From lab tragedy to industry reaffirmation: a perilous journey

By Carren Bersch, MLO Editor

Last month, MLO revealed the background of two unfortunate incidents in the State of Maryland in the recent past — one at Maryland General Hospital (MGH) and another at Reference Pathology Services (RPS). The repercussions put the spotlight on private-organization laboratory inspections vs. governmental regulation, and whistle-blowing. After months of very public government contentions and industry/association finger-pointing, the “lab scandal” has resulted in a flurry of activity among the many players in this high-stakes game. What have they accomplished and, in the end, who will be the winners?

Maryland continues uncovering lab failures

The Dark Report published details of the MGH scandal early in 2004. Its editor, Robert Michel, says, “There are several strategic implications from the MGH laboratory fiasco. First, it demonstrates how quickly the bond of trust can be broken between a laboratory and the patients it serves. Second, the uproar by Maryland health officials and Congressional representatives brought long-established laboratory accrediting practices under unwelcome scrutiny. Third, the reaction by newspapers and the public reveals that public tolerance for laboratory errors is lessening. This creates greater consequences for any laboratory that puts a patient at risk due to an error or operational failure.

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On Dec. 9, 2004 — echoing the early sentiments of his state’s secretary of the Department of Health and Mental Hygiene, Nelson J. Sabatini, that MGH was “merely a symptom of a system failure” — Congressman Elijah E. Cummings (D-MD) issued a statement citing Baltimore’s Good Samaritan Hospital and Union Memorial Hospital as having failed to provide patients with accurate laboratory tests.

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duce legislation on the first day of the 109th Congress under the Clinical Laboratory Improvement Amendments (CLIA) to ensure that laboratories performing medical testing comply with federal standards and to ensure protection for laboratory whistle-blowers.

From the outset of the MGH scandal, Sabatini’s outspoken critique of the relationship between accrediting bodies and laboratories made headlines, while industry experts privately questioned how Maryland state regulators could have ignored complaints lodged with them in 2002 from MGH lab personnel regarding their long-term problems with testing procedures and malfunctioning equipment. The state’s explanation was that the reports were “vague” and did not constitute reason for investigation at that time.

At the May 18th Congressional hearing of the Committee on Government Reform’s Subcommittee on Criminal Justice, Drug Policy, and Human Resources, Sabatini lambasted the accreditation organizations as well as regulators, suggesting that state and federal governments had subcontracted patient safety. While his perception of a too-cozy relationship of accreditors and laboratories got broad press, Sabatini testified, “We all dropped the ball. We are all responsible. We all should be held to account for this … there is nothing to be gained by playing blame games; we all are to blame for this problem, and it is up to all of us to work together to fix it.” He noted, however, that “the current system is frightening; it is cumbersome; it is bureaucratic. Even if there were good communication [among] all the agencies, there are too many of them.”

By the end of 2004, he had retired. (At press time, MLO had not received a response to its inquiry to Maryland’s Department of Health and Mental Hygiene employees regarding the details of Mr. Sabatini’s future plans.)

Clarifying CAP’s position

Now under the scrutiny of the state and federal governments and the public, medical-laboratory accrediting organizations are conducting extensive self-examination after two Congressional proceedings. The May hearing kicked off a scramble to strengthen the laboratory-accreditation process and to create a better-protected whistle-blowing process. Both issues are at the heart of the catastrophe at MGH and are the crux of the legal battle being waged by a lone former MGH medical technologist, Kristin S. Turner, whose charges against that hospital, the equipment manufacturer, and her supervisor brought these issues to the fore.

The subcommittee’s hearings gave the College of American Pathologists (CAP) an opportunity to put on record the results of its own probe into questions raised by its MGH inspection after which it awarded MGH’s lab accreditation “with distinction.” In May, Ronald B. Lepoff, MD, FCAP, and chair of CAP’s Commission on Laboratory Accreditation, explained at the hearing that its accreditation with distinction is a designation that “recognizes that CAP-accredited laboratories adhere to additional College [CAP] standards that exceed those mandated by CLIA and are, therefore, ‘distinct’ from federal standards.” It is only one of two accreditation levels, the other being to meet only basic CLIA standards.

At July’s subcommittee hearing, Mary E. Kass, MD, FCAP, and president of CAP, challenged in her testimony Sabatini’s viewpoint that MGH was merely a symptom: “We believe the MGH case is highly unusual and does not point to a pervasive problem in the accreditation or inspection process.” She indicated that the MGH situation highlighted “important issues that can translate to improvements in the accreditation process.” Further, Kass’ remarks pointed to CAP’s conclusion that neither its inspection nor any other could have detected problems at MGH “without the benefit of the whistle-blower complaint information, which ultimately led to the state’s findings.”

In a report offered directly to MLO from CAP, the organization outlined many of the changes it has implemented during 2004 in light of its belief that “laboratory medicine is an evolving profession and the accreditation process must be continually enhanced to meet changing needs.” Among the improvements CAP illustrates in its memorandum are the development and implementation of its policy that (1) requires that labs develop a procedure for the appropriate investigation of all complaints and that provides for the reversion of CAP accreditation if complainants are harassed; (2) ensures that all lab employees are aware (through a checklist question) of their organization’s policy and complaint procedure, including how to contact CAP if problems are not fully and quickly resolved, as well as a requirement that all CAP-accredited labs post a sign encouraging employees to contact CAP with any unresolved quality issues; and (3) establishes toll-free telephone numbers [see “You ain’t just

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whistle-blowing Dixie,” this issue, p. 4] for laboratory employees to use to confidentially contact CAP regarding patient- or employee-safety issues that are not being resolved in their labs.

In addition, according to its report to MLO, CAP has increased its observation of laboratories with quality-assurance deficiencies, requiring that these laboratories institute verifiable quality-assurance measures that result in sustained compliance with its standards and with CLIA. To assure compliance, CAP is now looking even more critically at each situation and, if appropriate, conducts a second on-site, focused re-inspection prior to granting accreditation. Further, CAP is addressing its accrediting-body responsibilities by strengthening communications with directors of its accredited labs, with laboratory employees, and with other accrediting and regulatory bodies.

CAP also stated its intent to continue to work with regulatory bodies, such as the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO), state agencies, and CMS, to establish formal communication mechanisms, including the timely release of information. CAP also has implemented expanded notification to external regulatory agencies (JCAHO, state agencies, Departments of Defense and Veterans Affairs, and CMS) for all nonroutine complaint inspections and substantiated complaints.

While CAP plans additional enhancements in the coming year, and while its attention to “whistle-blowing” adds a new dimension to furthering communications between CAP and lab personnel, there is not yet a definitive response to Sabatini’s uneasiness with the accrediting inspector/laboratory director camaraderie he claimed was untenable. Accreditation inspectors are known to be peers of laboratory managers and directors and — according to some industry experts’ suspicions and those of Sabatini — do not aggressively seek discovery of serious problems in those labs because the very laboratories accreditation personnel are inspecting eventually may supply the inspectors for their own labs.

**Eliminating cross-purposes**

About the time the Food and Drug Administration (FDA) whistle-blower, Dr. David J. Graham, announced to Congress in November that the public is “virtually defenseless” against serious side effects discovered after a drug is approved by the FDA, another segment of the nation’s healthcare system was coalescing. As FDA officials struggled with the backlash from Graham’s public comments that his agency was “dependent on the industry it regulates,” representatives from state agencies, accrediting organizations, and the Centers for Medicare and Medicaid (CMS) met on Nov. 16, perhaps warding off similar criticism. These “Partners in Laboratory Oversight” discussed best practices, including the survey entrance conference, interviews (during survey), information gathering, sample selection (for path of workflow), investigation/technological procedures, record review, root-cause analysis, surveyor selection and training, and the overall survey process. This meeting is only one of many that will address the issue of whether or not the current accrediting procedures can endure without government intervention.

According to Max Williams, director of Policy and External Affairs for COLA, who attended the meeting, “The spotlight is on oversight. We all understood from the outset that we have a common goal of assuring accurate and reliable test results. Accreditors have a common interest in protecting the patient.” Williams looks forward to the April conference of the Institute for Quality in Laboratory Medicine (IQLM) — another organization of which COLA is a member and for which the Centers for Disease Control and Prevention is the convener — where IQLM goals include establishing recognition of best practices (see MLO’s Washington Reports of December 2004, p. 48, and July 2004, p. 56).

Williams revealed that an extensive amount of time at the Nov. 16th meeting was spent discussing how to effectively communicate with the various interested parties when a complaint or other issue arises in a laboratory. This oversight group — committed to looking for a standard process to keep everyone in the loop and to understanding who is accountable for resolving the concern — surmised that this may lead to changes in the State Operations Manual and with the official agreements between CMS, approved accreditors, and state licensing programs.

The Partners group was primarily interested in finding solutions, not casting blame or judgment, reports Williams, and focused on “sharing information about how and why processes fail, so we can all learn and begin to improve systems. There is so much negative publicity around these events in Maryland that, generally, no one is encouraged to share their experience, which means we all end up having to make our own mistakes and to learn as we go … if we could share errors for the value of learning and not penalize, great turnarounds could be achieved.” Further exploration of this territory will take place, and the group plans to collaborate again next month.

Its redesigned website (www.cola.org), says Williams, is the first step in COLA’s renewed commitment to provide laboratory professionals with information they need when they need it. From basic to highly complicated materials, COLA’s Lab University offers just-in-time training and continuing education courses in a member-interactive format, and can provide consultants when necessary — another constructive pursuit to upgrade knowledge and skills in the laboratory. Williams stresses that laboratories can institute “a culture of quality” and recognize in a positive — rather than a punitive — way the staff members who bring forward problems so that the entire team can be shown appropriate analytical procedures and understand nonanalytical written procedures.

**CLIA says who does what — and why**

Pennell C. Painter, PhD, professor emeritus of pathology, and director of laboratory operations at LabCorp/Dynacare Tennessee Laboratory within the University of Tennessee Medical Center in Knoxville, comments, “The detection and eradication of laboratory errors and opportunities for laboratory errors should be an essential part of ev-
ery laboratory’s quality system. Where significant opportunities for error are found, some way needs to be put in place to mitigate the risk, or testing should be diverted elsewhere. Sometimes, the opportunity for error is due to testing-personnel issues — such as where the person(s) involved may need in-servicing or training before they are permitted to perform certain clinical tests.” In today’s highly automated clinical laboratories, he continues, “the opportunity for significant clinical-testing error due to analyzer or reagent problems is often a contributing factor in many situations where both random and systematic errors occur, leading to incorrect patient results being reported. One of the things that all laboratories and laboratory managers should take from the Maryland General Hospital experience is that when significant opportunities for laboratory-testing error are identified, effective action must be taken by all responsible parties.”

Michel notes, “The breakdown of laboratory procedures and operations at Maryland General Hospital provides a rare look at how a system of checks and balances can totally collapse within a laboratory and has no parallel in recent decades. It is a warning to all laboratory managers and pathologists that serious problems can quickly emerge if senior laboratory administration fails to respond to warning signs that instruments or test protocols are failing to meet acceptable standards.”

Painter explains, “Almost always, the first line of responsible parties in any clinical laboratory is the technical staff performing the test. In most situations, testing personnel are in the best position to detect instrumental problems developing with an instrumental system or assay. When supervisors, managers, and directors are made aware of the problems with instrumental systems or assays that could impact patient results, the most effective response would be to immediately investigate the claims and initiate actions that would correct any problems identified.” Painter also reminds that a 1986 lab scandal involving the test results from Pap smears brought about CLIA ’88.

While Painter believes that every member of the team is important, “under CLIA ’88, the medical director has broad responsibilities for all patient sample testing done and reported from a medical laboratory — something hinted at by the fact the medical director is the only person’s name appearing on a lab’s CLIA certificate. Since the medical director clearly has great exposure if erroneous results are reported from the laboratory he directs, he should insist on being in the information loop about significant problems with instrumental systems or assays that could negatively impact patient results.

“As far as CLIA is concerned,” Painter continues, “virtually everyone else working in a clinical laboratory is doing his job in a manner approved by the medical director. People working in states with laboratory-personnel licensure often have an additional statutory responsibility to ‘protect the people’ of that state and have specified responsibilities as medical-laboratory testing personnel.

“Many people may not be aware that CLIA ‘88 regulations do lay out specific responsibilities for those individuals involved with the various aspects of clinical-laboratory testing in Section 493 (www.cms.hhs.gov/clia/). Anyone performing clinical-laboratory testing should familiarize himself with his responsibilities in that section. This delineation of personnel responsibilities in the CLIA regulations is an indication that the crafters of the regulations recognized that errors and opportunities for error can and do occur in clinical laboratories and that all parties must be doing their part.” Painter says his favorite phrase is “delegate tasks but not responsibility.”

The next turn in the road

Certainly, the players in this ongoing drama have made strides in taking on the mantle of responsibility. Legislation is being re-introduced in Congress this month that will deal with federal compliance issues and with whistle-blower protections. The enhancements put forth by CAP and COLA, the upcoming meeting of the IQLM minds, the possible additional unveilings of flawed lab-test results by a tenacious Maryland congressman, the testimonial charge to all parties by a now-retired lifelong government servant, and the ongoing legal struggle involving an injured medical-laboratory worker who pitted herself against an equipment manufacturer defending its analyzer comprise a cadre of varied travelers taking an assortment of paths in the perilous quest of ultimately remanding patient healthcare into safe hands in safe laboratories.

“Every medical technologist should pay attention to this [MGH] story,” urges Michel. “It represents a worst-case example of everything that can go wrong when lab administrators, hospital human-resource staff, and senior hospital administrators fail to acknowledge the issues identified by medical technologists as violating the basic principles of laboratory medicine and healthcare ethics.”

Note: At press time, MLO awaited the results of an attorney-approved written interview with Kristin S. Turner, which will be published at a future date. Background material for this article included telephone and e-mail interviews with Robert Michel, Max Williams, and Pennell Painter, as well as testimony from the May 18, 2004, and the July 7, 2004, hearings of the Committee on Government Reform’s Subcommittee on Criminal Justice, Drug Policy, and Human Resources. For a detailed list of references, see the MLO website.