

# When a “good” lab goes “bad”: Where do we go from here?

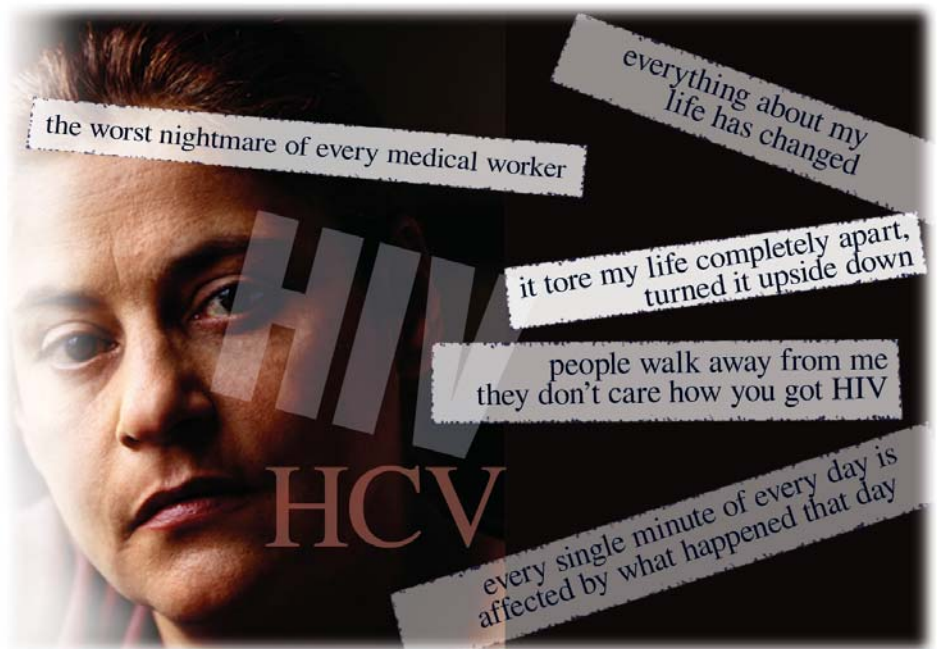
By Carren Bersch, MLO Editor

**T**wo unfortunate incidents in the state of Maryland in the recent past — one at Maryland General Hospital and another at Reference Pathology Services — have called into question what have been standard operating procedures in laboratory inspections, spurred congressional actions which likely will result in regulatory changes, and helped pave the way for medical laboratorians to confidentially report complaints. How all those details fall into place in some final resolution remains to be seen. In what has been widely referred to as a “scandal” (covered here), the conclusion (coming next month) will have been a lesson learned the hard way.

## Preface to the story

A year has passed since December 7, 2003, when Kristin S. Turner sent her now-famous “whistle-blowing” letter to Dr. James Stewart, her then boss and now former laboratory director at Maryland General Hospital (MGH) in Baltimore, MD. Turner’s four-page conveyance not only to her superior but also to other hospital administrators as well as local and state health inspectors, of her fears about longstanding problems in MGH’s laboratory sparked a flurry of investigations by state and federal regulators over the last 12 months — investigations that many of the MGH chemistry/immunology laboratory employees had known for years needed to be conducted.

In essence, Turner opened the MGH “lid” to a clinical laboratory “Pandora’s box.” She later filed a 26-page, \$30-million-dollar lawsuit in Baltimore Circuit Court against the hospital, Dr. Stewart, and Adaltis USA Inc., the Pennsylvania manufacturer of the Labotech Open Microplate Blood Testing System (Labotech), which malfunctioned, she claims, and exposed her to HIV and hepatitis C. Turner’s journey from mild-mannered laboratory worker to crusading patient has



*“Not only has the sky fallen but the bottom has dropped out.”*

been a flashpoint in the often-complicated story of “a good laboratory gone bad.”

## First signs of trouble?

As early as May 25, 1999, Labotech’s recurrent inconsistent performance had been cited by the British National Health Service (NHS), which warned that false-negative test results had been recorded by a number of users. The NHS “considered the risk assessment together with the possible implications of a false-negative result for clinical management” and issued a number of general recommendations on the need

for repeat testing for HIV, HBV, and HCV. Although general repeat testing was not considered appropriate, the NHS asked that laboratory directors (1) comply with the country’s Medical Devices Agency Hazard Notice (HN 1999[01]), (2) check that precautions were in place to ensure the correct functioning of the Labotech analyzers, (3) inform relevant clinicians of the risk assessment and

recommendation, and (4) ensure that consideration was given by the clinicians to repeat testing within any specific clinical group or for any individual patient.

Meanwhile, the Labotech analyzer did not at that time — nor on June 4, 2002, when MGH received the one now in question — appear on the U. S. Food and Drug Administration (FDA) MedWatch database, a compilation of *reported* medical-device problems. It still does not.

### MGH's faulty analyzer

The Labotech testing equipment was at the center of the MGH tempest. According to her Dec. 7, 2003, e-mail letter, Turner asserted that the equipment had “consistently failed self tests, cross-contaminated samples, and failed runs ... [this] automated machine required hands-on interven-

proper placement. Following Adaltis' training procedures, she undertook the adjustment, then proceeded to verify proper operation. Suddenly, various samples of contaminated blood with controls containing known HIV- and hepatitis C-infected blood serum were broken as the control arm fell off when the washer head moved across the plates. Turner's protective goggles and mask — worn as suggested by Adaltis' training personnel — did not preclude the infectious blood from spraying into her eyes, mouth, and nose.

### Life after Labotech

Immediately, Turner sought aid from co-workers; the supervisor could not be found. After washing off the contaminated blood, she went directly to the emergency room.

She began taking prescriptions designed for victims exposed to the viruses. Within three to four months, Turner found herself suffering severe flu-like symptoms. A weeklong hospital stay in June 2003 verified her worst fears: She was infected with both HIV and hepatitis. “It was,” the 32-year-old told reporter Roche, “the worst nightmare of every medical worker. Everything about my life has changed. It tore it completely apart, turned it upside down.”

Subsequently, Turner was fired from her position at MGH after sending her Dec. 7 letter. She takes a dozen pills a day and complains that the HIV medications are especially noxious. Not only has Turner had to adjust to a complete change in her personal healthcare habits, she has dealt, sadly, with social and family issues. “People walk away from me ... they don't care how you got it [HIV]

... every single minute of every day is affected by what happened that day,” she says. After a flier was posted in her apartment building notifying residents of her condition, Turner moved out of state.

Meanwhile, MGH asked that Turner's complaint be dismissed, asserting that her right to sue the hospital was terminated when she filed an undisputed worker's compensation claim. The hospital eventually was dismissed this past July as a defendant in the case by a federal judge. Adaltis USA filed a response in U.S. District Court in mid-April denying Turner's claim that a malfunction in its equipment caused her infection.

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### Another MGH witness

A former MGH Chemistry II Lead Tech, Teresa Williams, soon confirmed Turner's allegations in a lengthy letter dated March 31, 2004, which was directed to Nelson J. Sabatini, secretary of Maryland's State Department of Health and Mental Hygiene, U.S. Representative Elijah

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tion at every step, and patient specimens were compromised through the actions of the machine every day.” Additionally, she stated, “the machine was never able to pass the routine validation procedures needed to prove it was reliable and that the results obtained could be reproduced.” Turner revealed that the testing equipment, bought used by MGH, arrived at the hospital lab with “the inside ... completely contaminated with blood.”

Days after her accident, Turner told *Baltimore Sun* reporter Walter F. Roche, Jr., who broke the story, that her personal struggle with the equipment began in the autumn of 2002: “Every run had different errors. Three of every five tests were wrong. The machine would often skip over required steps in the testing process.” After continuous complaints from MGH, Adaltis delivered a second machine to the hospital as a backup.

According to her court filings, on March 12, 2003, Turner was operating the original analyzer when an error message indicated that the washer head was not in its

*“This really didn't have to happen.”*

Cummings (D-MD) of Baltimore, and attorneys for Turner and the Maryland General Hospital. Williams opened her 11-page letter with the reminder that MGH lab techs and staff members had approached the hospital's administrators two years prior to Turner's accident with their concerns about the infectious-disease testing. She claimed that employee complaints were labeled by certain administrators as analogous to Chicken Little's "the-sky-is-falling" caterwaul. "Now," she wrote, "not only has the sky fallen but the bottom has dropped out."

Beginning with her hire on Jan. 15, 2001, Williams substantiated much of what appeared in Turner's lawsuit in a date-by-date explanation of the MGH laboratory problems. In one entry, citing the September 2001 hire of Dr. Stewart as the new lab director, Williams wrote: "We believed so much in him." Williams' account includes Stewart's decision to purchase a refurbished Labotech analyzer from Adaltis, as well as the verification that the instrument arrived with dried blood caked inside. Stewart directed that the equipment be decontaminated, and Labotech training began on June 12, 2002.

From that point forward, Williams documented what became a struggle between her and Stewart partly regarding his instructions, which clashed with her knowledge and experience, over the use of the analyzer ("The machine was a lemon," she opined). On July 11, 2002, Williams and five other staff members met with the vice president of MGH's human resource office to verbalize their complaints. While assured at this meeting that their names would be kept anonymous, the six women were summoned shortly to a meeting, which included Stewart. Williams recounted that Stewart's reaction to employee complaints about poor lab practices and inadequate patient care was: "What I do is none of your [expletive] business." Williams also documented Stewart's Aug. 9, 2002, written admonishment to a lab worker who voiced concerns, describing her as "a focal point of destructive criticism" and warning disciplinary action if she continued to complain to others in the laboratory. Another employee who took her issues about testing to the MGH human resource office later received a written citation for insubordination.

Williams' passionate diatribe included explanations of shortcomings of other laboratory procedures and the disinterest of supervisory personnel, including her challenge to Stewart that the hospital was overcharging for a variety of tests — which had no result. She contends she continued to perform her du-

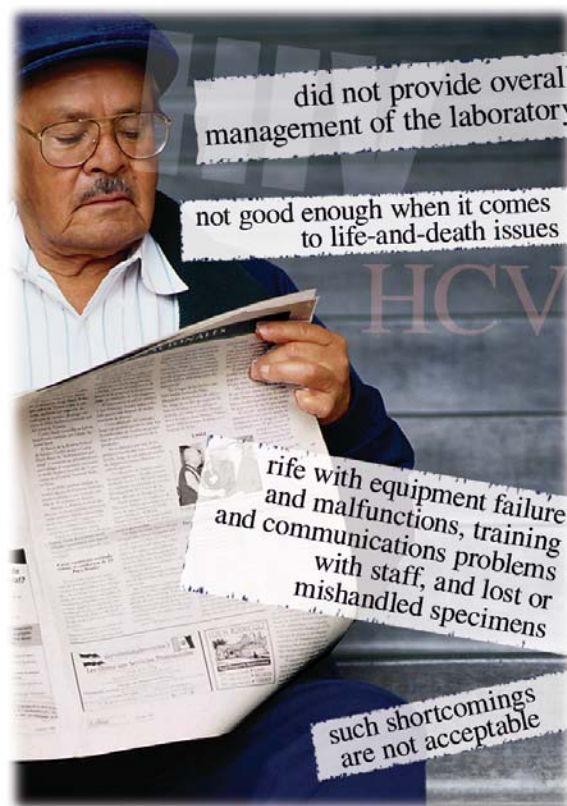
ties as directed but began to struggle with her conscience. "It felt like the Tuskegee experiments but on a larger scale [involving] ... poor Blacks, Latinos, and whites ... I wanted no part ... but had to let someone know who had a vested interest in protecting the public." She and several of her co-workers agreed to send a letter to officials in the state of Maryland, but the others — "afraid for their jobs" — eventually bowed out. On August 12, 2002, Williams resigned her position.

On October 31, 2002, Williams received calls from several lab employees, panicked because Dr. Stewart had advised them not to say anything that would jeopardize the hospital when state inspectors made a surprise visit to MGH. "Out of fear," Williams noted, "they remained silent." Later, Williams learned that most of the technologists who initially had come forward were intending to quit their jobs. In March 2003, she met with Kristin Turner, who told Williams that Stewart's comment about her accident was that Turner "should have been more careful." Williams also noted that a *Baltimore Sun* article on March 11, 2004, regarding MGH's Labotech problems outraged her because the published account stated that hospital administrators were blaming the laboratory technicians for the very offenses they had brought to light.

### Other possible victims

By August 2003, MGH had stopped using the Labotech to perform tests. State health officials had acted on the information provided by MGH's "whistle-blowing" employees — there had been general, not specific, complaints in 2002 as well. After a limited review in January 2004, a state inspection team returned between March 16 and 24 in an unannounced evaluation to inspect the hospital's laboratory operations. In a lengthy report after their MGH visits, they noted that problems with the Labotech analyzer began almost immediately after the first one was delivered to the hospital in June 2002. Inspectors also learned that laboratory personnel overrode controls in the testing equipment that showed the results might be in error and, despite that, notified MGH patients of those results. Evidence suggested hospital personnel erased data showing recently completed test results were suspect and ignored guidelines requiring automatic retesting.

The accuracy of the HIV tests performed by MGH lab personnel over a 14-month period ending in August 2003 was in question. Approximately 460 unknowing patients tested for HIV were involved — 280 who have not been found. Some of these might be, as one state employee observed, "walking time bombs," unwittingly spreading the



HIV virus. While MGH had determined that many of its patients' initial tests were accurate, the search was on for the others — many of them likely substance abusers or members of Baltimore's homeless population. A former advocate for the Homeless Persons Representation Project said of the notification process, "A lot of these folks aren't ever going to be found."

And while the then-president and CEO of MGH — Timothy D. Miller — denied knowing about the questioned accuracy of the tests until Maryland's inspectors finalized the January 2004 on-site inspection, evidence indicated that he was among some 20 MGH officials who had received Turner's December 2003 written warning.

### Other MGH problems

In their March 2004 visit, state inspectors also found that MGH's microbiology section's lab work involved patient testing at a nearby nursing home: Faulty tests for Legionella bacteria were discovered. Eleven sputum samples from nursing home residents had been housed in a hospital refrigerator for two to three weeks in 2003, despite the fact that such tests were to be initiated within a 24-hour period after samples were collected. State inspectors acknowledged that five of those samples were not handled appropriately, a fact that was confirmed by a hospital spokesperson. Free retests were offered to the nursing home facility.

In addition to the allegations about faulty equipment and other serious problems in the laboratory, MGH was confronted not only with the risk of lawsuits against physicians using its suspect lab test results but also with several other legal difficulties. Dr. Adam F. Dorin, who had headed up MGH's anesthesiology department from 2001 to 2002, had filed a lawsuit against the hospital in 2002 under the federal "whistle-blower" law alleging Medicaid fraud. Dorin claimed MGH regularly overcharged the federal program for anesthesiology services, confirmed by a consultant he had reviewed billing records in 2001. Audits found billing questions in other areas of MGH as well. Dorin described his tenure with MGH as "like living in a bad dream. I can identify with the laboratory workers who were frustrated with harassment and threats for simply trying to fix problems and make things better for their patients."

In August of this year, another lawsuit was filed on behalf of a woman who alleged that MGH mistakenly told her that she was HIV-positive; however, retesting of her blood at her doctor's office found that she was not. MGH classified the suit as frivolous, stating the allegations were false. Nonetheless, the hospital now found itself a target for challenges from patients, in addition to former employees and — by now — the source of much rumination throughout the clinical laboratory industry.

### The legal aftermath at MGH

By March 2004, MGH's legal headaches had mounted. The hospital had filed a complaint, reporting the Labotech analyzer to the FDA, whose inspectors were scheduled this past summer to visit the Italian plant that manufactures the

equipment. MGH had established a hotline that month for patients to call regarding HIV and hepatitis C retesting. It had a plan to post retesting notices in homeless shelters, halfway houses, and other locations where patients might be found. It extended to 24/7 the hours for retesting at the hospital and sent two letters to any patient — a total of 2,169 — whose testing was in question. It filed a formal corrective action plan with the state. These were but a few of the actions MGH took in response to the investigations and recommendations by Maryland's inspectors.

The state inspectors were shortly followed by the state Office of Health Care Quality (threatening \$10,000-a-day fines unless corrective action was undertaken); the federal Centers for Medicare and Medicaid Services (CMS) and the Maryland attorney general's office (investigating possible fraudulent MGH Medicaid billing with regard to testing); and the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) (the nation's primary laboratory accrediting agency). Additionally, a subpoena came from the U.S. Department of Health and Human Services' Office of Inspector General seeking information and records related to HIV and hepatitis testing conducted at the hospital between January 2002 and August 2003.

### Major MGH management changes

Another aspect of MGH's laboratory quandary was the restoration of its reputation within its immediate healthcare community and the clinical laboratory industry at large. Shortly after the story broke in March this year, MGH hired Park City Solutions of Midway, UT, to provide immediate lab-management support, perform a comprehensive review of the hospital's lab, and make any changes necessary to conform to its corrective action report.

While only one personnel action was taken by the hospital — Dr. James Stewart was placed on paid administrative leave beginning last April and resigned within the month — those who had overseen the lab operations during the period in question left MGH. Stewart's management of the lab, and that of Dr. Philip Whelan, MGH's lab director, was so poor that state regulators stated that patients had been put at risk.

Whelan also was noted for failing to follow up on problems existing from August 2002 to February 2004 and for neglecting to report those problems to his superior. Whelan, suggested the inspection report, "did not provide overall management of the laboratory;" the report described the MGH lab as "rife with equipment failure and malfunctions, training and communications problems with staff, and lost or mis-handled specimens."

Edmond Notebaert, president of the University of Maryland Medical System of which MGH is an affiliate, announced the resignations of Whelan and Miller on April 21, 2004, who both generally stated that their departures would aid in the hospital's ability to put the laboratory episode behind it and restore the community's faith in MGH. Notebaert's two-page statement agreed that the state and federal inspections had revealed "significant" problems with the management and opera-

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*"It's the very definition of the fox guarding the hen house."*

tion of MGH's laboratory: "Such shortcomings are not acceptable." Whelan was replaced by board-certified pathologist Dr. John Braun; Miller was replaced by Colene Y. Daniel, a well-respected former Johns Hopkins Health System executive.

## Public policy and safety issues

At the end of September, Daniel told *The Baltimore Sun* that the hospital had "taken giant steps over the last six months, and the hard work and focus on constant improvement will continue." Maryland health officials' concerns heightened further, however, after another area laboratory — Reference Pathology Services of Maryland (RPS) in Rosedale — was closed the same month for violations of state and federal rules, which regulators said posed an eminent public health and safety threat. At issue here were problems with tests being performed for cervical cancer and sexually transmitted diseases (STDs) — and the lab, while agreeing to close, also offered free retesting to as many as 3,000 to 6,000 patients. Lab personnel did not perform required controls on lab equipment and materials to ensure the accuracy of test results. Still in question is whether they reported cases of STDs and cervical cancer to the county health department and the state's cancer registry, respectively.

RPS' deficiencies, detected during an inspection prompted by another laboratory "whistle-blower," were investigated by the College of American Pathologists (CAP) — the non-profit board-certified pathologists' association. CAP has deemed status from CMS, which permits it to perform Clinical Laboratory Improvement Amendments (CLIA) compliance inspections. CAP's on-site inspections required corrections of RPS' deficiencies; but, after the lab neglected to rectify the problems, CAP revoked its certification and Maryland suspended the laboratory's license. This particular case was reason enough to open yet another avenue of investigation with a further and more thorough look at CLIA oversight methods.

While swift action took place with regard to Reference Pathology Services, the question remained as to why CAP previously had given its highest rating — "accredited with distinction" — to Maryland General Hospital in July 2003, only months before Kristin Turner's complaint about the MGH history of lab deficiencies had surfaced. How had CAP failed to ascertain that serious problems existed in the MGH lab over many long months and were ignored until state inspectors were alerted via Turner's complaints last December? When the lone MGH laboratorian stood her ground to safeguard the health of patients, including herself, was Turner aware of the overwhelming response that would follow? The wide-ranging MGH legal tumult, the upheaval of MGH personnel, and the

discovery of similar problems at another Baltimore laboratory were only the first inkling of what was to come.

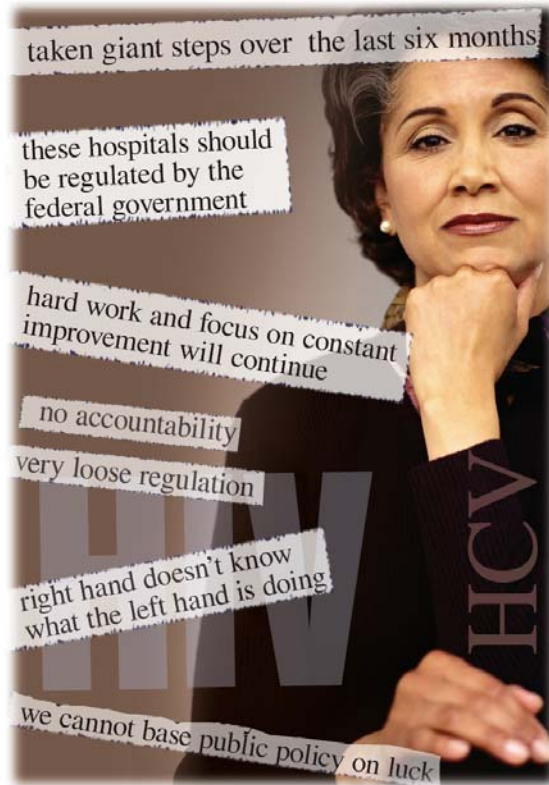
Sabatini, a lifelong government servant and educator, and Peter C. Beilenson, Baltimore Health Commissioner, introduced an entirely new focus by questioning the relationship between the hospital and the private accrediting agency that inspected MGH. Both men were, at first, primarily concerned with the retesting of MGH patients as well as how MGH laboratory personnel performed the original tests. At the outset, Beilenson had voiced his concern: "I'm really quite disturbed.

They apparently knew there was a problem," he said of MGH. Indeed, at the point when MGH was ordered by state health officials to either take action or receive daily fines, their report indicated that top administrators within the MGH culture were not aware of the lab's problems and that the hospital's governing body had failed to take action.

Early on, Sabatini's interests quickly converged on the inspection process. He suspected that MGH was an example of a system failure, not an isolated incident — and pointed out that the hospital accreditation process, conducted by private organizations with links to the healthcare industry, is inadequate in its present form: "We have a totally ineffective process to make sure problems are corrected or people are put out of business."

Sabatini's view of the system that bars state regulators from inspections until complaints are lodged with them is less than complimentary. "They'll draft a plan of correction, then they'll have a meeting and rework it, then there will be a few more meetings ... 'old boys' reviewing their friend's operations ... collegial ... [with] 'uncomfortably close ties' [to hospitals] is how Sabatini has referred to the relationship between hospitals and the inspecting national accrediting agency. Agency reviews were, he argued, "leisurely." A complete overhaul of the entire system is desirable, according to Sabatini, with a single responsible agency. "Patient safety is ultimately a government regulatory responsibility," Sabatini declared, "and we have subcontracted it out."

In late April, Sabatini threatened CAP with the revocation of the state's automatic approval for more than 120 medical laboratories in Maryland unless CAP agreed to release its inspection reports on MGH. He set a deadline for CAP's response to his demand. The tussle over whether CAP was required to turn over to the state its MGH inspection report — those that gave the hospital its highest ranking — hinged on CAP officials' message that the organization "does not have a relationship with the state of Maryland." Sabatini's



stance was that because Maryland accepts CAP accreditation, the relationship is implicit and that CAP must share its reports upon the state's request. After Sabatini strongly urged CAP to reconsider its position, CAP produced the reports in question.

Both state and federal law requires that routine inspections and accreditation of hospitals — and there are some 5,764 registered in the United States — be done by the non-profit JCAHO, established first to inspect hospitals and later given jurisdiction over other types of healthcare operations. When a hospital receives JCAHO accreditation, it is generally accepted that the facility is in compliance with both state and federal requirements.

JCAHO's vice president, Margaret Van Amringe, believes the opinion of Dr. Peter Lurie, a representative of Washington-based advocacy group Public Citizen, is outdated, but Dr. Lurie says the conflict is fundamental. "The problem is these hospitals should be regulated by the federal government. Instead, you have people with a massive conflict doing the inspections," he told a *Baltimore Sun* reporter. "It's the very definition of the fox guarding the hen house. All their instincts are toward accreditation or very loose regulation, and no accountability."

Maryland legislative hearings were initiated last May by Rep. Cummings, who cited patients as the ones who suffer in a situation "where the right hand doesn't know what the left hand is doing." He indicated that major changes in laboratory regulation — "a tightening of federal standards" — might be required, based on the serious nature of MGH's violations. Cummings claimed that patient retesting did not resolve the problem for the hospital. "They were very lucky," he said, since many retested patients learned their original MGH test results had been accurate. "We cannot base public policy on luck. That's not good enough when it comes to life-and-death issues." Cummings and U.S. Representative C.A. "Dutch" Ruppersberger (D-MD), at further meetings in September and November, continue to pursue answers to a host of questions raised during the past year about nearly every phase of MGH's and RPS' laboratory operations — including a related issue as to whether the FDA is regulating testing equipment sufficiently. Rep. Ruppersberger noted, like Sabatini, that these two examples of problems with lab testing "could affect any patient, in any region of the country."

Several involved organizations met, too. In late September the CLIA Advisory Committee explored whether or not regulatory response is going to be necessary in light of voluntary CAP, JCAHO, and COLA programs, while the CMS held a November meeting to bring state, federal, and private accrediting officials and state regulators together to debate improving the CLIA accreditation and inspection process. The advisory committee will gather again in February to pursue the issue. Thus far, CAP has responded by defending its certification processes at both MGH and RPS and has implemented changes that (1) require its certified laboratories to alert employees that a confidential "whistle-blower" hotline now exists, (2) demand immediate revocation of lab certification should any workplace whistle-blower be harassed, and (3) track specimens throughout a laboratory's workflow instead of depending upon laboratory records as the basis for inspection reviews.

### What comes next?

Obviously, the pursuit of a wide range of solutions by a variety of existing groups that may affect more than 293,000 U.S. laboratory professionals is well underway. There may be others who eventually join in what is, from outward appearances, a civilized fray. In *MLO's* second segment to this ongoing story scheduled for January 2005, the breadth and depth of those organizational policy recommendations will be explored; the opinions — and hopes — of diverse officials will be examined; and the responses and reactions of clinical laboratory personnel will be summoned.

What will be the final outcome of what started for one technologist as an ordinary day at the hospital and ended up a national laboratory humiliation? Kristin Turner awaits these answers as well as the result of her own personal court battle: "This really didn't have to happen."

**Note:** Background material for this article included *The Baltimore Sun*, Washington G-2 Reports "National Intelligence Report," *The Dark Report*, and copies of court papers submitted on behalf of Kristin S. Turner and other evidence provided to local, state, and federal health officials. For a detailed list of references, see the *MLO* website and the online version of this article. □

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