employees may use as a means to report issues directly to me if their internal reporting mechanisms have failed in some way.

We also are replacing certain members in senior management, including the CEO at Maryland General Hospital, with individuals who reflect this new management philosophy and who understand accountability. Specifically, we envision the new management personnel to be aggressive and ambitious in achieving quality outcomes, able to see the potential in the organization and anxious to facilitate that potential, and fully engaged in taking the resources available to make all of our hospitals the best they can be.

In addition, Maryland General Hospital's Board is changing in many ways. Historically, Maryland General Hospital's Board and management were proud of Maryland General Hospital's legacy. When Maryland General Hospital became affiliated with UMMS in 1999, Maryland General Hospital asked, and we agreed, in respect of Maryland General Hospital's history and professed community orientation, to maintain for three years Maryland General Hospital's existing Board and management.

Since the end of that three-year period, in an effort to accelerate positive integration between UMMS and Maryland General Hospital, as well as the Maryland General Hospital community, we have appointed a number of individuals whose main interests are improving Maryland General Hospital's service to the community. Indeed, as soon as the System could impact Maryland General Hospital's board, we appointed Jerry Lymas who is sitting here with

me today, Ken Harris, a Baltimore City Council member and H. Mebane Turner, Ed.D., the former President of the University of Baltimore. Mr. Lymas is currently serving as the Chairperson of Maryland General's Community Development Committee, and, in that capacity, has begun economic development partnerships with local minority owned financial institutions and the Coppin State College Helene Fuld School of Nursing located in West Baltimore. In addition, Maryland General Hospital has hired a new Community Outreach Manager, Keith Hobbs. Mr. Hobbs has been initiating meetings with dozens of community organizations, churches, not for profit agencies, government officials, providers and other entities to expand the dialogue with such community organizations and promote partnering opportunities, including health fairs and screening programs. Overall, we believe that these efforts are beginning to bear fruit and will prove to be the foundation for stronger ties between Maryland General Hospital and the community in the future. We believe that these changes will bring diversity and differing perspectives to Maryland General Hospital's governance and staff, and will ensure that Maryland General Hospital's focus is serving its community with the high level of quality care that it deserves.

At the Maryland General Hospital management level, in addition to interviewing for a new Chief Executive Officer who will implement the new management philosophy, we have assigned a new and well-respected Medical Director, Glenn Robbins, M.D. who we handpicked from one of our other facilities. He was the senior vice president and medical officer at another UMMS hospital and we have enormous confidence in his ability. In fact, in the past year, he has begun developing System-wide quality measures and a set of hospital-wide quality indicators. His first task is to work with Maryland General Hospital's Board to facilitate a hospital-wide assessment of all quality improvement systems and to implement immediate action to correct any

identified deficiencies. In addition, we have created new reporting relationships and data elements that must be reported in an effort to create sufficient redundancy so that identified issues are brought to the appropriate person's attention. The Maryland General Hospital Board will now receive more timely and accurate information to enable them to fulfill their oversight responsibilities.

Finally, at the laboratory level, there have been significant changes in personnel and processes to ensure that appropriate quality control is in place. As previously discussed, PCS has been engaged to enhance quality within the laboratory, operate the laboratory on a day to day basis, review and revise policies, procedures and processes within the laboratory, perform equipment validation, supervise each section of the laboratory, and train laboratory personnel. In effect, PCS will remain in charge of the laboratory until it has implemented necessary processes and trained personnel so that they are fully competent to perform their job functions. The Maryland General Hospital Board also appointed Dr. John Braun as the new Laboratory Director and Technical Supervisor. His job duties will include oversight of the quality and compliance of the laboratory. We have redesigned the supervisory structure to eliminate any structural ambiguity and ensure clear accountability.

All new laboratory personnel will be trained, and annual training will be conducted for all existing personnel. Maryland General Hospital is actively recruiting new lab personnel and is impressed with the quality and quantity of the candidates<sup>1</sup>. We also are implementing incentives to encourage laboratory personnel to remain at Maryland General Hospital.

---

<sup>1</sup> To date six new medical technologists and eight phlebotomists have been hired. We are also recruiting a full time quality assurance professional and a laboratory technical supervisor. This is the result of a comprehensive staffing analysis and comparison to local and national benchmarks.

As I stated earlier, what happened at Maryland General Hospital does not meet the quality expectations that we have set for the University of Maryland Medical System. A breakdown in quality control processes is unacceptable both in your eyes and mine. I assure you, however, that Maryland General Hospital is an excellent hospital whose goal is to provide quality care to the community it serves. I believe that the issues identified have been responded to in an immediate and decisive way. We have implemented, and will continue to implement, significant changes at the System level, Maryland General Hospital level and laboratory level to assure that the lab and Maryland General Hospital will be a model for the System, the state and the country and a true partner in the health and well being of the community it serves.

Thank you for allowing me to speak with you today.