



*Advancing Excellence*

Statement to the  
Subcommittee on Criminal Justice,  
Drug Policy and Human Resources,  
Committee on Government Reform,  
U.S. House of Representatives

Hearing on HIV and Hepatitis Testing  
At Maryland General Hospital

Statement Presented by  
Ronald B. Lepoff, MD, FCAP  
Chair,  
Commission on Laboratory Accreditation  
College of American Pathologists

May 18, 2004

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The College of American Pathologists (CAP) is pleased to appear before the Subcommittee on Criminal Justice, Drug Policy and Human Resources for its hearing on HIV and hepatitis testing at Maryland General Hospital. The CAP thanks the subcommittee's chairman, Rep. Mark Souder, R-Ind., and Rep. Elijah Cummings, D-Md., the ranking member, for recognizing the need to ensure the highest quality laboratory testing.

The College is a medical specialty society of nearly 16,000 board-certified physicians who practice clinical or anatomic pathology, or both, in community hospitals, independent clinical laboratories, academic medical centers and federal and state health facilities. The CAP inspects and accredits more than 6,000 laboratories worldwide. The College has deemed status from the Centers for Medicare and Medicaid Services (CMS) to inspect laboratories on behalf of CMS to ensure compliance with the Clinical Laboratory Improvement Amendments of 1988 (CLIA).

**2003 Laboratory Inspection at Maryland General Hospital**

In April 2003, a 13-member CAP inspection team, acting on behalf of CMS, conducted a required, biennial inspection of the laboratory at Maryland General Hospital (MGH). The multi-disciplinary team used a 2,100-item checklist to guide its evaluation of the laboratory. A copy of that checklist has been provided to the subcommittee. The inspection team cited the laboratory with nine deficiencies, including failure to carry out its quality improvement plan as designed and failure of the laboratory's medical director to monitor standards of performance and quality control. The College gave the laboratory 30 days to remedy the deficiencies or face possible revocation of its accreditation. Subsequently, the laboratory attested and provided documentation to show that it had corrected the cited deficiencies, including the issues surrounding its quality assurance plan. Only after evaluating this documentation, did the CAP re-accredit the MGH laboratory. This documentation has been provided to the subcommittee.

In hindsight, however, it is clear that quality assurance issues and extensive employee complaints about MGH extend back to 2002, when Theresa Williams filed her formal complaint with the state of Maryland. The CAP only yesterday obtained a copy of this letter, which documents many troubling allegations. The complaint alleges that the laboratory routinely failed to monitor quality controls and instrumentation; falsified federally required proficiency testing results; failed to follow manufacturer instrumentation protocols; and reported patient results on runs for which quality control checks failed. These violations, had they been substantiated, almost certainly would have led to revocation of CAP accreditation and, possibly, additional penalties by CMS.

The state subsequently received the December 2003 complaint that alleged improper alteration of quality control results for HIV and hepatitis testing.

In response to that complaint, the state inspected the MGH laboratory in January 2004 and found that laboratory personnel improperly altered quality control values on reports produced by the instrument when initial reports indicated values outside an acceptable range. This improper practice would have concealed the quality control problems from the CAP inspectors, who, in 2003, would have relied on examination of the quality control reports and interactions with laboratory personnel to detect problems. The College believes that absent self-reporting by laboratory personnel, receipt of a complaint or specific information on tensions in the laboratory, no inspection team would have uncovered the quality control issues based on a standard review of quality control records because those records had been altered.

### **The Vital Role of Self-Reporting**

While the College believes the Maryland General Hospital case is unique, it underscores that self-reporting of quality control concerns by laboratory personnel is critical to the inspection process. The College commends the laboratory personnel who came forward in the MGH case. They did the right thing. According to press reports, laboratory personnel repeatedly complained about the quality issues to laboratory management, who failed to address their concerns, and filed two formal complaints with the State of Maryland. Both the state in 2002 and CAP in 2003 cited the laboratory director with a specific deficiency related to quality assurance. However, regrettably, neither the state in 2002 nor CAP in 2003 uncovered the serious quality control issues specific to HIV and hepatitis testing because the issues were concealed from inspectors.

This case highlights the fact that no inspection can identify every possible deficiency and that federal, state and private accrediting bodies must promptly share complaint information. Multiple levels of oversight and review are necessary, including the laboratory inspection, proficiency testing, responsible laboratory quality assurance management, and self-reporting by laboratory personnel. In any given laboratory inspection, only a subset of laboratory processes may be examined and only a sample of quality control data, studied in detail. Therefore, it is critical laboratory personnel be able to interact openly and identify issues for inspectors without fear of retaliation from their employers.

In this case, the laboratory personnel report working “beneath a cloud of fear” and, according to reports, remained silent even when the state inspectors were onsite in 2002. We do not know why laboratory employees did not disclose this to our inspectors in April 2003. We can only speculate that employees were too intimidated by laboratory management to convey their concerns to the inspection team. The College routinely receives complaints and investigates each one. In the past three years, the College has received 272 complaints from various sources, including laboratory personnel and state governments. The CAP will examine ways it can encourage laboratory personnel to more readily share information regarding laboratory deficiencies.

We also believe more must be done to ensure that employees can reveal complaints to accrediting organizations without fear of retaliation from their employers. Specifically, the CAP believes the whistleblower protections outlined in patient safety bills pending in Congress should be extended to complaints filed with accrediting organizations.

### **Communication is the Key**

The College believes it is critical that governmental agencies develop and utilize clear protocols for communicating with private accrediting bodies in a timely manner regarding complaints so that private accrediting organizations can meet their obligations.

The College recognizes that communication is a two-way street and that we need to do our part to communicate with state and federal agencies. The College has a record of successful collaboration with state governments, the federal government, and private accrediting organizations. We routinely receive complaint referrals from state governments and investigate every one. The College wants to work with the State of Maryland on a protocol for sharing information on laboratory complaints consistent with agreements the College has in other states. We have scheduled a June 17 meeting with Secretary Sabatini to discuss these issues.

### **The College Response to the MGH Complaint**

Once the College became aware of the problems at MGH, it took various actions to address the issues at the hospital’s laboratory:

- First, it examined the reports from the 2003 and 2004 MGH laboratory inspections conducted by the CAP, the state, CMS and Joint Commission on Accreditation of Healthcare Organizations (JCAHO).
- Second, informed by the findings of these investigations, the College scheduled a focused re-inspection of the MGH laboratory in April 2004. The findings of that re-inspection have been communicated to the laboratory, the state of Maryland, CMS and JCAHO. The CAP required the laboratory to respond to and correct each deficiency.

- Third, based on its April 2004 re-inspection, the College has denied accreditation for several areas of the MGH laboratory.
- Fourth, the College has notified MGH officials that it will conduct an unannounced inspection sometime before May 25, 2004.

### **Value of CAP Accreditation**

State officials have raised questions about the College's designation of the MGH laboratory as "accredited with distinction" following the April 2003 inspection.

The College believes its designation has been misinterpreted as being the highest rating on a multilevel, graded scale. But the College does not grade laboratories on a qualitative scale from poor to excellent and, in fact, recognizes only two accreditation levels: meeting basic CLIA standards or meeting the College's additional standards to merit accreditation with distinction. The "accreditation with distinction" designation recognizes that CAP accredited laboratories adhere to additional College standards that exceed those mandated by CLIA and are, therefore, "distinct" from federal standards. Specifically, the CAP requires laboratories it accredits to:

- Participate in proficiency testing three times a year for all tests done in the laboratory, not just regulated tests, as required by CLIA.
- Document correction of all deficiencies within 30 days of an inspection, compared with up to 12 months for some deficiencies under CLIA.

For a number of reasons, the CAP revokes the accreditation of few laboratories. Laboratories voluntarily choose CAP accreditation and many do not enroll in the College's program due to the stringency of the requirements. CAP accreditation is recognized as requiring a greater commitment of time and resources than required for compliance with CLIA. Further, among the laboratories that do enroll, many fail to pass their CAP inspection, withdraw and seek accreditation from either CMS or another accrediting organization. For example, in 2003, out of 294 new laboratories, 48 withdrew from the CAP program before accreditation. Revocation of a laboratory's accreditation is rare among all accrediting entities, private and governmental, since revocation for hospital laboratories would have the effect of closing not only the laboratory, but the hospital as well. Corrective measures, such as demands for corrective action plans and sanctions, are applied more routinely.

CMS annually monitors the quality of CAP inspections to ensure they meet federal standards. To do this, CMS conducts validation surveys of a sample of CAP-accredited laboratories to evaluate whether those laboratories meet federal standards. The College's record with respect to these validation surveys has been very good.

CMS recognizes the inherent variability of inspections and permits a reasonable level of disparity, up to 20 percent before a CMS review is triggered of the deemed status of any

accrediting organization. In the past five years, the College's disparity rate has ranged from a low of 1 percent (1997) to a high of 9 percent (1999). The College's most recent disparity rate was 7 percent in 2002.

### **College Recommendations**

The College is committed to enhancing its processes and working with state and federal authorities on other steps to prevent or reduce the likelihood of events such as those at MGH. To that end, the CAP will:

- **Modify its inspection and accreditation process to promote self-reporting by laboratory staff of performance deviations.** Possible tactics to accomplish this include:
  1. establishing a toll-free telephone number for complaint reporting;
  2. signage in the laboratory before and after an inspection to publicize College-sponsored complaint reporting systems;
  3. standardizing a set-aside of time during an inspection for discussions between laboratory personnel and CAP inspectors; and
  4. offering an Internet-based complaint reporting system.

The College also recommends:

- **Enactment of laws to protect laboratory workers from retaliation for reporting quality concerns.** Specifically, we would recommend that provisions in the pending Patient Safety and Quality Improvement Act (S. 720, H.R. 663) pertaining to whistleblower protections be extended to include worker reports to accrediting organizations.

The College thanks the subcommittee for its interest in ensuring the highest quality laboratory testing. The CAP is firmly committed to working with stakeholders at all levels, public and private, to achieve that goal.

