



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
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President,
College of American Pathologists

July 7, 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 continuing hearing of issues related to HIV and hepatitis testing at Maryland General Hospital (MGH). 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), meaning its inspection process meets or exceeds the requirements of the Clinical Laboratory Improvement Amendments of 1988 (CLIA).

The CAP regrets that Dr. Ron Lepoff, who chairs the CAP Commission on Laboratory Accreditation and appeared before this subcommittee at its May 18 hearing on MGH, could not attend today's session because of a scheduling conflict.

We are here today to update the subcommittee on our activities with regard to Maryland General Hospital since the last hearing and to respond to any questions you might have. Since the May 18 hearing, the College has conducted an unannounced inspection of the MGH laboratory as a follow-up to our April 2004 decision to deny accreditation for two disciplines, chemistry and point-of-care testing. This inspection revealed few deficiencies and the hospital has responded to those cited. The College's Commission on Laboratory Accreditation is scheduled next week to review those responses and the status of the MGH laboratory.

As you may recall, the CAP stated in its May 18 testimony that quality control deficiencies for HIV and hepatitis C testing were not apparent to CAP inspectors in a routine April 2003 inspection or to state inspectors in fall 2002 because quality control data in this area were found to have been edited. Specifically, Maryland state inspectors alleged in their report that:

- “[F]or a period of approximately 14 months, the laboratory intermittently reported invalid hepatitis C and HIV test results due to improper quality control.”
- “Review of HIV records from June 2002 through August 2003 show that approximately 10 to 15 percent of patient runs were invalid because of unacceptable values of the negative controls used to determine cutoff values.”
- “The instrumentation (Labotech) printouts on many days of patient testing showed edited quality control values.”
- On May 14, 19, 21 and 23, 2003, “instrumentation printouts showed edited control values, but there were no printouts for the plates and no other records to show repeat testing for either the control materials or the entire plate of patient specimens.”

Based on the state’s report, we have concluded that neither our inspection process nor any other would have detected these problems without the benefit of the whistleblower complaint information, which ultimately led to the state’s findings. We have attached a copy of the state’s report for the record.

Any claim that CAP accreditation is not rigorous or objective is not supported by the facts. Attached to this statement is the Sept. 12, 2001, *Federal Register* notice extending to the College deemed status under CLIA. A review of this document will clearly show that the CAP inspection process exceeds CLIA requirements in several areas. Moreover, our program is subject to annual CMS validation surveys conducted by state inspectors. These surveys traditionally have shown results comparable to CAP findings and a discrepancy percentage well below the threshold that would trigger a CMS review of our program. CMS, in fact, has clear authority to revoke the College’s deemed status if it finds our program to be substandard. Most recently, at the May 18 hearing, CMS reaffirmed its support of CAP accreditation.

The College welcomes and has encouraged state authorities to review our program to determine whether CAP accreditation meets the requirements of their respective state laws. For example, College representatives met with Maryland Health and Mental Hygiene Secretary Nelson Sabatini June 17 as an initial step in efforts to improve communication and formalize our relationship with the state. As a result of that meeting, we have received a letter from department director Carol Benner requesting information from the College so the state can formally evaluate the College’s program for equivalence to the state program. We are encouraged by this development and look forward to continued discussions with the state.

We believe the MGH case is highly unusual and does not point to a pervasive problem in the accreditation or inspection process. But the case highlights important issues that can translate to improvements in the accreditation process.

Improved Communication

The MGH case underscores the need for improved communication and sharing of inspection information between accrediting organizations and governmental entities involved in the inspection process. As already noted, the College has moved forward in this area with the State of Maryland. The CAP also has asked CMS to schedule a meeting of stakeholders to discuss ways to improve communication among state and federal oversight agencies and private accrediting bodies, such as the CAP. We understand that CMS intends to convene such a meeting, but has not yet scheduled it. CMS leadership in this effort is essential to having a process in place by which accrediting bodies and state oversight entities can formally and effectively exchange complaint and inspection information.

Enhanced Complaint Reporting

Laboratory employees must have easily accessible and effective ways to communicate complaints and other concerns to accrediting organizations, such as the CAP. The College has moved forward with plans to enhance communication with clinical laboratory personnel to ensure their awareness of the College's complaint reporting system. We expect to soon have in place a dedicated toll-free telephone number to allow ease of reporting. To promote the toll-free number, we are developing special laboratory signage for use in our accreditation process.

Protections for Whistleblowers

We commend the whistleblowers in the MGH case. Without their courageous actions, the state and hospital might never have learned about the testing problems and taken steps to identify recipients of potentially erroneous laboratory results. We believe this case clearly illustrates the need for strong federal protections for whistleblowers, both for the individuals who report problems to governmental or private oversight bodies and to the oversight bodies themselves. Patient safety legislation now before Congress would establish whistleblower protections and we urge Congress to extend those protections to reports to private organizations.

The College thanks the subcommittee for its interest in ensuring the highest quality laboratory testing. The CAP is firmly committed to working with Congress and federal and state agencies to achieve that goal.