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ENSURING ACCURACY AND ACCOUNTABILITY IN LABORATORY TESTING: DOES THE EXPERIENCE OF MARYLAND GENERAL HOSPITAL EXPOSE CRACKS IN THE SYSTEM? PART II

HEARING

BEFORE THE

SUBCOMMITTEE ON CRIMINAL JUSTICE, DRUG POLICY AND HUMAN RESOURCES

OF THE

COMMITTEE ON GOVERNMENT REFORM

HOUSE OF REPRESENTATIVES

ONE HUNDRED EIGHTH CONGRESS

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ENSURING ACCURACY AND ACCOUNTABILITY IN LABORATORY TESTING: DOES THE EXPERIENCE OF MARYLAND GENERAL HOSPITAL EXPOSE CRACKS IN THE SYSTEM? PART II

WEDNESDAY, JULY 7, 2004

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON CRIMINAL JUSTICE, DRUG POLICY AND HUMAN RESOURCES,
COMMITTEE ON GOVERNMENT REFORM,
Washington, DC.

The subcommittee met, pursuant to notice, at 3 p.m., in room 2203, Rayburn House Office Building, Hon. Mark Souder (chairman of the subcommittee) presiding.

Present: Representatives Souder, Cummings, Ruppersberger, and Carter.

Staff present: J. Marc Wheat, staff director and chief counsel; Roland Foster, professional staff member; Malia Holst, clerk; Tony Haywood, minority counsel; and Teresa Coufal, minority clerk.

Mr. SOUDER. The subcommittee will come to order.

Good afternoon. I thank you all for being here. Today's hearing will continue to examine the investigation of lab testing at Maryland General Hospital in Baltimore, MD.

At the request of the ranking democratic member of the subcommittee, Elijah Cummings, we held a hearing on this topic on May 18th. Due to time constraints, and a lot of votes, we were unable to complete the questioning of the final panel. Today we will welcome back that panel of witnesses, as well as Kristin Turner, a former lab worker at the Maryland General Hospital who was unable to attend the May 18th hearing due to illness at that time.

During the 14 month period between June 2002 and August 2003, the hospital issued more than 450 questionable HIV and hepatitis test results. Despite the instrument readings showing that the test results might be inaccurate, managers at the hospital failed to act. Similarly, State insepctors did not respond to a 2002 letter from lab workers who warned of serious and longstanding testing problems that put patients and problems at risk.

During this period in July 2003, the hospital lab was inspected and accredited by the College of American Pathologists. CAP officials have assured the subcommittee that their inspection standards were even more stringent than required by the Federal Government. Yet the inspection did not identify the ongoing deficiencies in lab testing. The problems at Maryland General Hospital weren't taken seriously until this year, when State insepctors in-

vestigated another warning letter sent in December from a former employee, Kristin Turner.

State officials have confirmed the existence of the 2002 letter. They said they took the allegations seriously, but found them vague and did not discovery the serious problems until this year. Subsequent inspections by State officials prompted by the whistle blower showed that the laboratory was in the midst of serious problems at the very time the accreditation inspection was conducted. State inspectors concluded the lab was understaffed and rife with equipment malfunctions. And State and Federal inspectors later turned up pages and pages of violations of testing standards.

The College of American Pathologists has since suspended its approval for two key laboratory divisions. The complaint that led to these findings alleged that the machinery used in HIV and hepatitis testing was not adequately maintained and that possibly erroneous test results were provided as a result.

In all of these inspections, similar issues were identified concerning the management and quality assessment process of the laboratory that were found to be deficient. Each oversight entity addressed these issues, but did not inform all the remaining involved parties of their findings. Therefore, each oversight entity did not have the benefit of the findings of the others.

Only after a December 2003 complaint to the State survey agency that pinpointed a specific problem area to investigate did the entities involved begin to communicate their findings to each other. Yet, the College of American Pathologists did not even receive the 2002 lab workers complaint until the day prior to this subcommittee's first hearing on this matter in May. Fortunately, the hospital has retested many patients and found the original results were mostly accurate and steps have been taken to ensure patients are now receiving reliable test results. State and Federal regulators are now overseeing Maryland General's efforts to improve its laboratory operations. A State Medicaid fraud investigation and a Federal investigation by the Department of Health and Human Services' Office of Inspector General are also ongoing.

The purpose of this hearing, therefore, is to gain a better understanding of all the issues that led to the deficiencies at Maryland General Hospital and how these problems went undetected and not addressed for such a long period of time, despite inspections and warnings from lab personnel. Our goal is to make sure that a similar situation never happens again at other hospitals, and that patients can be assured that when they visit a hospital and have tests taken that the results they receive are accurate and reliable. We also want to be sure that all those adversely impacted by the problems at Maryland General Hospital are identified and given proper test results.

Our first panel will be Kristin Turner, former employee the Maryland General Hospital. The second panel will include Mr. Edmond Notebaert, President and Chief Executive officer of the University of Maryland Medical System; Ms. Carol Benner, Director of the Office of Health Care Quality for the State of Maryland; and Dr. Mary Kass, President of the College of American Pathologists.

Thank you all for being here today and we look forward to your testimony and insights on this issue. Now I'd like to yield to the ranking member, Mr. Elijah Cummings.

[The prepared statement of Hon. Mark E. Souder follows:]

Subcommittee on Criminal Justice,
Drug Policy and Human Resources

Opening Statement of Chairman Mark Souder

Part II
Ensuring Accuracy and Accountability in Lab Testing:
Does the Experience of Maryland General Hospital Expose Cracks in the System?

July 7, 2004

Good morning and thank you all for being here.

Today's hearing will continue to examine the investigation of lab deficiencies at Maryland General Hospital in Baltimore, Maryland.

At the request of the ranking Democratic member of this Subcommittee, Congressman Elijah Cummings, we held a hearing on this topic May 18, but due to time constraints we were unable to complete the questioning of our final panel. Today, we welcome back that panel of witnesses as well as Kristin Turner, a former lab worker at Maryland General Hospital who was unable to attend the May 18 hearing due to illness.

During a 14-month period between June 2002 and August 2003, the Hospital issued more than 450 questionable HIV and hepatitis test results. Despite instrument readings showing that the test results might be inaccurate, managers at the hospital failed to act.

Similarly, state inspectors did not respond to a 2002 letter from lab workers who warned of serious and long-standing testing problems that put patients and employees at risk.

During this period, in July 2003, the hospital lab was inspected and accredited by the College of American Pathologists. CAP officials have assured the Subcommittee that their inspection standards were even more stringent than those required by the federal government. Yet, the inspection did not identify the ongoing deficiencies in lab testing.

The problems at Maryland General Hospital weren't taken seriously until this year, when state inspectors investigated another warning letter, sent in December from a former employee, Kristin Turner.

State officials have confirmed the existence of the 2002 letter. They said they took the allegations seriously but found them vague and did not discover the serious problems until this year.

Subsequent inspections by state officials, prompted by the whistleblower, showed that the laboratory was in the midst of serious problems at the very time the accreditation inspection was

conducted.

State inspectors concluded the lab was understaffed and "rife with equipment malfunctions" and state and federal inspectors later turned up pages and pages of violations of testing standards.

The College of American Pathologists has also since suspended its approval for two key laboratory divisions.

The complaint that led to these findings alleged that machinery used in HIV and hepatitis testing was not adequately maintained and that possibly erroneous test results were provided as a result. In all of these inspections, similar issues were identified concerning the management and quality assessment processes of the laboratory that were found to be deficient. Each oversight entity addressed these issues but did not inform all of the remaining involved parties of their findings. Therefore, each oversight entity did not have the benefit of the findings of the others.

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The purpose of this hearing, therefore, is to gain a better understanding of all of the issues that led to the deficiencies at Maryland General Hospital and how these problems went undetected and not addressed for such a long period of time despite inspections and warnings from lab personnel.

Our goal is to make sure that a similar situation never happens again at other hospitals and that patients can be assured that when they visit a hospital and have tests taken that the results they receive are accurate and reliable.

We also want to be sure that all those adversely impacted by the problems at Maryland General Hospital are identified and given proper test results.

Our first panel will be Kristin Turner, former employee at Maryland General Hospital.

The second panel will include Mr. Edmond Notebaert, President of the University of Maryland Medical System, Ms. Carol Benner, Director of the Office of Health Care Quality for the state of Maryland and Dr. Mary E. Kass, President of the College of American Pathologists.

Thank you all for being here today. We look forward to your testimony and insights on this very important issue.

Mr. CUMMINGS. Thank you very much, Mr. Chairman, and I thank you for holding this second hearing to examine issues related to the release of invalid HIV and hepatitis tests to hundreds of patients at Maryland General Hospital in Baltimore City. This subject is extremely important to my constituents, who like myself receive health care from Maryland General Hospital. I appreciate your taking an interest in this controversy, and the broader oversight issues it raises for the Congress of the United States.

In May, we held a first hearing looking into allegations first reported by the Baltimore Sun in March, that from June 2002 to August 2003, Maryland General Hospital released more than 450 invalid HIV and hepatitis test results despite error message from testing instruments indicating that results might be incorrect. On May 18th, we heard testimony from FDA concerning the process for approving the Adaltis Labotech device that produced the invalid test results, and from the Centers for Medicare and Medicaid Services, concerning implementation of Federal regulations to ensure accuracy and accountability in lab testing.

We also heard compelling testimony from Teresa Williams, a former laboratory technician and supervisor at Maryland General, who made numerous attempts to call attention to deficiencies in laboratory operations, ultimately and unfortunately to no avail.

On the last of the three panels, we heard statements from representatives of the parent institution of Maryland General Hospital, the private accrediting body responsible for federally certifying the Maryland General laboratory as them being in compliance with Federal standards, Maryland's Department of Health and Mental Hygiene and the manufacturer of the Labotech testing instrument.

Because of time constraints we encountered during the final panel, our questioning was cut short and today's hearing provides a rare opportunity to continue the dialog we began in May with the latter group. And I do appreciate your holding this second hearing.

We are joined today by Edmond Notebaert, President of the University of Maryland Medical System; Carol Benner, Director of the Office of Health Care Quality for the State of Maryland; and Dr. Mary Kass, President of the College of American Pathologists.

Today's hearing also gives an opportunity to hear from former Maryland General employee Kristin Turner, who was unable to attend the hearing in May due to poor health. Ms. Turner is responsible for bringing the Maryland General lab testing problems to the light of day. I salute her for her courage in coming forward, and I am happy that she is able to join us today to share her experiences and perspective.

Although the events that initially caught the subcommittee's attention occurred at a single hospital in Baltimore, MD, they have implications for health care consumers all across this great Nation. My goal in requesting these hearings is to ensure that nothing like what occurred at Maryland General happens again anywhere in the United States. Fortunately, in the case of Maryland General, 99 percent of those who received invalid tests had their original test results confirmed.

But we cannot rely on luck as a public health safety net when lives are in the balance. The American people are entitled to have

faith that the laboratory tests that helped to determine the course of their medical treatments are as reliable and accurate as they can possibly be. That is a promise set forth in the Clinical Laboratory Improvement Amendments Act and we must ensure that the regulatory system established to enforce CLIA is adequate to fulfill that promise.

Sadly, the case of Maryland General appears to be one in which laboratory supervisors not only failed to ensure their proper quality controls were in place, but also deliberately altered or concealed information that would have led to the discovery of invalid test results being released to patients. Moreover, employees who expressed concerns about the inadequate quality controls and unreliable results were discouraged from expressing their concerns within the laboratory and outside of it.

It shocks the conscience that health professionals would deliberately engage in conduct that clearly places the lives of patients at unnecessary risk but it is equally disturbing that the process for detecting deficiencies was so easily circumvented. One would hope that such abhorrent conduct by laboratory personnel is rare. But the system of enforcement should account for the fact that there may be bad actors in positions of authority who will seek to conceal evidence of serious lab deficiencies from inspectors.

It is far from clear to me that the system in place does this adequately. I must say, Mr. Chairman, I've had an opportunity just recently, last week, to visit Maryland General. And I am very pleased with the progress that has been made by Mr. Notebaert. I think there have been just tremendous efforts to No. 1, find those patients that were tested, and improve the lab. As I said last week, I think now the lab and the hospital is probably one of the best run in the country, because it has come under the eye of so many agencies. And I want to applaud Mr. Notebaert for your efforts.

So today, each of our witnesses is in a position to provide an informed perspective on what gaps in the system may exist and how they can and should be addressed. I thank all of our witnesses for their appearance before the subcommittee today and I look forward to their candid testimony.

Thank you very much.

[The prepared statement of Hon. Elijah E. Cummings follows:]

Rep. Elijah E. Cummings, D-Maryland
Ranking Minority Member
Subcommittee on Criminal Justice, Drug Policy and Human Resources
Committee on Government Reform
U.S. House of Representatives
108th Congress

Hearing on "Part II: Ensuring Accuracy and Accountability in Laboratory Testing: Does the Experience of Maryland General Hospital Reveal Cracks in the System?"

July 7, 2004

Mr. Chairman,

Thank you for holding this second hearing to examine issues related to the release of invalid HIV and hepatitis tests to hundreds of patients at Maryland General Hospital in Baltimore City. This subject is extremely important to my constituents who, like myself, receive health care from Maryland General Hospital. I appreciate your taking an interest in this controversy and the broader oversight issues it raises for Congress.

In May, we held our initial hearing to look into allegations, first reported by the Baltimore Sun in March, that Maryland General Hospital released more than 450 invalid HIV and hepatitis test results from June 2002 to August 2003, despite error messages from the testing instrument indicating that the results might be incorrect.

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- More -

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Each of our witnesses is in a position to provide an informed perspective on what gaps in the system may exist and how they can and should be addressed. I thank all of our witnesses for their appearance before the Subcommittee today and look forward to their candid testimony.

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Mr. SOUDER. Two brief things before I yield to Mr. Ruppersberger. First, I want to commend Tony on the Democratic staff for arranging the musical accompaniment to your opening statement. Second, this hearing appears to forever trigger votes. So you just heard the bell, so we're going to have a vote to start. Fortunately, it's only one vote, so we'll have Mr. Ruppersberger's opening statement, we'll go over, vote and then be back as quick as we can walk over and back.

Mr. Ruppersberger.

Mr. RUPPERSBERGER. First, Mr. Chairman, thank you, and Congressman Cummings, you've really done a great job in pulling this together and I think that your efforts, and working closely with Maryland General Hospital, will improve hopefully our whole system throughout the country. That's what we're really here about. So, good job.

The followup hearing today is very important for two main reasons. First, it allows us to revisit this topic and discuss the steps Maryland General Hospital has taken in the interim to address the problems its lab experienced. We need to make sure the plan Maryland General Hospital has and is in the process of implementing is accurate in design and scope. Both the employees and patients of Maryland General Hospital deserve the best lab environment to ensure the community is receiving the quality of care they deserve. I look forward to today's testimony and hearing and update on these critical concerns.

Second, returning to this topic allows us to look nationwide and consider what Congress can do to protect labs throughout the country. In light of all that has happened, Maryland General Hospital is probably one of the best places to have your lab test performed today.

But I worry about labs elsewhere. What we have learned in the first hearing and what still needs to be addressed is how we will ensure that this problem does not happen again in another lab. It is the second question that promoted me to request an analysis from the Congressional Research Service in May 2004, outlining the questions raised in the first hearing, the background involved and the questions Congress should be considering to assure quality in clinical labs.

Mr. Chairman, I ask unanimous consent to have the CRS memo inserted into the record as part of my opening statement.

Mr. SOUDER. Without objection, so ordered.

Mr. RUPPERSBERGER. Thank you. The questions raised by the Congressional Research Service cover several categories. These include defining the scope of the problem, oversight and coordination and compliance and enforcement. I encourage my colleagues to consider this memo as we explore legislation options to address this important issue.

Thank you.

[The prepared statement of Hon. C.A. Dutch Ruppersberger follows:]

Congressman C.A. Dutch Ruppersberger
Subcommittee on Criminal Justice,
Drug Policy and Human Resources
MGH Part II
Opening Remarks
7.7.04

Once again I would like to thank you Mr. Chairman and Ranking Member Cummings for calling attention to this important topic.

This follow up hearing today is very important for two main reasons. First, it allows us to revisit this topic and discuss the steps Maryland General Hospital has taken in the interim to address the problems its lab experienced. We need to make sure the plan MGH is in the process of implementing is accurate in design and scope. Both the employees and patients of MGH deserve the best lab environment to ensure the community is receives the quality of care they deserve. I look forward to today's testimony and hearing an update on these critical concerns.

Second, returning to this topic allows us to look nationwide and consider what Congress can do to protect labs throughout the country. Quite frankly, in light of all that has happened, MGH is probably one of the best places to have your lab tests performed today. But I worry about labs elsewhere. What we learned in the first hearing and what still needs to be addressed is how we will ensure that this problem does not happen again in another lab.

It is this second question that prompted me to request an analysis from the Congressional Research Service in May 2004 outlining the questions raised in the first hearing, the background involved, and the questions Congress should be considering to assure quality in clinical labs. Mr. Chairman, I ask unanimous consent to have the CRS memo inserted in the record as part of my opening statement.

The questions raised by CRS cover several categories. These include defining the scope of the problem, oversight and coordination, and compliance and enforcement. I encourage my colleagues to consider this memo as we explore legislation options to address this important issue.

I thank the witnesses for appearing today and look forward to their testimony. Thank you Mr. Chairman.

Memorandum June 4, 2004

TO: The Honorable Dutch Ruppersberger
Attention: Sheilah Mirmiran

FROM: Michele Schoonmaker
Specialist in Genetics
Domestic Social Policy Division

SUBJECT: Follow up to Hearing on "Ensuring Accuracy and Accountability in Laboratory Testing" held May 18, 2004

Executive Summary

You requested additional information about how the federal government, states and private organizations interact to regulate, accredit and inspect clinical laboratories in the United States. Testimony at the hearing, "Ensuring Accuracy and Accountability in Laboratory Testing" held May 18, 2004, suggested that a possible failure in laboratory equipment, a breakdown in one laboratory's quality assurance system, and a lack of communication between federal, state, and private agencies, contributed to a laboratory worker becoming infected with HIV and hepatitis, and to the reporting out of 450 questionable HIV and hepatitis test results.

In the United States, clinical laboratories are regulated by the federal and state governments. At the federal level, all clinical laboratories must follow the Clinical Laboratory Improvement Act (CLIA) regulations, which are administered by the Center for Medicare and Medicaid Services (CMS). Additional responsibilities of the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) complement CMS activities. CLIA establishes standards that laboratories must meet in order to be certified as a provider of laboratory services. Either CMS, or one of six private organizations approved by CMS, will determine if a clinical laboratory meets the CLIA requirements or higher standards for laboratory practice. Using tools of inspection and proficiency testing, CMS and the private organizations will determine compliance with the requirements. Once the laboratory has been determined to meet the requirements, CMS will certify the laboratory to conduct clinical testing. In addition to CMS certification, laboratories may need to meet additional state requirements in order to obtain a license to operate in a particular state.

Professionals have questioned the effectiveness of the inspection process. The sheer volume of documents and test protocols that exist in most laboratories make inspection for

compliance a challenging process. Most inspectors get only a cursory view of how the process of testing works, with the potential for many specific test-related problems to fall through the cracks. Some laboratories, such as those performing waived tests[1], rarely get inspected. Inspections examine a cross-section of laboratory function, are often announced, and documents are usually provided ahead of time allowing laboratories to prepare for the inspection. Anecdotal evidence suggests that these methods enable laboratories to bring records up to compliance immediately prior to the inspection, and avoid deficiencies for which they may have otherwise received a citation. In fact, testimony at the May 18th hearing suggested that sometimes employee reports of sub-optimal laboratory practice are the only way the inspecting bodies may become aware that such a practice is occurring. In their testimony on May 18th, all witnesses indicated a need for improved communication between government, the state, and private bodies.

This memo will describe the roles, responsibilities, and co-ordination between federal and state government agencies, private organizations, manufacturers of laboratory tests and equipment, and clinical laboratories in identifying, correcting, and preventing the occurrence of adverse events. At the end, the memo will also present questions that Congress may wish to consider as the debate on assuring quality in clinical laboratory testing continues.

Oversight of Clinical Laboratories.

In the United States, clinical laboratories are regulated by the federal and state governments. All clinical laboratories must follow the federal Clinical Laboratory Improvement Act (CLIA) regulations. CLIA regulates the process of laboratory testing, but does not evaluate the tests themselves. In a complementary process, the Food and Drug Administration (FDA) regulates laboratory test kits, and active reagents (the chemical or substances that react to produce a test result) that are produced and commercialized by manufacturers. The Occupational Safety and Health Administration (OSHA) regulates the laboratory environment to ensure safety in the workplace. States establish requirements for and grant licensure to clinical laboratories. State programs may be granted waivers from participating in CLIA if they design their own regulatory and accreditation system that is at least as stringent as CLIA (currently Washington, Oregon, and New York operate under a CLIA waiver). Thirteen other states, including Maryland, have additional requirements beyond CLIA for licensing laboratories. Accreditation is the formal recognition of the technical competence of a laboratory based on assessment by a private organization of laboratory process according to predetermined qualifications or standards.

CMS and CLIA

CLIA was established in 1988 to impose minimum uniform standards on all laboratory practice, regardless of the type of laboratory. Practice standards include personnel requirements, quality control, and quality assurance. The Centers for Medicare and Medicaid Services (CMS), in implementing CLIA, uses inspection and proficiency testing to examine

[1] Waived tests are procedures that are so simple and accurate that the possibility of error is very small or that pose no reasonable risk of harm if the test is not performed properly (42 CFR 493.15(b)).

the testing process from the acquisition of the patient sample through reporting of the results. This includes making sure that: samples are labeled properly, reagents have not expired, test reagents have been validated (gives correct results on known samples), analyses are correct, interpretation is by qualified individuals, and results are reported in appropriate manner to proper persons.

Complexity. CLIA requirements on standards, such as personnel, depend on the type of testing that the laboratory performs. Laboratory tests can be high complexity, moderate complexity or waived. FDA determines the CLIA complexity of commercialized test kits, while the Centers for Disease Control and Prevention (CDC) determines the complexity of other tests that are performed as laboratory services (i.e, the test kits themselves are not commercially distributed). In order to categorize complexity, FDA or CDC considers: the knowledge, training and expertise of those performing the test, the difficulty associated with preparing reagents, patient materials and operational procedures, availability and ease of use of calibration, control or proficiency testing materials, how difficult troubleshooting and/or equipment maintenance will be, and the level of judgement needed to properly interpret test results. Generally, the more difficult tests are to run and the more expertise that is needed for proper interpretation, the higher the complexity of tests. Most laboratory tests are of moderate complexity. Waived tests are usually simple to run, and presumably have little chance for error. Unlike moderate or high complexity testing facilities, laboratories performing waived tests receive little oversight once the waiver has been granted.

Personnel. CLIA requires that the education and the highest level of experience (including time in service) of personnel be commensurate with the complexity of testing that the laboratory performs.

Quality control. Quality control (QC) refers to the process of testing each batch of laboratory tests to ensure that the system provides results within the acceptable range for the assay. Good laboratory practice urges providers to include both positive and negative controls (i.e., specimen material with known positive and negative values) within a given time frame or with each batch of patient samples run on a system. The laboratory professional can compare the results of patient samples with the positive and negative controls to determine the status of the patient sample. Having material with known values helps to control for variation that can occur with different batches of reagents or different equipment, and assures that accurate results are obtained (i.e., testing the positive control should return a result that is within the acceptable range of positive values). In general, patient results should not be reported back to the referring physician unless the QC values are acceptable.

Quality assurance. Quality assurance (QA) refers to the laboratory's internal process for making sure specimen collection, testing and result reporting provides accurate results to patients. Minimum elements of a QA program include: documentation of specimens, specimen tracking, QC performance and documentation, complaint handling procedures, adequate training of personnel, and continuous discussions about laboratory concerns.

FDA

FDA examines the safety and effectiveness of a laboratory test kit. The manufacturer of the kit submits an application for review. "Classification" of product determines the level of review that FDA applies to a marketing application. Classification depends primarily on two things: the risk of inaccurate results to the patients, and the sufficiency of medical knowledge that may be available to mitigate those risks. In brief, Class I tests are subject to general controls, Class II to special controls, and Class III, the highest risk, to pre-market approval (PMA).[2] Though the standards for review are different for different types of applications, FDA assessment will typically include an evaluation of the individual reagents, procedures, and review of the data to demonstrate that the test is safe, and that it works as the manufacturer says it should. This includes making sure the results can be achieved in several independent testing sites, by people with a level of training that is representative of the target population (e.g., laboratory technicians).

There is no relationship between the classification system used by FDA and the CLIA categorization system. FDA's classification is contingent on the risk that a new device may pose to a patient, and the amount and quality of information (such as medical literature) that is available to mitigate the risk. CLIA categorization describes how difficult the test is to perform. In fact, new tests seeking a "waived" categorization may actually undergo a Class III review so that FDA can be assured that the test will be safe and effective in the hands of intended users (for "waived" tests, users typically are not highly trained).

Besides FDA, no other government or private inspection agency evaluates the actual tests to make sure that they are giving correct or accurate results.

Intersection of FDA and CLIA. Not all laboratory tests are required to undergo FDA review. Under the scope of the practice of laboratory medicine, laboratories are given the flexibility to design their own assays, make their own reagents, and design their own computer programs for data analysis using general purpose equipment. Laboratory developed assays are also known as "home brew" assays. In addition, laboratories can modify assays approved by the FDA - that is, they can manipulate assay parameters to optimize test performance in their particular environment (known as "off-label use"). They are, however, required by CLIA to validate any assays they develop, or validate any changes they make to FDA approved systems. Laboratory professionals assert that this flexibility to modify assays

[2] General controls include: registering the manufacturing facility with FDA, listing all of the medical products that are sold, adherence to the Quality Systems Regulations (QSR; 21 CFR part 820) when manufacturing the test or equipment (including reporting any adverse events experienced by patients that may occur from use of the device), labeling the device in accordance with requirements in 21 CFR part 801 or 809, and, if the test is not exempt, filing a pre-market notification with FDA. Special controls are additional controls needed to assure safe and effective use of the device. They may include: special labeling requirements, mandatory performance standards and postmarket surveillance. Premarket approval (PMA) is the most stringent review of safety and effectiveness. A PMA usually involves a clinical study performed by the manufacturer or well documented in the medical literature, an inspection of the manufacturing plant to assure compliance with QSR, and sometimes a recommendation from an independent advisory panel comprised of experts in the relevant field(s). See: [http://www.fda.gov/cdrh/devadvice/3132.html].

is critical to their being able to provide cutting edge diagnostic information within the framework of their institutions. For the most part, only high complexity laboratories are permitted to use these practices. The risk to patients is believed to be mitigated by the fact that all such developments and manipulations are under the supervision of a trained laboratory director who has expertise in the types of testing under consideration.

However, not all manipulation is considered good practice. Generally, while optimizing assay parameters is acceptable laboratory practice, such manipulation usually occurs within the bounds of instrument specifications where equipment is concerned. In fact, many software programs for laboratory instruments have "user interfaces" which facilitate the process of enabling the laboratory worker to make such modifications. On the other hand, there are certain features - such as safety features, moving parts, and electrical or laser connections - which are not supposed to be manipulated, as doing so would place an operator in danger of being injured or exposed to the chemicals or samples being used on the equipment. Failure to heed safety precautions would fall under the jurisdiction of OSHA requirements and guidelines.

States

In addition to receiving certification by CMS to provide clinical testing services, laboratories must be licensed to do business in the state in which they are located. Thirteen states have additional licensing requirements (beyond CLIA certification), which vary in scope.

With regard to meeting CLIA, states can defer inspection of clinical laboratories to CMS or one of the deemed organizations, or they can establish their own requirements for licensing that include certifying that laboratories meet -- at a minimum – the CLIA requirements. The CLIA-exempt states (Washington, New York and Oregon) regulated 6,259 laboratories (of all types) in 2003 (See the CLIA Statistics for the Last Decade, at http://www.cms.hhs.gov/clia/decadestats.pdf).

Ensuring compliance with federal regulations: coordination between government and the private sector

Accreditation. Accreditation refers to the assessment of a laboratory's technical competency by an independent organization. A laboratory can choose to be evaluated by CMS or accredited by one of six CMS approved accreditation organizations: the American Association of Blood Banks (AABB), the American Osteopathic Association (AOA), the American Society for Histocompatability and Immunogenetics (ASHI), the College of American Pathologists (CAP), the Commission on Office Laboratory Accreditation (COLA), and the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). These six organizations have developed standards to ensure that laboratories are meeting, at a minimum, the CLIA requirements.[3] Accreditation is granted and maintained through

[3] Some organizations - like CAP - have requirements for accreditation that are higher than the standards established by CLIA. Because accreditation by a third party is a voluntary choice made (continued...)

inspection by one of these organizations and proficiency testing. The requirements for accreditation can be found online for most of the private organizations[4].

Of the 183,874 laboratories certified under CLIA in 2003[5], 101,090 were physician office laboratories (POL) and 6,259 were located in the three exempt states. COLA accredited 6,218, CAP accredited 4,872 and JCAHO accredited 3,797. The other three organizations accredited a total of 390 laboratories. CMS was responsible for the oversight of 23,000 non-waived/non-POL[6] based laboratories[7].

Proficiency testing. Proficiency testing (PT) is the testing of laboratory samples, where the results are unknown to the laboratory but known to the organization evaluating the results. PT is used to assess the accuracy of the laboratory's test results. Under the CLIA regulations, laboratories test PT samples three times a year for the tests the laboratory performs (42 Code of Federal Regulations (CFR) part 493, subpart I). A laboratory's performance is graded as satisfactory, unsatisfactory or unsuccessful. A satisfactory performance is granted when the laboratory attains a passing score for all of the PT samples that they are sent. Unsatisfactory performance results when a laboratory fails to attain the minimum satisfactory score for a testing event. Unsuccessful performance occurs when a laboratory exhibits unsatisfactory performance for two consecutive testing events, or two out of three consecutive testing events. PT can be required as part of the inspection, particularly if inspection is for cause. However, this option is not used routinely by inspectors.

The American Society of Clinical Laboratory Science estimates that there are anywhere from 1000 to about 25,000 different laboratory tests, with many clinical laboratories performing as many as 500 or more tests (See: http://www.ascls.org/labtesting/index.asp). In contrast, proficiency testing is available for only a fraction of those tests (CAP offers PT for 650 tests), and only those laboratories that perform moderate or high-complexity tests are required to undergo PT.

Currently CMS uses PT as an educational mechanism to assist laboratories to identify and solve problems, evaluate personnel, and improve test performance. Section 493.1838 of Title 42 of the CFR gives laboratories the opportunity to train personnel or obtain technical assistance when the laboratory has an unsatisfactory or unsuccessful PT run. In the past, the agency has been reluctant to use enforcement action solely for unsatisfactory performance on PT, except in cases where there is an immediate jeopardy to patient health or safety, or

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[3] (...continued)
by the laboratory, some laboratories may avoid seeking accreditation by an organization with higher standards.

[4] For example, the CAP provides checklists for accrediting in 17 sub-specialites of laboratory medicine at: http://www.cap.org/apps/docs/laboratory_accreditation/checklists/checklistftp.html.

[5] See CLIA decade statistics at: [http://www.cms.hhs.gov/clia/decadestats.pdf]. The numbers are not intended to add to the total.

[6] Many POLs perform only waived testing (such as dipstick tests), or microscope studies.

[7] Personal communication with Judith Yost, CMS.

when a laboratory demonstrates an inability or unwillingness to provide evidence of corrective action.

As part of a QC/QA program, laboratories may also make use of reference material such as NCCLS[8] standard material to adjust their testing parameters. NCCLS provides both material standards - material with known values that can be independently tested and used for calibration of laboratory equipment - and document standards - which are documents that describe the best laboratory practices for certain types of tests. NCCLS standards are voluntary, but are widely recognized as best laboratory practice to ensure consistency between laboratories performing similar tests. FDA recognizes NCCLS standards during the review process.

For laboratory assays that do not have proficiency tests available, laboratories may make other arrangements to ensure the accuracy of their results. One popular method is to have a sample tested and the result independently verified by a second laboratory. This method is preferred for testing of rare analytes where testing may only be available from a very small number of laboratories.

Inspection. CLIA regulations require that inspections must be performed biennially. CMS uses discretion in adjusting the time frame towards more frequent inspection of laboratories requiring the closest supervision, and using alternative methods (such as the Alternate Quality Assurance Survey, a self survey questionnaire) to inspect on-site less frequently laboratories that have sustained a record of compliance. CMS investigates the number and types of deficiencies cited by CMS inspectors, PT performance and complaints against the laboratory. Most CMS inspections are announced for initial or re-certification inspection to allow the laboratory the opportunity to include multiple staff members in the process and to make records accessible before the inspection. However, most "for cause" inspections are unannounced and conducted during normal business hours to minimize disruption to the laboratory and to ensure that key laboratory personnel are present to answer questions. Since 1998, CMS inspections have been moving toward a focus on outcomes rather than process-oriented inspections (*Federal Register*, May 14, 1998, pp. 26722-38), where the outcome is the effect of the laboratory's practices on patient test results and/or patient care.

CLIA surveyors for CMS are employees of the state health department of the state in which the laboratory is located. Many states have only one surveyor. Most surveyors have general experience and expertise in laboratory practice, though some will also have specialized experience. All surveyors receive comprehensive training from the state, the CMS regional office and the CMS central office on the regulations and what to look for during an inspection. CMS inspects approximately 12,000 laboratories - of all complexities - in a year. In addition, CMS re-surveys approximately 5% of laboratories as a validation of the accreditation process.

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[8] NCCLS used to be an acronym for the National Center for Clinical Laboratory Standards. However, in recent years the organization has focused on international harmonization efforts in laboratory methods and standards. As a result, the organization goes by the name "NCCLS".

In addition to deficiencies found on inspection, CMS investigates complaints against laboratories in order to determine if the alleged violation involves CLIA requirements or other laws that could be under the jurisdiction of another agency (e.g., OSHA). If CMS finds that the complaint is a violation of other laws, they will refer the complaint to the appropriate agency for investigation.

FDA inspects manufacturing facilities and sites where clinical investigations are ongoing in support of a marketing application.

Most private accreditation bodies rely on checklists, guidances, or other standards that they develop, and reporting by employees to identify deficiencies. Routine inspections are often announced, but can be unannounced if there is reason to suspect a problem ("for cause" inspection). JCAHO indicated that in 2006, all surveys will be conducted on an unannounced basis. Laboratories are routinely surveyed biennially, however if there is a concern that a problem could pose "an immediate threat to life", inspections can be expedited - usually within 1-2 calendar days. If significant non-compliance is discovered, JCAHO will re-survey the laboratory within 4-6 months.

JCAHO uses professional evaluators as inspectors, who are required to pass a certification examination every 5 years. Surveyors are randomly assigned to a laboratory based on availability. JCAHO enforces a strict conflict of interest policy that prohibits them from inspecting a laboratory where they have a real or perceived conflict, including those with whom they have a supportive or competitive business relationship. JCAHO routinely reports information on the date of accreditation, CLIA number, speciality and subspecialities reviewed, and annual testing volumes for each accredited laboratory. They will also provide CMS and state licensing agencies with immediate notification of serious situations that could jeopardize patient safety. JCAHO does not routinely report specific deficiencies to CMS or the state. However, the deficiencies are noted on the accreditation report, which some states require as part of the licensing process.

CAP inspectors are part of a multi-disciplinary team with expertise in laboratory practice. The team leader is chosen from a laboratory of similar size and scope of services as the laboratory being inspected. CAP inspectors also are chosen for the expertise and familiarity they have with the tests and instrumentation used in the laboratory. Inspectors are not permitted to conduct reciprocal inspections of each other's respective laboratories. If deficiencies are found, the CAP team will follow up with the laboratory to ensure that a corrective action plan is submitted within 30 days. Like JCAHO, CAP will not submit the inspection reports to CMS unless the laboratory fails to come into compliance within the 30 day time frame or unless the deficiency was one of immediate jeopardy.

Deficiencies found by CMS surveyors or inspectors from private organizations are evaluated at the time of their discovery and ranked according to the potential impact on patient outcomes. Some may be corrected on-site at the time of inspection. Others may require that the laboratory submit a plan for corrective action to CMS or the private accreditation organization within 30 days. Depending on the acceptability of the corrective plan, CMS or the private organization may re-inspect the laboratory within 4-6 months of the original report. "Immediate Jeopardy" is the most serious violation, defined in 42 CFR 493.2 as "a situation in which immediate corrective action is necessary because the laboratory's noncompliance with one or more condition-level requirements has already caused, is causing,

or is likely to cause, at any time, serious injury or harm, or death, to individuals served by the laboratory or to the health or safety of the general public. This term is synonymous with imminent and serious risk to human health and significant hazard to the public health". For deficiencies that are perceived to present an immediate threat (such as reporting inaccurate results on blood typing for transfusions), CMS may order the laboratory (or the section of the laboratory with the deficiency) to cease testing and institute immediate corrective action. In extreme cases, CLIA certificates or state licenses could be revoked and other penalties imposed.

Accreditation organization inspectors are required to supply CMS with a report of summary findings. CLIA requires that the accreditation organizations have a protocol on following up with their own inspections. Only the most serious deficiencies -- those potentially life-threatening impacts -- are likely to be reported immediately to CMS by the private organization. If there is a problem, CMS may request a specific report. However, CMS does not normally give the report to their surveyors because they prefer to keep surveyors unbiased in their approach to an inspection, even if the inspection is to investigate a particular problem.

In CAP surveys, deficiencies are presented to the laboratory director at the time of the on-site inspection, and many are corrected at that time. For those that cannot be corrected while the inspector is on-site, laboratories must provide a correction within 30 days. Between October 1997 and March 1998, a CAP survey found that most deficiencies were in the areas of quality control and quality improvement wherein the responsible laboratory personnel failed to review standard operating procedures, instrument function or QC results in routine procedures (see Hamlin WB. "Requirements for Accreditation by the College of American Pathologists Laboratory Accreditation Program," *Arch Pathol Lab Med*, Vol 123, June 1999, pp. 465-7).

Adverse Events. An adverse event consists of unintended abnormal signs (including abnormal laboratory findings), symptoms, or disease diagnoses incurred by a patient as a result of using a medical product. For example, an adverse event associated with a faulty laboratory test could be misdiagnosis of a serious illness (i.e., false positive or false negative result for HIV or cancer). Alternatively, the faulty test result (such as blood typing) could directly contribute to injury to a patient from a treatment that was applied as a result of the test (such as a blood transfusion). The federal government has no way of knowing how many adverse events result from laboratory tests, nor can it know what percentage is reported. One retrospective study reported that laboratory errors were relatively few (129 incident reports in 15 months compared to the 3.8 million test results reported out per year).[9] Most -- 95% -- were potential adverse events (i.e., they did not actually cause injury to a patient, but otherwise could have). In 60% of the incidents, the hospital laboratory was responsible for the incident, with many occurring at the sample processing stage. In 85% of the cases, there was a delay in the provider receiving the results, and in 40% of the cases, a specimen had to be recollected. The study did not provide details on the actual adverse events (i.e., those that resulted in injury to a patient). A similar study found that delayed or incorrect result reporting

[9] Astion ML, et. al. "Classifying laboratory incident reports to identify problems that jeopardize patient safety", *AmJ Clin Pathol*,2003, vol. 120, pp. 18-26.

were the most common problems within the laboratory, and that wrong patient identification and/or requisition forms were the most common problems found outside of the laboratory.[10]

FDA has the largest system for reporting adverse events that happen as a result of a faulty medical test (see http://www.fda.gov/cdrh/mdr/). Potential problems can also be reported to inspectors during inspection. Anyone can report adverse events to FDA, including consumers, laboratory professionals, healthcare workers, and manufacturers, by mail, fax, telephone or via the Internet. However, only user-facilities, such as hospitals and nursing homes are legally required to report suspected medical device-related deaths or serious injuries to both FDA and the manufacturer of the device (for FDA purposes, laboratory tests are a type of medical devices). In some circumstances, manufacturers themselves are required to report events to FDA. Adverse event reporting is considered an important part of assessing the safety and effectiveness of a test in part because even lengthy or large clinical trials often will not uncover rare events.

In a report by the Department of Health and Human Services Office of the Inspector General, two shortcomings were noted with regard to reporting of adverse drug reactions which have bearing on the present discussion. The shortcomings were: poor tracking and coordination of reports between the office that received the reports and individual review divisions, and a lack of a quality system to ensure that reports of serious events were not overlooked.[11] For laboratory tests, FDA's Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD) at the Center for Devices and Radiological Health, monitors and follows up with adverse event reports. OIVD is a unique office within FDA in that it incorporates both pre-review and post-market compliance functions in a single office, thus maximizing opportunities for information sharing and coordination. Risk assessors that review the reports ascertain whether a problem is potentially serious. The data quality issue is more difficult to address. Reports can be submitted by many individuals with various educational and training backgrounds, and are often submitted with imperfect information. However, electronic formats do include a place where the person reporting the event can indicate if a death or injury resulted from the event.

When something goes wrong with an element of the quality system in a laboratory, the laboratory worker will generally notify a supervisor or other member of management. If a test or piece of equipment is producing results on quality control material (i.e., material with known values) that fall outside of the range of values recommended by the manufacturer, then either the worker or the supervisor may contact the manufacturer of the reagents or equipment to try and troubleshoot the problem. If no patient results have been reported out, the laboratory personnel can work with the manufacturer to correct the problem. If patient results have been reported out, or if an adverse event is known to have occurred, the laboratory managers have two options: they may report the event directly to the FDA or they may report to the manufacturer who would decide if reporting to FDA is necessary (that is, they should report to one or the other).

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[10] Goldschmidt HMJ and Lent RW. "Gross errors an workflow analysis in the clinical laboratory," *Klin Biochem Metab,* 1995, vol. 3, pp. 131-40.

[11] Brown JG, Inspector General. Department of Health and Human Services, Office of Inspector General Report #A-15-98-50001, "*Review of the Food and Drug Administration's Handling of Adverse Drug Reaction Reports*", December, 1999.

JCAHO has a system to which adverse events can be reported; however, the number that they receive for clinical laboratories is small (<1%) compared with events that occur within the general hospital care setting. CAP does not collect adverse event reports (usually reported to the hospital's error reporting system), but does receive and investigate (within 24 hours) complaints .

There are no mandatory reporting requirements for adverse events that occur as a result of home brew tests (tests that are designed, developed and produced entirely within the laboratory). However, FDA has recently implemented a voluntary reporting system that could accommodate limited reporting of events from those laboratories. FDA's authority to enforce compliance action however, is unclear in those situations, but the agency could help to co-ordinate or refer the laboratory to the appropriate CMS personnel for follow-up.

Responding to the need for improved communication, CAP indicated that they would modify their inspection and accreditation process to enhance self-reporting by laboratory staff of quality issues, and JCAHO indicated working to improve sharing of complaint and deficiency data with CMS and other oversight bodies. CAP and JCAHO already share information between themselves about inspections for CAP inspected laboratories within a JCAHO-accredited facility. CMS conducts regular conference calls with regional offices, and communicates with the accreditation organization on key issues.

Postmarket Surveillance Studies. For products identified in a premarket phase to have the potential to represent a serious risk to human health, FDA can require that the manufacturer conduct postmarket surveillance studies as necessary to protect the public health. The intent is to identify problems, issue safety warnings, and provide information that is not available from the medical device reporting system. Postmarket surveillance is usually applied to implantable devices, or those that are intended to support or sustain life, rather than laboratory test devices. Similarly, FDA has discretion to require a manufacturer to track devices whose failure would likely have serious, adverse health consequences. Medical device tracking is intended to ensure that manufacturers can quickly remove from the market potentially dangerous or defective devices and notify patients of significant device problems. Like post-market surveillance, however, this tool is rarely applied to laboratory devices.

Enforcement. For laboratories found in violation of CLIA, the Secretary of Health and Human Services has the authority to suspend, limit or revoke the CLIA certificate, or impose civil suits upon any illegal laboratory activity that constitutes a significant hazard to public health, including fines or imprisonment of any individuals found to intentionally violate CLIA (42 CFR 493.1800). CMS further has the right to impose alternative sanctions (such as a directed plan of correction, on-site monitoring or suspension of Medicare or Medicaid payments) as warranted by the situation. Sanctions are published annually.

In past 5 years, CMS proposed enforcement action in 6,084 cases and carried out action in 487 instances (testimony of Dr. Sean Tunis, Chief Clinical Officer and Director, Office of Clinical Standards and Quality, CMS at May 18th, 2004 hearing on laboratory errors before the Subcommittee on Criminal Justice, Drug Policy and Human Resources).

If a laboratory test failure is found to result from something the manufacturer did wrong, FDA has authority to change the labeling of the test, send letters to health professionals

advising them of the potential error, restrict distribution or use to specialists, recall and remove defective tests and equipment from market, and impose penalties on manufacturers. Based on testimony of Dr. Gutman, FDA considers the following points when deciding if a widespread compliance action or national recall is warranted: the number of reports received and from different location(s) (i.e., is it a national, international or local problem?); whether the event can be duplicated for troubleshooting processes; if there have been reports in literature or on laboratory list serves suggesting a widespread problem; and the results of inspection of manufacturing facilities and followup with the testing facility.

Questions for Congress to Consider: Assuring Quality in Clinical Laboratories

Congress may wish to consider the following questions to determine if additional federal oversight of clinical laboratories is warranted, and if so, how oversight should be applied.

Defining the scope of the problem

- Is the current level of oversight for clinical laboratories appropriate, or are there certain categories or types of laboratory tests that pose additional concerns (e.g., waived tests? High complexity tests?)
- In relation to the number of laboratories, the federal government imposes relatively few sanctions for deficiencies. Is that because the quality assurance programs implemented by the laboratories really prevent (or correct) problems as they should or because the current system of inspection and oversight fails to identify them?
- What is the best mechanism to facilitate further exploration of the sufficiency of the checks and balances on laboratory quality to identify whether changes are needed at federal or state level? Should Congress:
  - Establish a federal task force or an advisory committee (such as to the Secretary of Health and Human Services) comprised of stakeholders in laboratory testing[12] to report back to congress?
  - Commission an independent study (i.e, GAO, or IOM)?

Oversight and co-ordination

Accreditation.

- Should coordination of laboratory inspections and accreditation be centralized at the federal level or decentralized to state level[13]?

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[12] Stakeholders may include, but are not limited to representatives from: federal agenies (e.g, FDA, CMS), private accreditation organizations, the National Council of State Legislatures, a consumer group, different laboratories (e.g., one commercial/reference, one academic/hospital, one small/rare disease testing), and manufacturers of laboratory tests and/or equipment.

[13] Currently, no one organization coordinates efforts to inspect, accredit and/or certify and license laboratories, particularly when deficiencies are discovered. Consideration may include an assessment of the interaction between existing legislation on regulation and current or proposed legislation on (continued...)

- Centralized coordination evokes concerns over potential privacy violations (need patient information to follow up) while decentralized laboratory regulation presumably could be more responsive to local concerns.
- If decentralized, should the federal government provide financial assistance or support?
- Should CMS be granted additional resources to deem more third-party organizations to perform inspections?
- Are the CLIA requirements and/or standards developed by private organizations appropriate tools for assessing the competence of clinical laboratories?

Inspection and proficiency testing.

- Should inspections be announced or unannounced? Should laboratories be supplied with a checklist or guidance beforehand?
- Are inspectors adequately trained to recognize deficiencies in proper performance of different kinds of laboratory tests? In safety issues?
- What is the extent of training for employees with respect to proper use of testing procedures and laboratory equipment or with respect to proper handling of potentially infectious or biohazardous patient specimens (OSHA requirements)?
- Is routine inspection effective in identifying problems, or should inspection focus on "for cause" activities? Should/could proficiency testing results be used for regulatory purposes?
- Should there be a federal process or standards to delineate what type of adverse events warrant priority inspection, when the inspection should occur, and which agency should take the lead and/or be accountable for coordination?

Reporting deficiencies and adverse events.

- Should there be a mandatory reporting system for adverse events and/or deficiencies outside of the inspection process?
  - Which federal agency or private organization would be best suited to administer such a system?
- Should reports from laboratory employees that are sent to laboratory management also be copied to a regulatory agency?
  - If copied to the regulatory agency (such as CMS), would they be made available under the Freedom of Information Act? If so, what protections would need to be in place to protect patient confidentiality?
- If there is malfunctioning equipment, what pressures exist (e.g., cost) on the facility to keep that equipment in place?
- Should there be established a point person or organization for ensuring followup between incidents?

Compliance and Enforcement

- Should laboratory deficiency letters be made public (like FDA publishes warning letters)?Are additional sanctions needed for laboratories with continued instances of noncompliance?

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[13] (...continued)
privacy and patient safety.

- Should there be a "safe harbor" provision under which a laboratory is protected and immunity granted to encourage reporting if the laboratory takes corrective action to solve the problem prior to an adverse event occurring?
- Does the federal government need to provide additional protections for laboratory employees who come forward with information to inspectors, whether state, professional organization or CMS?

Mr. SOUDER. I thank you. And the subcommittee stands in recess.

[Recess.]

Mr. SOUDER. The subcommittee will come to order.

It's the custom of this committee that we swear in our witnesses, as the oversight committee. So if you'll raise your right hand.

[Witness sworn.]

Mr. SOUDER. Let the record show the witness responded in the affirmative.

I'm glad you are able to join us today, and we look forward to your testimony.

STATEMENT OF KRISTIN S. TURNER, FORMER EMPLOYEE OF MARYLAND GENERAL HOSPITAL

Ms. TURNER. Thank you for inviting me to testify, and thank you for making this issue important enough that you're going to make sure that what happened at Maryland General happens nowhere else.

I want to thank the University of Maryland medical system for taking the steps that they took in making sure that the issues were taken care of in such a quick manner.

I don't have an additional written statement from the statement of before. I'm here more, if there's any other information you would like to know from me, in addition to my written statement. I had a couple of concerns about some of the testimony that was given in May as far as, and just very minimal things. I have a lot I would like to say, but it would be more than we have time for.

But just initially, I think that it worries me that the lack of action that the FDA seems to be able to take as far as medical devices goes. I think that there needs to be more people in the loop as far as reporting of incidents with medical devices.

I realized, I noticed after reading the statement from them that Adaltis didn't, it was left up to the responsibility of Adaltis to report the incident happening, and that they didn't report it initially because there was no infection that resulted. They didn't even think that it was important enough to report unless something happened secondary to that exposure.

And I think that the incident itself is what needs to be reported immediately to whoever is doing the oversight for medical devices. That is part of what worries me the most, is whose responsibility is it to report problems with medical equipment to the FDA. If it's left up to the manufacturers, that just scares me. It doesn't seem like they would be real excited about reporting their failures. It seems like there needs to be something that says, when something happens, no matter how minimal you might think it is, it needs to be reported as an incident and investigated.

That's pretty much it. I'll just answer anything you have to ask me.

[The prepared statement of Ms. Turner follows:]

Statement of Kristin S. Turner – May 18, 2004

Thank you for inviting me to testify at this very important hearing. I am sorry that I cannot attend in person but I have become ill and was unable to travel to Washington. I hope these comments are of some help to you as you consider these important matters.

In March of 2003, my life was forever changed because of the at best irresponsible conduct of a hospital and a biomedical equipment company. The focus of this hearing is not what happened to me, but rather why the hospital and company were allowed to engage in such dangerous practices.

There are 2 immediate things I hope are achieved through this hearing. First, I am not sure how much emphasis is being placed on the issues surrounding the Labotech. This is the instrument that in my view was designed poorly and dangerously, resulting in unreliability, inaccuracy, and injury. I am now aware that there have been international warnings issued regarding the lack of reliability of the results because of both mechanical and programming errors. Maryland General utilized 3 different Labotechs during the time of my employment, and all 3 consistently malfunctioned and failed runs. Adaltis, the distributor of the machines in use at Maryland General Hospital, was responsible for repairing the machines and many times each month sent people in to "fix" the machines, yet they were never able to be used for more than 2 or 3 days after each repair without having more problems.

The most frightening and consistent malfunction to occur with the Labotech was missed samples. Missed samples means that a patient's sample was not dispensed onto the test plate, and therefore a negative result was obtained. In reality the machine never performed the test. The negative result obtained could possibly have been a "false negative". There is no way of knowing how many "false negatives" have been reported to patients. The thought of patients being delayed prompt treatment and unknowingly spreading a disease they were just tested for because of a false negative is frightening.

The problems with the Labotech are not related to any individual instrument, the problem is in the design and the programming. Adaltis must be required (since they apparently haven't taken the proper steps on their own) to remove every Labotech from service and hire an outside company to inspect each instrument for safety and reliability before it is allowed to be put back into use. There are over 2500 Labotechs currently in use in the US. The number of potentially inaccurate results being reported out to patients each day because of instrument malfunctions is staggering. Please take some action to protect the public from this machine. There must be more stringent requirements enforced before allowing an instrument like the Labotech to be released and put into use.

The second action I hope is taken is to make sure that better oversight is put in place for hospitals and hospital labs. The problems at Maryland General stemmed from a lack of accountability at every level in administration, and a grave disregard for the health and safety of the people in the community. In the laboratory, one man was allowed to choose profit over patient safety and his actions were never questioned by his superiors; making them just as responsible for the multitude of problems that resulted from his decision. Patients were provided less than optimal care, and were provided results from a machine that he knew was unreliable and unable to be validated. He demanded that the results be run in house instead of sent out, even with the equipment problems,

because the Labotech was the "money-maker" for the laboratory and to send out tests would have cost the hospital money. In my view his conduct was a betrayal of the communities trust which the administration allowed to continue.

He also refused to provide a safe environment for the employees in the lab. By refusing to replace a defective piece of equipment (the Labotech) and inform the employees of the seriousness and longstanding malfunctions, he knowingly placed employees in harms way. On March 12th, 2003, the instrument had a major malfunction exposing me to blood. I did everything I was instructed to do, from the protective equipment I was wearing to how I handled the malfunction, and the treatment following the exposure. However, in June, while hospitalized for a severe flu-like illness, my blood tests came back positive for both HIV and Hepatitis C (I tested negative on the day of the incident). My life has been irreversibly changed in every way imaginable. I only tell you this, because this incident could have been completely prevented. I learned only after the accident, that administrative director of the lab (James E. Stewart) was made aware of serious problems with the machine from the very first week it was brought into the lab. He also knew that the machine had never been safety tested or inspected by the hospitals own engineering staff. I later learned that on numerous occasions many of the laboratory staff requested that the machine be sent back and replaced by a different machine from a different company that was actually proven to be reliable and safe. Instead, another dysfunctional Labotech was brought in and put to use. If proper safety procedures were followed as set out by both the hospital and OSHA, after the extreme number of problems with Labotech, it should have been removed from service, long before I began my employment. Please don't let what happened to me, happen to anybody else with this or any other dangerous and defective piece of equipment.

What is particularly disappointing is Maryland General Hospital's response to this public health catastrophe. When its laboratory practices were first called into question, the hospital circled the wagons around Mr. Stewart and the other administrators who failed to do their jobs. They denied responsibility and awareness of the serious problems their lack of action caused. Also disappointing is the fact that following my complaint, the state found many more problems in the Laboratory than those I cited, yet Maryland General's Lab had passed all the accreditation and certification inspections that had recently been conducted. This flies in the face of all common sense and seriously calls into question the validity of the inspections and accreditation process established to insure public safety. The agencies responsible to insure the proper operation of hospital labs must also be held accountable and required to take responsibility for their failures and breach of the public trust. I fear the problem of lack of proper oversight is not a problem limited to Maryland General Hospital. New guidelines ought to be considered and/or the old ones enforced for the health and well being of every patient.

Thank you again for the opportunity to share my information with this congressional sub-committee. I have all of the confidence in the world that you will take whatever action is appropriate to help prevent these messes from occurring in the future in other hospitals and with other pieces of biomedical equipment. You have the power to prevent what happened in Baltimore and to me from happening anywhere else.

Sincerely,

Kristin Turner

Mr. SOUDER. Your full statement will be inserted into the record again. As you probably know, we read your statement the last time, so it was already read into the record.

I'm going to yield to Mr. Cummings for first questions.

Mr. CUMMINGS. Thank you very much. Ms. Turner, as I've said to you before, when I first met you, and I say it to you again, I do thank you for coming forward. I have seen with my own eyes, and I've heard with my own ears vast improvements at Maryland General Hospital. I don't know if you know this, but many employees that you may have worked with are so pleased with what has happened there that they have come back to work in the lab.

Ms. TURNER. Good.

Mr. CUMMINGS. By the way, you may be getting some notes from them, they got a pay raise.

Ms. TURNER. Great.

Mr. CUMMINGS. Because of you. And we heard some testimony—so I thank you very much. Do you know Teresa Williams?

Ms. TURNER. I met her once.

Mr. CUMMINGS. Teresa Williams testified before us back in May, and she talked about feeling intimidated. As a matter of fact, it was on a lot of news shows. I guess one of the things we're trying to get to, and the committee is very concerned about, is how do we make sure that people like you, when the College of American Pathologists come in, for example, or the State comes in, have an opportunity to express their concerns? What are your feelings on that?

Ms. TURNER. I was at Maryland General for a couple of CAP inspections. I know that we were aware that they were there, but they never actually communicated with the individuals who were actually doing the work. They were communicating with the supervisors and the lab directors and things like that.

I guess it would be very helpful if there was a way that we were able to talk to them, and if there was anything that needed to be done, it would be done in an anonymous manner. So if there was a problem with the machine, for example, or problems with a section in general as far as like, we're worried about results or worried about how something was being done, if we could report that to CAP and know that our name was not going to be brought up as being the person who said, this is really messed up, and all that, so there could be an anonymous way for us to report to CAP. Face to face would be great.

Mr. CUMMINGS. One of the things that has happened as a result of your actions and people like Teresa is that Mr. Notebaert has established a system by which anonymous complaints can be made directly to him. Is that good enough, do you think?

Ms. TURNER. I definitely think that's a great step.

Mr. CUMMINGS. Say that again?

Ms. TURNER. I think it's a great step. I'm not sure how well—it depends, I guess, on what the response would be to complaints that were made. Because complaints were made to the directors of the lab and that obviously wasn't enough. So I guess to be able to go to the top would be a good thing.

Mr. CUMMINGS. And if there were a system by which, when inspectors came in, they, say from CAP or from the State, that em-

ployees were, it was made known, say, for example, to the employees, that they were looking for any concerns that the employees might have. Say for example, they gave them a little card and said, you can send in an anonymous, typed-up bit of information. Do you think that would be helpful.

Ms. TURNER. I think that would be great. I think it would be very helpful. I was thinking also that it might be really good if there were concerns made that maybe there were three copies, and three different departments or three different people were notified of that, so that if two people dropped the ball, then there's one person to followup on that, so there's accountability at every level. I think that would be a very good thing to happen.

Mr. CUMMINGS. Now, you went to great lengths within the system and outside the system to put the word out that you had concerns, is that right?

Ms. TURNER. I did, yes.

Mr. CUMMINGS. Tell us what you did.

Ms. TURNER. Probably, in my recollection, it seems like I did this on a weekly basis, told the administrative laboratory director, as well as my supervisor over the department. I was told, actually, to keep it within the lab. Because I asked on a number of occasions about going to risk management, which is something that we're told you can do.

When you come in for your employee orientation, you're told you can go to risk management if you have an issue. But I was told in the lab that the lab handles the lab's business.

Mr. CUMMINGS. So basically what you had was, although you were giving information, telling the people in charge of the lab what the problems might have been, there was no way for that information, the information to your knowledge wasn't flowing past your supervisors or whoever was right there in the lab.

Ms. TURNER. And it took a while to realize that. But that was what I came to understand was happening, was that it was stopping there rather than being reported further on, where something was actually going to be done. And in fact, it seemed to me that the problems regarding the particular issues that I knew about were almost being kind of kept away from the other people who should know about it, even in the lab itself.

Mr. CUMMINGS. When I had an opportunity to talk to you a few months ago, you said something that was very interesting. You said a number of people at the hospital, particularly in the lab, had left because they were so frustrated that they could not, that nothing was happening. So I assume that you could see certain problems recurring, and you didn't see any results taking place. Did you ever try to go above the lab and the supervisors in the lab?

Ms. TURNER. I did not. The farthest that I went was to Dr. Stewart.

Mr. CUMMINGS. And Dr. Stewart was the head of the lab?

Ms. TURNER. He was the administrative lab director. So he was, there was a medical director above him. My understanding was that they communicated about everything. But that didn't turn out to be the case. So that is where I took it, that was the top of the lab for me in my position.

Mr. CUMMINGS. What was the thing that got all of this started? What's the first thing that you noticed that kind of got you upset?

Ms. TURNER. Well, I was concerned about the machine and the results that were coming from it, just because there were so many errors with the machine. There were also things that were happening with the machine, like it was missing steps or missing reagents. And every step is required to have a valid result. But the machine wouldn't be aware that it had made this mistake. So if I didn't happen to be standing there watching it, then I would think the results were OK at the end, which is not really such a good thing.

So I voiced those concerns lots of times. And the machines were always broken, and nothing, they would never be fixed adequately. They would be fixed and maybe they would work for a couple of days and then we would have to call service again. It seemed like that wasn't such a good deal. It seemed like something could be done better.

Then, the incident that resulted in my exposure happened and I went in the day after the accident to fill out some paperwork and things like that. I went into the lab and the very next day, they had people working on the same machines. Well, then Labotech, I don't know if it was the same machine in particular, but all of the machines there showed the same problems. That worried me, because it seems that you would investigate to make sure that you weren't putting your employees in harm's way, being that there had just been a serious accident that happened. I would think they would at the very least look into that before just putting people back on the machines.

And most of the information that I have I received after my accident, and it was as a result of other people, outside people looking into the accident and how it happened, other departments in the hospital. They uncovered all kinds of information that was kind of, it was in, I guess kind of little, not cubicles, but it was separated from everything else. So somebody had knowledge of it, but it wasn't being connected with what was happening now. So the seriousness of everything, since the machine got to the lab, didn't become apparent until after my accident occurred.

So it was at that time that everybody now had all of the information from when Teresa Williams was there all the way up through my accident. And the realization came that somebody knew that there was something really wrong from a really long time ago. So I thought that maybe now that everybody had this information, surely the hospital would fix it. So I gave them quite a while to fix it.

When I found out that I had been terminated, I found out by accident, they didn't actually even tell me this. That was kind of my signal that they had decided not to deal with it, but they had decided more to push it under the rug. And I had really given them every chance and every benefit of the doubt that they were going to fix it on their own.

Mr. CUMMINGS. You said you knew about when CAP came in, is that right?

Ms. TURNER. Yes.

Mr. CUMMINGS. Did you know when the State came in?

Ms. TURNER. No. And that's a huge issue, I think. Because for CAP, we knew weeks in advance they were coming and the labs were always, everybody from the supervisors on down, it was like, OK, CAP is coming so do this, clean up this area, or do this, do this, get ready. Everybody was getting ready at every level. For us, it didn't really affect us so much as just making sure that where we were working was maybe cleaned up or whatever, was organized better, so it didn't give them anything to have to look at.

But the supervisors and things like that, it was almost chaos for them trying to get ready for CAP coming. But the State, you have no warning. So I think that's an amazing thing.

Mr. CUMMINGS. Is that a better system, you think, no warning?

Ms. TURNER. Absolutely. Because I think, when the State comes in, it's my understanding that they come in and they don't say, no, not in 2 hours, I don't want this information, I want you to take me in now and I want the information and I want to see it for myself, what's happening now. I think that is how inspections should be done of laboratories.

Mr. CUMMINGS. Let me just ask you this, and then I've run out of time, but let me ask you this. You just said there was a lot of cleanup, and I'm not trying to put words in your mouth, but it was almost panicking, panic time when it came time for the CAP inspectors. Did the CAP inspectors get a true picture of what the lab was like on a day to day basis, or did they get something else?

Ms. TURNER. I think they got the cleaned-up, Sunday church version of the lab.

Mr. CUMMINGS. The cleaned-up, Sunday church version.

Ms. TURNER. Yes.

Mr. CUMMINGS. OK.

Ms. TURNER. Honestly, I——

Mr. CUMMINGS. I just wanted to make sure I heard what you said.

Ms. TURNER. Yes. It's not the every day runnings in any way. Everything is just cleaned up, everything is shown in the very best light that it possibly can be, and kind of, you hope they don't look in the shadows, I think, is kind of how the lab approached it.

Mr. CUMMINGS. So if you were trying to, looking backward now, and looking at the fact that CAP came in and CAP didn't detect certain things, and maybe it's just the way they do it and the kind of information that might be available to them, what would your recommendations be with regard to—I know one of them would be that CAP not announce when it's coming in.

Ms. TURNER. Right.

Mr. CUMMINGS. What other recommendations would you have? You have to keep in mind that CAP is doing these inspections all over the country.

Ms. TURNER. Right. I think maybe there could be somehow more unbiased, I'm not saying that CAP is biased, but they are all members of the same organization, they are all laboratory members, it's to their advantage to have laboratories pass, because that's what they do. It's kind of hard. I'm not very organized with that answer.

Mr. CUMMINGS. Let me try to help you. Let me just ask you this. You've watched CAP do inspections, have you not?

Ms. TURNER. Yes.

Mr. CUMMINGS. And you talked about the cleanup before CAP came. It just seems to me that if we are operating a lab which is performing tests that could result in a person getting treatment for a life-threatening ailment or not, it seems as if the standards would be constant. It shouldn't be a cleanup.

Ms. TURNER. Right.

Mr. CUMMINGS. So I'm trying to figure out what it is you were cleaning up. What we're trying to come up with is trying to make sure that a hospital in rural Indiana, where Mr. Souder is from, if a CAP inspection team comes in that his constituents, just like my constituents in Baltimore, would feel comfortable that there is an agency like CAP that is doing a good inspection. And when they put the Good Housekeeping seal of approval on it, it means something.

What I'm asking you, and you may not be able to answer this, what would you like to see happen to make sure that Good Housekeeping seal is valid?

Ms. TURNER. Well, I think the surprise inspections, the chance that any minute of any day somebody can come in and revoke your ability to operate based on what they see, is an amazing motivator. I think that just maybe having there be some way where CAP sees something other than what the lab shows them.

I know that for paperwork and things like that, they see whatever the supervisors get ready and present to them. So they don't go looking on their own. It's my understanding that they don't. I never saw them go looking through the file drawers on their own. They took at face value what the lab said and what they told them or what they showed them as far as paperwork.

Other than that, maybe just making sure that there are other agencies that can maybe overlap that responsibility, so that they're not the final word, or there needs to be something other than passing CAP inspections for maintaining a lab and being able to operate a lab when people's lives are at risk.

Mr. CUMMINGS. Thank you, Mr. Chairman.

Mr. SOUDER. I have a couple of followup questions. You've raised some really problematic questions regarding your particular laboratory that I'm not sure I'm comfortable with extrapolating beyond that. If I understand, do you believe the person who ran your lab got a particular tip from the inspector, or what made you think that they knew about the inspection?

Ms. TURNER. CAP inspections are scheduled. So they know when CAP is coming. The laboratory is notified, if not a month in advance, it's earlier than that.

Mr. SOUDER. They testified under oath that isn't true nationally.

Ms. TURNER. Oh. Well, I'm not sure about that.

Mr. SOUDER. We'll hear that in the second panel. So if you place was——

Ms. TURNER. We were aware that CAP was coming.

Mr. SOUDER. That's what I understood them to say last time under oath, is that they were unscheduled.

They are scheduled in advance or not scheduled? Is the person who is going to testify from the Pathologists here? Can you nod your head, are they scheduled or not scheduled? They are scheduled. OK. I'm incorrect.

So if they are scheduled in advance, that is problematic. I agree with Mr. Cummings that they should be unscheduled, and I thought that we understood they were not, and that was a matter in debate. Why do you believe that, well, let me ask you another question? Were you terminated by the lab or by the hospital? I forget from the last time, is the lab an independent entity that rents space from the hospital?

Ms. TURNER. No, it's all part of Maryland General.

Mr. SOUDER. So your checks came from the hospital?

Ms. TURNER. Yes.

Mr. SOUDER. Do you have an appeal process if you get terminated?

Ms. TURNER. I was told no. I requested that it be looked at, because I was sent a letter that said I would be left on medical leave, that I wouldn't be terminated. And then I came to find out by accident that I had been terminated.

Mr. SOUDER. Did you appeal past the lab? Did you write a letter to the hospital or anybody beyond the lab?

Ms. TURNER. I did. And I sent a copy of the letter that I had received and they never——

Mr. SOUDER. The hospital didn't respond to you?

Ms. TURNER. No.

Mr. SOUDER. Did you raise concerns that it might be because you raised concerns in the lab? In other words, did you tell them?

Ms. TURNER. At that point, I didn't. I thought, but I also know that it's much easier to, if somebody is making trouble or bringing up issues that then have to be dealt with, it's easier to push them under the rug or get them out of the circle, so they can't make noise any more within the organization.

Mr. SOUDER. But you don't know whether the hospital knew you were in fact—because what I understood, let me see if I understood this correctly, that you gave, you went to the lab director inside the lab, but they didn't want you to go outside their unit. Did you make anybody aware outside the unit that you had concerns?

Ms. TURNER. Not at that point, no.

Mr. SOUDER. At any point before you were terminated?

Ms. TURNER. I'm not sure.

Mr. SOUDER. Because part of the question here is what did the hospital know. If they didn't know you were complaining, they can't——

Ms. TURNER. Well, I know that my termination came from inside the lab, the lab turned in the papers. Because when I had talked to human resources, they were kind of in a shuffle trying to figure out how that actually happened, because they weren't aware on all the levels that they needed to be aware that had actually taken place.

Mr. SOUDER. And at the last hearing we had testimony that the Labotech equipment, other than two kind of minor concerns, one was more significant than the other, over many years they had not had this problem at other locations. Is that what they told you, and what did they tell you on a regular basis when you filed the complaints?

Ms. TURNER. Are you talking about what Adaltis told me? Their technical service did tell me that we seemed to have more problems

than anywhere else. And I guess I questioned that, because there was a variety of people running the machines, from medical technologists with 20 plus years of experience to people with less than 1. But there was not just one single person that was having problems with the machine.

And both machines that we had there, we had a total of three, that the two machines that were in service at the time had significant problems constantly. So every time that we called and every time they sent service out, they acted like it was something that was different, and yet service was constantly busy.

Mr. SOUDER. Did you hear any discussion inside the lab if in fact there wasn't problems at other labs why your lab just didn't get new machines in?

Ms. TURNER. Well, there was a lot of concern as to if our labs were having this many troubles, then how can this be OK.

Mr. SOUDER. But let me give you an example. We had a regular problem with one of our Xerox machines, presumably Xerox, whatever it was, in our office, breaking down. At some point we said, "we're sick of the service complaints, give us a new one." Did that happen, because that would force them to either say, look, it's the machine or the operators?

Ms. TURNER. That did happen, actually, with the very first machine that we had. And Adaltis' response was to agree to provide Maryland General with another machine, exactly the same. So now Maryland General had two machines. The problem was that the other machine that they provided had the same problems.

So it should be maybe that if one machine was broken you had another one to turn to. But more often than not, you couldn't rely on either one. And they refused, the hospital or the laboratory administration refused to replace the machines, even with all the problems we had. And every machine, there can be a lemon, no matter, if it's a Mercedes or whatever it is, it doesn't matter, they can make lemons. Adaltis refused to even acknowledge that was possible.

But I think that the chances of getting three lemons all at the same time are kind of strange. It's a little bit low on the chance thing there.

Mr. SOUDER. I understand. You'd think that one of them would work.

Ms. TURNER. Right. It's kind of a bad sign if you get three machines and they all have the same problems.

Mr. SOUDER. The normal thing is you look for a different machine.

Ms. TURNER. Right, which actually we provided information about other options and other companies that made machines that had been tested and that other laboratories loved and were relied upon. They wouldn't even hear of the option of replacing it. We brought it up, and they said no, keeping the Labotechs.

Mr. SOUDER. Mr. Ruppersberger.

Mr. RUPPERSBERGER. First, I thank you for coming forward and your courage, and you will make a difference in this whole issue. I'm going to save my questions for the second panel.

Mr. SOUDER. Thank you. Judge Carter, do you have any questions?

Mr. CARTER. I think I'm going to wait, thank you, Mr. Chairman.

Mr. SOUDER. Mr. Cummings.

Mr. CUMMINGS. I just want to go to the one thing that's very, very important. In a few minutes, Dr. Mary Kass, president of the College of American Pathologists, is going to testify. Part of her testimony, I want you to comment on, because we won't be calling you back except for some written questions.

She says here, as you may recall, this is part of her testimony, the CAP stated in its May 18 testimony that the quality control deficiencies for HIV and hepatitis C testing were not uncovered by CAP inspectors during a routine April 2003 inspection or by State inspectors in the fall of 2002. Now, listen to this. Because quality control data in this area was found to have been edited.

Who would have done that editing?

Ms. TURNER. That depends on——

Mr. CUMMINGS. Do you know what this means, first of all? Are you familiar with these terms?

Ms. TURNER. I think I do. I think that would be, she was probably referring to the internal quality controls. Those are the values that there was a big issue when the Labotech would fail a run, and it would be because the positive control was out of range, or the negative control was out of range. At that point, we were instructed to call Adaltis. And when we would call Adaltis, they would say, OK, actually they'd give us passwords and all this other stuff to go in, and they'd say, OK, change this number. And it was like, well, is that OK? These are controls for the entire assay. This should just be run again.

And at that point it was more of a money thing, it was a cost thing, because to rerun it, regardless of what it means to the patients on the other end, it would cost, you would have to re-use almost every single, you'd have to use up almost a whole kit to rerun it. A whole kit for one run is ridiculous. So it was cost reasons, I think, was the thing.

But when I asked Adaltis about that, they said that they have ways, they have a formula or something that shows them that actually it is only this that maybe went wrong, so then they can just tell us to change the numbers to this. And what happens through is if you change the control value to where it works, it changes the other values, obviously it changes the patient values the same, based on whatever formula they give you.

So say the positive control is like 2.1 or something and it was low. So instead you'd take it up, you add something to the positive value so that it will be in the positive control range. Then it adds that same amount to the patients——

Mr. CUMMINGS. Let me try to put it in lay language. Let me make sure I understand what you're saying. You're saying that you, when these tests were done, and there was a question as to their accuracy, instead of them being rerun, you all might call Adaltis, the manufacturer of the machine, is that right?

Ms. TURNER. Right.

Mr. CUMMINGS. And you would say to Adaltis, what would you say to Adaltis?

Ms. TURNER. Well, usually it was that Dr. Stewart expected us to call them, first of all, because we would go to him and say, look,

we had this failed run, well, the controls are out of synch with each other, and they just aren't in the right range.

Mr. CUMMINGS. So that's like a red flag going up?

Ms. TURNER. Yes.

Mr. CUMMINGS. Whatever would have caused you to go to Dr. Stewart would have been like lights going off saying something is wrong.

Ms. TURNER. Right. Only because when we would rerun them, if he would find out that we automatically reran them, then that would not be OK with him.

Mr. CUMMINGS. So he would be upset, based on what you just said a moment ago, because he was worried about the costs of rerunning tests that may have been inaccurate for the person who did or may not have had AIDS or hepatitis?

Ms. TURNER. Exactly.

Mr. CUMMINGS. Because of money?

Ms. TURNER. Yes. And his instructions were to call Adaltis and see if they could get it to work.

Mr. CUMMINGS. Then when you would call Adaltis, they would give you a formula——

Ms. TURNER. They would give us new numbers to put in the control values, so that the whole assay passed. And their explanation was that actually all of the values were valid, all of the results were valid, but just the controls, maybe it was contaminated, or maybe the reader was just reading that particular well too high or something like that. It was really frightening.

Mr. CUMMINGS. Let me just ask you——

Ms. TURNER. The positives were automatically repeated. I repeated them, anyway. Those are the things. But it's like, with the mistakes that the machine made, how many samples got missed, and the possibility was there that there were positives that were missed, because they weren't even sampled.

Mr. CUMMINGS. Last question. You just said it was frightening. Why did you say that? What was frightening?

Ms. TURNER. Just the fact that we're being told to go in and change control values. Because controls are the only basis, like the controls have gone through the assay, all of the reagents, all of the patients, every well represents a patient. So the controls are the only thing that has gone through that. That's your indicator of whether everything was done correctly. If your positive control works, your negative control works and they're in duplicate, then you know that probably you can count on the results that are coming out at the end.

But that's really the only kind of way that you know that if every reagent was dispensed, or if everything went through the right time period of incubation or anything like that. That's your indicator. So if that's wrong, it should automatically be trashed and rerun. They should never be changed. And it should never be allowed that you're told to change it as part of your job.

Mr. CUMMINGS. Did you ever say to Dr. Stewart, Doc, this is just something awfully wrong with this, I just think that there's something that just doesn't sit right? I mean, did you ever say that to him when you were going through that process you just described?

Ms. TURNER. Absolutely.

Mr. CUMMINGS. And what did he say?

Ms. TURNER. He said, how do we—well, my problem was that, I sent this on a number of occasions to him, I said we were running this test on a machine that fails a run, we don't know why it fails, maybe it's controls, maybe it's reagents, maybe—who knows what's wrong with it. And you're telling me to go rerun it on the machine, on the same machine. And if the machine is broken, you can't ever rely on those results that come out of there.

So these are people, I don't think that he really made the association, at least it's my opinion that he didn't make the association that the numbers on the page represented people in the community. Because to him it was just numbers and make it work. So it's scary just that somebody would ask you to change controls. Because that is the only scientific way that you know that everything went correctly.

Mr. CUMMINGS. Well, let me say this, and this is my last comment. It is thoroughly frightening, you're absolutely right, when someone can look at numbers and forget that there are people, there are real live people, there's somebody's mother, father, brother, sister, neighbor, and deal with it from a statistical standpoint trying to get it right.

Ms. TURNER. Right.

Mr. CUMMINGS. Thank you.

Mr. SOUDER. I'd like to make a couple of comments and see if you have any last. There are some things that I think become fairly clear from your testimony, and that is that the people who were doing the auditing, the normal auditing, the pre-planned auditing, it would be best if it's done unannounced. Almost every category of inspections we do, we do it unannounced.

That, however, doesn't mean that if it had been unannounced by anybody that they would have caught it if the information had been doctored. In other words, just because a place has been cleaned up and tidied up does not mean if the—garbage in, garbage out, if you have the wrong information there, it doesn't mean that a surprise inspection would have caught it, either. You had another substantive problem in the system.

It's also not a given, and I think it's important for the record to show that a medical group monitoring a medical group is going to be any less effective than an outside group that doesn't have a medical background. I understand the risk of that, and that's why I asked you, did the persons seem to know the people, what made you make the statement? Was it an inside inspection that while sometimes you wonder, particularly when you see bad results coming out, in the sense of they didn't catch the problem, generally speaking, if the pathologist in charge of the lab is deliberately, or one way or another, because of either cost pressures from the hospital which is in itself under tremendous cost pressures in a community, if anybody is under tremendous duress, many doctors, for example, aren't very happy with the cost constraints hospitals give them or that medical plans give them or that health insurance gives them or anybody else gives them? They would just as soon do whatever.

But once they're in violation of the Hippocratic oath, which is to put the person first, your problem is far more than an inspection.

Because in fact they've given up the No. 1 goal of their medicine, which is to protect the individual. And I think while I understand, given the history of what's happened there, to make a leap and say that the bureaucratic staff are coming out of a State government or a Federal Government is going to be any more reliable in figuring out what's in a lab than a medical person, I do believe it's good to have checks and balances.

But here, why do you think your letters of concern weren't given to the inspectors? Because they didn't hear about your letters until we had the hearing.

Ms. TURNER. Right.

Mr. SOUDER. We can talk about whether it got caught, but they didn't know about it until Elijah Cummings asked for a hearing. They didn't even know, the inspectors didn't know. That is another problem that's deeper than who's doing the inspection.

Ms. TURNER. Right. And I think actually at Maryland General it's important to kind of make a distinction between the medical director of the laboratory and the administrative laboratory director. The M.D., the pathologist of the laboratory, obviously it's his job to know, so there was something wrong there. But I think that the information about specifically the Labotech was kept from him by the administrative laboratory director. I think that's part of the concealment.

Mr. SOUDER. Shouldn't it be a mandatory policy of the hospital and the lab that any complaints are given to whoever's doing the inspecting in any hospital?

Ms. TURNER. Absolutely.

Mr. SOUDER. I would think this would be a national standard that we ought to——

Ms. TURNER. That's kind of why I think that maybe there needs to be three or four copies of every single complaint or anything that's made, and have it go to four different people, so that at least one person can followup.

Mr. SOUDER. But like you say, if that stays even, the reason I wanted to elaborate on that is you said three copies. But if that stays within the hospital and not the inspection group, in other words, it should be——

Ms. TURNER. Maybe it needs to go to CAP and FDA and the risk management of the hospital as well as the lab, so that there's just somebody keeping an eye on everybody and making sure that happens.

Mr. SOUDER. Well, thank you for your willingness to come forth and testify. I hope you continue to have good health.

Ms. TURNER. Thank you.

Mr. SOUDER. With that, you're dismissed. And would the second panel come forth.

Ms. Carol Benner, Director of the Office of Health Care Quality, Department of Health and Mental Hygiene; Dr. Mary Kass, president, College of American Pathologists; Mr. Edmond Notebaert, president, University of Maryland Medical System. As soon as you get comfortable, I'll ask you to stand again. [Laughter.]

If you'll raise your right hands, please.

[Witnesses sworn.]

Mr. SOUDER. Let the record show that each of the witnesses responded in the affirmative. We'll start with Dr. Notebaert, since you're getting round two. We appreciate your coming again today.

STATEMENTS OF EDMOND F. NOTEBAERT, PRESIDENT AND CHIEF EXECUTIVE OFFICER, UNIVERSITY OF MARYLAND MEDICAL SYSTEM; MARY E. KASS, M.D., PRESIDENT, COLLEGE OF AMERICAN PATHOLOGISTS; AND CAROL BENNER, DIRECTOR, OFFICE OF HEALTH CARE QUALITY, MARYLAND DEPARTMENT OF HEALTH AND MENTAL HYGIENE

Mr. NOTEBAERT. Thank you very much, Mr. Chairman, Congressman Cummings, distinguished members of the committee, members of the staff.

My name is Edmond Notebaert. I'm President and Chief Executive Officer of the University of Maryland Medical System, which is the parent organization of the Maryland General Hospital as well as a number of other hospitals in the Baltimore region.

I have provided testimony on previous occasions, and I have provided written testimony before this committee began. I would like to offer a few remarks, and I'm not going to be quite as wordy as I was in previous testimony, to provide opportunity for questions and answers. But I would like to say simply that the Maryland, University of Maryland Medical System's response to the issues at Maryland General Hospital has been swift, it's been decisive, and it's been comprehensive in its nature.

I would like to just briefly review, provide you with an overview of the matters that have occurred. We have engaged in a full-blown laboratory improvement program. We have engaged independent third parties to come in and assist us with this process. We have done so without regard to expense, to make sure that this problem is fixed properly. We have restructured the hospital from top to bottom, including a new administrative director in the laboratory, a new pathologist heading up the laboratory. We're in the process of searching for a new chief executive officer and there have been a number of other organizational changes inside the hospital.

We have conducted retesting of as many individuals as we can find. And I'm pleased to report to you that over 1,800 of the total of 2,700 individuals tested have been accounted for and in the retesting process, the accuracy, not the validity, but the accuracy of the original test has been affirmed in 99.4 percent of the cases. I acknowledge the issue related to the validity questions around the quality control and those matters have been addressed and are in the process of being finalized in preparation for inspections by all of the various agencies that inspect the hospital.

On the issue of, well, why don't I just simply stop there. But I would maybe make one comment with respect to one of the matters that was raised by Ms. Williams in the previous testimony.

I was as shocked as the members of the committee were to hear her testimony regarding fear of reprisal. We have put in comprehensive systems, not only in the Maryland General Hospital, but systems to allow employees to go outside of the Maryland General Hospital, designed to remove any hesitation that an employee might have regarding problems that he or she feels are not being

properly addressed, including confidential hotlines and including a restricted e-mail address that's directed to me exclusively.

We have done our best to put in place many mechanisms that will allow employees to go out of channel without fear of reprisal. I wish to say before this panel that as long as I have the privilege of serving in my position, that kind of attitude will not exist in any of our institutions.

So I think with that, Mr. Chairman, I would like to relinquish my time and be available to respond to any questions that the committee might have. I recognize that I didn't cover all the testimony, but I know it takes more than my 5 minutes. I'm sure that the questions might be more insightful than my testimony.

Thank you, sir.

[The prepared statement of Mr. Notebaert follows:]

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
July 7, 2004

Testimony of Edmond F. Notebaert
University of Maryland Medical System

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 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. I have more than thirty years of health care management experience in urban hospitals.

In my testimony before this Committee on May 18, 2004, I addressed how the System investigated the issues that Maryland General Hospital recently confronted and developed a comprehensive approach to change not only the laboratory but also the management and quality systems throughout Maryland General Hospital. Specifically, I discussed the changes we have implemented in the Maryland General Hospital laboratory to make it one of the best labs in the country, and to refocus the corporate culture towards quality, transparency and community integration.

Our approach includes hiring Park City Solutions ("PCS"), the leading laboratory consulting and management services provider in the United States and Canada, which continues to provide lab management services to Maryland General Hospital. PCS has been engaged to enhance quality throughout 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. PCS will

remain in charge of the day to day operations of the laboratory until it has implemented necessary processes and trained personnel so that they are fully capable of performing all necessary job functions.

Dr. John Braun was also appointed by the Maryland General Hospital Board as the Laboratory Medical Director and Technical Supervisor. Dr. Braun's job duties include oversight of the quality and compliance of the laboratory, and in cooperation with PCS, he is overseeing the development and implementation of corrective action plans.

We also have implemented significant changes in personnel and processes at the laboratory level to ensure that the appropriate quality controls are in place. Those changes include adding and training new staff. For example, in the past, monitoring the quality control systems in the lab was the responsibility of one person who also had a number of other responsibilities. Now we are in the process of recruiting a full time quality control supervisor for the lab. In the interim period, PCS is filling this role. Moreover, all new laboratory personnel are being trained, and annual training will be conducted for all existing personnel. We are confident that these changes serve to increase both the capabilities and job satisfaction of staff members in the lab as well as increasing supervision of staff in the lab. In fact, from March 2004 until June 2004, we reduced the turnover rate of laboratory staff from 35% to 6%.

As an effort to remedy the immediate issues, we 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. We continue to expend considerable effort to locate and contact all patients who were identified as having been tested on the Labotech machine. The vast majority of tests have been reconfirmed. In particular, 99.4 % of HIV test results have been reconfirmed to be consistent with the original tests.

Significantly, these actions are just a beginning. Our comprehensive approach at Maryland General Hospital goes beyond instituting new quality control systems in the laboratory. It also includes fundamentally changing the existing culture and instituting a new management philosophy. In that regard, Maryland General Hospital is currently undergoing a significant transformation in order to refocus its corporate culture on quality, transparency and community integration. We have started by changing the key management personnel at Maryland General Hospital starting with a search for a new CEO who will understand accountability. During Maryland General Hospital's period of transformation, the System has assigned to Maryland General Hospital a new and well respected Medical Director, Dr. Glenn Robbins, who was the senior vice president and Chief Medical Officer at another UMMS hospital. He has begun developing System-wide quality measures and a set of hospital-wide quality indicators. He also works closely 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, Maryland General Hospital's Board has changed to reflect the new management philosophy and includes recent additions: Jerry Lymas, a Baltimore community activist and entrepreneur, Ken Harris, a Baltimore City Council member and H. Mebane Turner, ED., the former President of the University of Baltimore. Each of the Board members actively embraces the new direction and spirit of change at Maryland General Hospital. The Board of Maryland General Hospital is also participating in a system-wide assessment of governance which will review present approaches to governance and develop a blueprint for the best governance model for the future. One of the goals of that assessment is to ensure appropriate reporting of information to the Board by Maryland General Hospital's senior management.

Maryland General Hospital also has hired new personnel such as a new Director of Community Outreach, 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 to promote partnering opportunities, including health fairs and screening programs.

The changes at Maryland General Hospital are sweeping and the process is comprehensive. 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. Ensuring that quality services are provided at Maryland General Hospital is our most important goal and we are focused on making that goal a reality.

Our comprehensive approach is also focusing on employee complaints and the process by which those complaints are raised and addressed. Because this issue was raised by Ms. Theresa Williams in her May 18, 2004 testimony before this Committee, we want to inform this committee of our initiatives and set the record straight regarding this issue. During her testimony, Ms. Williams alleged that the laboratory staff at Maryland General Hospital did not or could not air their complaints out of a fear of retribution by the administration. However, our review of this issue has established that several of the laboratory staff members, including Ms. Williams, brought their complaints to the attention of the Human Resources Department on a number of occasions. Those complaints specifically addressed the managerial style and qualifications of the top two managers of the lab. While the Human Resources Department attempted to resolve the issues Ms. Williams and others presented, it apparently did not adequately resolve those issues to the satisfaction of certain laboratory staff. It is critical to note

that no lab staff member was ever terminated after raising any complaints as implied by Ms. Williams. Our review also indicated that actions or inactions by certain prior management personnel created a bottleneck that slowed the flow of necessary information to top management and the Board regarding the issues in the lab.

As a result, we are in the process of enhancing the various reporting avenues available to staff throughout Maryland General Hospital to ensure that all staff are able to communicate any concerns effectively to the appropriate leadership, especially in an instance where concerns have not been appropriately resolved.

In the event that a staff member is concerned about some actual or perceived problem in the lab, or throughout Maryland General Hospital, that staff member is able to discuss that issue with the appropriate department leadership. If the issue is not resolved to that staff member's satisfaction, or if the issue involves that department's leadership, that staff member is able to directly contact the Maryland General Compliance Officer or the Compliance Manager. Where preservation of anonymity is important, that staff member may contact the Compliance Department by use of a 1-800 Hotline number which has been implemented to address specifically such types of calls. Staff members are made aware of the Compliance Office telephone numbers as well as the Hotline number through flyers, the monthly hospital newsletter, and new employee orientation. The telephone numbers also are included in the MediTech computer information system that staff must access to maintain patient data. The Compliance Office documents and investigates each call. At the conclusion of the investigation, if the Compliance Office determines that the complaint has merit, it will direct the appropriate department director to address, and if necessary, to create and implement a Corrective Action Plan. The Compliance Office will then monitor the progress of the department director's

activities, including the Corrective Action Plan to ensure the issue is resolved. A summary of each call is also presented to the Board's Corporate Compliance Committee, which meets every two months.

In addition, all staff members now have the option of contacting Maryland General Hospital's Department of Quality Improvement and Risk Management by completing a Risk Occurrence Report form to report an issue. These reports may be filled out anonymously if the staff member so chooses. Each report is analyzed, and appropriate corrective measures are assessed and implemented. Further, the Department of Risk Management has recently enhanced its data collection systems to track all reported occurrences as well as the progress of any Corrective Action Plan that is being acted upon. Summary reports of any occurrences are also circulated to each departmental vice president as well as to the Board's Professional Affairs Committee.

Finally, a staff member has the option of contacting me or my staff directly. We have implemented and advertised a new web-based feedback form that allows staff members to directly and confidentially contact me about their concerns. Once I receive any such forms, I will either direct the issue to the Chief Medical Officer to investigate and report back to me, and I will oversee the resolution of the issue, or, I, as a board member, will bring that issue directly to the attention of the Board of Maryland General Hospital for resolution. In addition, management is now empowered and instructed to report to the UMMS's VP for Strategy and Corporate Operations when any other management staff member is unresponsive to staff issues.

Although enhancing the various avenues for a staff member to report a potential issue is vital to improving quality, our comprehensive approach is also directed at enhancing systems

that foster the prevention or the early identification of quality issues about which employees may be concerned. By implementing such measures, we will mitigate and potentially eliminate the need for a reactive employee complaint system by acting in a more proactive manner to identify potential issues before they become problems. To that end, we have implemented several specific changes in mandatory reporting mechanisms at the System level, and at the hospital 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 and also to the Maryland General Hospital Board.

The changes made by the System require all outside reports about Maryland General Hospital to be disseminated to Board members and System executives to better hold hospital management accountable. Our efforts to expand the circulation of such information is continuous and, as we speak, the Maryland General Hospital Board is reviewing how its structure can be enhanced and streamlined so that information about Maryland General Hospital, good or bad, is disseminated to the appropriate Board members and Committees, and any problems are properly detected early and resolved quickly.

At the Hospital level, each department has a compliance workgroup aimed at identifying problem areas based on personnel concerns and 'hot topic' issues as expressed by the Center for Medicare and Medicaid Services, or in the United States Department of Health and Human Services Office of Inspector General's Annual Work Plan. The issues that are identified by each of these workgroups in their periodic meetings are conveyed directly to the Compliance Office because the Maryland General Compliance Manager attends each of those meetings in an effort

to coordinate the work of the various workgroups. Issues that are raised in those workgroups or otherwise discovered are investigated thoroughly by the Compliance Office through its proactive audit function, and reported to the necessary persons at Maryland General Hospital, the Maryland General Board or the System as appropriate.

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. At the lab level, PCS has conducted a top to bottom audit of the laboratory and fast-tracked the implementation of any necessary changes including new policies and procedures for the lab. The lab is now generating on a daily basis a lab proficiency testing report. Those reports monitor the accuracy of lab instruments. Each day, Dr. John Braun reviews the reports and implements any needed changes to correct an identified deficiency. As I have mentioned, we have also redesigned the supervisory structure in the lab to eliminate any ambiguity and ensure clear accountability. All functions of the Lab, including reporting by the lab technicians are reported to the Lab Director. In turn, the Lab Director reports administrative issues to the Senior Vice President of Administration and medical/technical issues to the Senior Vice President of Medical Affairs. Each of those Senior Vice Presidents, in turn, sits on the Hospital's Health Quality Control Committee, which reports to the Board.

Equally important is initial and ongoing training of the hospital staff in various aspects of their positions and in the general policies and procedures at Maryland General Hospital. For example, in the lab, we are implementing a training system that tests an individual's proficiency in their position through written and practical testing as well as one-on-one observation. Such proficiency training will be conducted for all new employees, at the new employee's six month employment date and annually thereafter. In addition, we are implementing a system of in-

services in the lab to refresh and retrain staff about techniques and other important processes. We are also developing an additional level of monitoring compliance with the reporting systems that will serve to alert leadership whether or not there is a lapse in quality controls.

The transformation of Maryland General Hospital will continue with the development of additional reporting mechanisms. For example, the System is currently developing a system-wide report card that monitors twenty nine different quality indicators. Those quality indicators are tracked for each of the System's hospitals. This permits the System to compare each hospital to other System hospitals as well as to national data. The data obtained by these report cards will be analyzed and used to detect potential areas of weakness for a hospital or the System. As such areas are identified, we will implement plans to resolve those issues.

Finally, we in leadership positions at the System level, and at the Maryland General Hospital level, are working hard to establish a system of transparency, and to convey the message to all that the new corporate culture will not tolerate any lax quality standards or nondisclosure of information. We have implemented, and will continue to implement, significant changes throughout the System to assure that the System, Maryland General Hospital and its lab will be a model in the state and the country and will serve as a true partner in the health and well-being of the community. I assure you that Maryland General Hospital is on the right path to becoming a great hospital whose goal is to provide the highest quality care to the community it serves. I believe that we have responded to the issues identified in an immediate, decisive and appropriate way.

Thank you for allowing me to speak with you today.

Mr. SOUDER. Everybody's written testimony will be inserted, and if you have any additional things you want to insert after today's hearing, you can do that too. That will supplement.

Dr. Kass.

Dr. KASS. Thank you. Good afternoon, Mr. Chairman, Representative Cummings and other members of the subcommittee. My name is Dr. Mary Kass, and I'm president of the College of American Pathologists.

Since the May 18th hearing, the College has conducted an unannounced inspection of the MGH laboratory as a followup to our April 2004 decision to suspend accreditation in two disciplines, chemistry and point of care testing. This inspection revealed few deficiencies, and the hospital has responded to those that were 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 18th testimony that quality control deficiencies for HIV and hepatitis C testing were not uncovered by CAP inspectors during a routine April 2003 inspection or by State inspectors in the fall of 2002, because quality control in this area were found to have been edited.

Specifically, Maryland State inspectors allege in their 2003 inspection report that, "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. On May 14th, 19th, 21st and 23rd, 2003, instrument 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. In a run for hepatitis C testing on July 18, 2003, the instrumental printout showed manually edited acceptable values for the negative control materials, but the plate printout showed unacceptable negative controls."

Based upon these findings by the State, we have concluded that neither our inspection process nor any other would have detected these problems without the benefit of the whistle blower complaint information which ultimately led to the State's findings. I 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.

Mr. Chairman, I have attached to my statement the September 12, 2001 Federal Register notice extending to the College deemed status under the Clinical Laboratory Improvement Amendments of 1988. 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 typically are unannounced to laboratories and never announced to the College. CMS validation surveys always have shown results comparable to CAP findings and a discrepancy percentage well below the threshold that would trigger a Federal 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 18th hearing, CMS reaffirmed its support of CAP accreditation. The College welcome and has encouraged States 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 on June 17th 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 that 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.

First, better communication. The MGH case underscores the need for better communication and sharing of inspection information between accrediting organizations and governmental entities involved in the inspection process. The CAP also 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 developing a protocol with clear requirements for sharing of complaint information amongst accrediting bodies.

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. As initial steps in a comprehensive program, we have developed a special laboratory signage promoting a dedicated toll-free number to allow ease of use in complaint reporting. This is the signage that we will be posting in our accredited laboratories.

Protection for whistle blowers.

Mr. CUMMINGS. Mr. Chairman, could she read that for the record, please?

Dr. KASS. I'd be happy to. This laboratory is accredited by the College of American Pathologists. Please alert us to any questions or concerns you may have about quality patient testing or laboratory employee safety. Your communication with the CAP will be kept strictly confidential. Then there's a toll-free number at the bottom.

Protection for whistle blowers. We commend the whistle blowers 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 whistle blowers, both for the individ-

uals who report the problems to Government or private oversight bodies and to the oversight bodies themselves.

Patient safety legislation now before Congress would establish whistle blower protections, and we urge Congress to extend those protections to reports to private 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 Congress and Federal and State agencies to achieve that goal. We would be happy to responded to any questions.

Thank you.

[The prepared statement of Dr. Kass follows:]

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
Mary E. Kass, MD, FCAP
President,
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July 7, 2004

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Hearing on HIV and Hepatitis Testing
At Maryland General Hospital

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

July 7, 2004

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.

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-12-25
Baltimore, Maryland 21244-1850

Center for Medicaid and State Operations

AUG - 7 2003

RECEIVED
AUG 13 2003
LABORATORY ACCREDITATION PROGRAM

Ronald B. Lepoff, M. D.
Chair, Commission on Laboratory Accreditation
College of American Pathologists
325 Waukegan Road
Northfield, IL 60093

Dear Dr. Lepoff:

Enclosed is the report on the CLIA validation review of the College of American Pathologists (CAP) for fiscal year 2002 (FY 2002). A disparity rate of seven percent at the condition level was found between the results of your organization's inspections and the CLIA validation surveys.

As in the past, the report includes a Commentary and an Appendix. The Commentary continues to note the importance of an organization's capability to ensure that laboratory practices and testing outcomes continually meet the accreditation standards, so that the equivalency to CLIA is sustained. The Appendix discusses the validation review methodology as well as the statutory and regulatory mandates, including those pertaining to equivalency in the inspection process. The inspection process plays a major role in an organization's capability to ensure sustained equivalency.

If you wish to discuss the FY 2002 report further, we would be happy to arrange a conference call at a mutually convenient time. To arrange a call, please telephone Robin Sutton at 410-786-3531. The results of this evaluation will be included in the report, entitled *CMS Financial Statement 2003*, which will be published next spring. A copy will be sent to you as soon as it is available.

Thank you for your continued cooperation in forwarding your organization's inspection schedules and inspection results throughout the year. As always, we appreciate your interest in promoting quality testing in clinical laboratories.

Sincerely yours,

Signed

Judith A. Yost
Director
Division of Laboratory Services
Survey and Certification Group

Enclosure

cc: Peter Mockridge, Ph.D.

Report on Validation Review

of

COLLEGE OF AMERICAN PATHOLOGISTS

Under the

Clinical Laboratory Improvement Amendments of 1988

Fiscal Year 2002

****

Centers for Medicare & Medicaid Services

Center for Medicaid and State Operations

Survey and Certification Group

Division of Laboratory Services

INTRODUCTION

This report covers the validation review of the College of American Pathologists (CAP) during fiscal year 2002 (FY 2002), as an approved accreditation organization under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). The College is an organization whose standards, as a whole, were approved by CMS as equivalent to, or more stringent than, the applicable CLIA condition-level requirements, as a whole.

The validation review, part of an evaluation mandated by the CLIA statute, is performed annually to verify that laboratories deemed to meet the CLIA requirements by virtue of their CAP accreditation are, indeed, meeting the CLIA requirements. The validation review begins with selection of a sample of CAP-accredited laboratories to receive a CLIA validation survey, which is an onsite visit to determine whether the laboratory meets the applicable CLIA condition-level requirements. After the validation surveys are completed, the CAP accreditation inspection findings for those laboratories are compared case-by-case for similarity with the CLIA validation survey findings at the condition-level. If the College's findings are not similar to the CLIA condition-level findings, the case is a "disparity." Upon completion of the comparisons, a disparity rate is calculated, as required by the CLIA regulations.

A more detailed discussion of the review methodology and rate of disparity, including the statutory and regulatory mandates, is in the Appendix.

VALIDATION SURVEYS—NUMBER AND RESULTS

A total of 75 surveys were conducted in CAP-accredited laboratories. Two surveys were removed from the pool: one for administrative reasons and one because it was not performed within 90-day window after the CAP survey (substantial allegation of non-compliance). Among the remaining 73 laboratories, six were cited with CLIA condition-level deficiencies. Comparable deficiencies were noted by the College in only one of the six laboratories cited with condition-level deficiencies.

Following is a table showing the CLIA identification number, location and the condition-level deficiency of the laboratory where the College's findings were disparate:

CLIA number	Location	CLIA Conditions
04D0467983	Arkansas	• Personnel: Technical Consultant—moderate complexity
04D0469292	Arkansas	• Quality Assurance
16D0384964	Iowa	• PT Enrollment and Testing of Samples • PT Successful Participation
19D0464540	Louisiana	• Quality Control: Bacteriology • Quality Control: General Immunology • Quality Control: Routine Chemistry • Quality Control: Endocrinology • Quality Control: Toxicology • Quality Control: Hematology • Personnel: Laboratory Director—moderate complexity • Quality Assurance
45D0940696	Texas	• PT Successful Participation • Personnel: Laboratory Director—moderate complexity • Quality Assurance

CONCLUSION

For FY 2002, the disparity rate between the College's inspection results and the CLIA validation survey condition-level findings was 7%. This rate of disparity is well below the threshold of 20% that would trigger a deeming authority review. There was no indication in the validation review that would raise questions about the overall equivalency of the CAP accreditation program.

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Commentary

Similarity of CAP-accreditation inspection findings to CLIA validation survey findings is an important measure of your organization's capability to ensure equivalency in the quality of CAP accredited laboratories' practices and testing outcomes. As indicated in previous years, we have found that another important measure is an organization's capability to ensure sustained equivalency. A pertinent question for examining this performance measure—from either a self-examination or oversight perspective—is, "Does the inspection protocol sufficiently identify, bring about correction and monitor for sustained correction, those laboratories whose practices and outcomes fail to meet the accreditation standards?" We continue to be interested in the mechanisms employed by all of the CLIA-approved organizations to ensure sustained equivalency, as we mutually promote improved quality of testing in clinical laboratories.

Appendix

This Appendix contains a description of the CLIA validation review methodology and disparity rate calculation along with statutory and regulatory mandates.

Legislative Authority and Mandate

Section 353 of the Public Health Service Act, as mandated by the Clinical Laboratory Improvement Amendments of 1988 (CLIA), requires any laboratory that performs testing on human specimens to meet the requirements established by the Department of Health and Human Services (DHHS) and have in effect an applicable certificate. Section 353 further provides that a laboratory meeting the standards of an approved organization may obtain a CLIA certification on the basis of its accreditation. Under the CLIA Certificate of Accreditation, the laboratory is not routinely subject to direct federal oversight by CMS. Instead, the laboratory receives an inspection by the accreditation organization in the course of seeking or maintaining its accreditation, and by virtue of this accreditation, is "deemed" to meet the CLIA requirements. The CLIA requirements pertain to quality assurance and quality control programs, proficiency testing, records, equipment, personnel, and others to assure consistent performance by laboratories of accurate and reliable laboratory examinations and procedures.

Section 353(e)(2)(D) requires the Secretary of DHHS to evaluate each approved accreditation organization by inspecting "a sufficient number of the laboratories accredited by such body, and such other means as the Secretary determines appropriate." In addition, section 353(e)(3) requires the Secretary to submit to Congress an annual report on the results of the evaluation. Regulations implementing section 353 are contained in 42 CFR Part 493-Laboratory Requirements. Subpart E contains the requirements for approval of non-profit accreditation organizations for deeming authority purposes, including the validation inspections. Included in this subpart are the requirements for validation inspections conducted by CMS or its agent to ascertain whether the laboratory is in compliance with the applicable CLIA requirements. The results of these validation inspections,

also called "surveys," provide:

- on a laboratory-specific basis, insight into the effectiveness of the accreditation organization's standards and accreditation process; and
- in the aggregate, an indication of the organization's capability to assure laboratory performance equal to, or more stringent than, that required by CLIA.

The CLIA regulations, at 42 CFR Part 493, Subpart E, section 493.575, provide that CMS can conduct a deeming authority review to re-evaluate whether the accreditation organization continues to meet the criteria for being granted deeming authority. A deeming authority review can occur as a result of either of the following circumstances:

- the validation survey results over a one-year period indicate a rate of disparity of 20 percent or more between the findings of the accreditation organization and those of the CLIA validation surveys; or
- the validation findings, irrespective of the rate of disparity, indicate widespread or systematic problems in the organization's processes that provide evidence that the organization's requirements, taken as a whole, are no longer equivalent to CLIA requirements, taken as a whole.

All of the criteria for approval, described in sections 493.555 and 493.557(a), are included in a deeming authority review. Of note are specific requirements pertaining to the comparability of the organization's inspection process to that of CMS:

- Procedures for routine inspections
- Procedures for investigation and response to complaints against laboratories
- Procedures for monitoring laboratories found to be out of compliance with accreditation requirements
- Other aspects such as frequency of inspections and experience and training of inspectors

Validation Review Period

The validation review period coincides with the Federal fiscal year, which is October 1 through September 30.

Validation Survey of an Accredited Laboratory

The CLIA validation survey is an onsite inspection of an accredited laboratory to determine whether it is meeting the applicable CLIA condition-level requirements. It is conducted in the same manner as surveys of laboratories that do not have deemed status, that is, surveyors utilize the outcome-oriented survey principles.

Any laboratory using its deemed status to meet the CLIA requirements is subject to a validation survey—either on a representative sample basis, called "sample validation survey," or on the basis of a substantial allegation of noncompliance, called a "complaint validation survey." Validation surveys may be performed up to 90 days after the accreditation inspection*, however, many are performed within 30 days. Occasionally validation surveys are performed simultaneously with accreditation inspections, as a means of enhancing insight and communication at the local level, and supporting mutual endeavors to improve quality of testing in clinical laboratories.

Validation Review and Methodology

Periodically, each approved accreditation organization provides CMS with its inspection schedule, from which a sample of laboratories is selected to receive validation surveys. Over the course of the review period CMS ensures, to the extent possible, that the sample:

- is well-distributed both geographically and among the various laboratory common-ownerships;
- includes laboratories of various sizes; and
- includes laboratories that encompass the entire range of specialty and subspecialty testing for which the accreditation organization was granted deeming authority.

Each accreditation organization also provides CMS with its most recent inspection reports on the selected laboratories.

The validation review is performed by a team whose members are knowledgeable about the CLIA requirements, standard laboratory practices, the validation survey process, onsite survey procedures, effective quality assurance programs and the accreditation programs.

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* Accredited laboratories may be surveyed at any time on the basis of a substantial allegation of noncompliance with the CLIA condition-level requirements, however, only the surveys performed within the 90-day time frame are included in the pool for determining the disparity rate.

The review begins with an examination of the validation survey findings for each laboratory. When a validation survey results in one or more condition-level deficiencies, the accreditation inspection information is thoroughly reviewed and compared with the survey to ascertain the extent of concurrence with the validation survey findings. For each of these comparisons, or "cases," the team determines whether the accreditation inspection information identifies the deficient practices and outcomes cited in each condition-level deficiency of the validation survey. If the accreditation inspection results are not comparable to each condition-level requirement found out of compliance, and it is reasonable to conclude that the condition-level deficiency was present at the time of the organization's inspection, the case is considered "disparate."

After the review team determines whether each case is a concurrence or a disparity, the disparity rate is calculated for each accreditation organization. The disparity rate is the percentage of disparate cases within the total number of validation surveys performed for each organization. The complete definition and the specifics for calculating the disparity rate are found at section 493.2 of the CLIA regulations, 42 CFR Part 493, Subpart A – General Provisions. A copy of the entire text follows.

Section 493.2 Definitions

"*Rate of disparity* means the percentage of sample validation inspections for a specific accreditation organization or State where CMS, the State survey agency or other CMS agent finds noncompliance with one or more condition-level requirements but no comparable deficiencies were cited by the accreditation organization or the State, and it is reasonable to conclude that the deficiencies were present at the time of the most recent accreditation organization or State licensure inspection.

EXAMPLE: Assume the State survey agency, CMS or other CMS agent performs 200 sample validation inspections for laboratories accredited by a single accreditation organization or licensed in an exempt State during a validation review period and finds that 60 of the 200 laboratories had one or more

condition-level requirements out of compliance. CMS reviews the validation and accreditation organization's or State's inspections of the validated laboratories and determines that the State or accreditation organization found comparable deficiencies in 22 of the 60 laboratories and it is reasonable to conclude that deficiencies were present in the remaining 38 laboratories at the time of the accreditation organization's or State's inspection. Thirty-eight divided by 200 equals a 19 percent rate of disparity."

Trans#	Acquiring	Acquired	Entities
20012272	Pegasus Partners II, L.P	Golden Books Family Entertainment, Inc., debtor-in-possession.	Golden Books Family Entertainment, Inc., debtor-in-possession.

FOR FURTHER INFORMATION CONTACT: Sandra M. Peay or Parcellena P. Fielding, Contact Representatives, Federal Trade Commission, Premerger Notification Office, Bureau of Competition, room 303, Washington, DC 20580, (202) 326–3100.

By Direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 01–22856 Filed 9–11–01; 8:45 am]

BILLING CODE 6750–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Committee on Vital and Health Statistics: Meeting

Pursuant to the Federal Advisory Committee Act, the U.S. Department of Health and Human Services announces the following advisory committee meeting.

Name: National Committee on Vital and Health Statistics (NCVHS).

Times and Dates: 9:00 a.m.—5:30 p.m., September 24, 2001, 9:00 a.m.—4:00 p.m., September 25, 2001.

Place: Conference Room 705A, Hubert H. Humphrey Building, 200 Independence Avenue S.W., Washington D.C. 20201.

Status: Open.

Purpose: The National Committee on Vital and Health Statistics is scheduled to meet on September 24–25, 2001. The NCVHS is the Department's statutory public advisory body on health data, statistics, and health information policy. In addition, the Committee advises HHS on the implementation of the Administrative Simplification provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPPA). The meeting will focus on a variety of health data policy and privacy issues. Department officials will update the Committee on recent activities of the HHS Data Council and the status of HHS activities in implementing the administrative simplification provisions of HIPAA. A briefing from the HHS Deputy Chief Information Officer is planned, and GAO staff will brief the Committee on confidentiality practices and issues in record linkage for research purposes.

The Committee is also expected to discuss and take action on recommendations to HHS from the Privacy and Confidentiality Subcommittee relating to the implementation of the HIPAA Health Information Privacy regulation, following a subcommittee public hearing on the subject in August. Subcommittee breakout sessions also are planned.

All topics are tentative and subject to change. Prior to the meeting, please check the NCVHS web site, where a detailed agenda will be posted when available.

FOR FURTHER INFORMATION CONTACT: Substantive information as well as summaries of NCVHS meetings and a roster of committee members may be obtained by visiting the NCVHS website (http://ncvhs.hhs.gov) where an agenda for the meeting will be posted when available. Additional information may be obtained by calling James Scanlon, NCVHS Executive Staff Director, Office of the Assistant Secretary for Planning and Evaluation, DHHS, Room 440–D, Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201, telephone (202) 690–7100, or Marjorie S. Greenberg, Executive Secretary, NCVHS, NCHS, CDC, Room 1100, Presidential Building, 6525 Belcrest Road, Hyattsville, Maryland 20782, telephone (301) 458–4245.

Note: In the interest of security, the Department has instituted stringent procedures for entrance to the Hubert H. Humphrey Building by non-government employees. Thus, individuals without a government identification card may need to have the guard call for an escort to the meeting room.

Dated: September 4, 2001.

James Scanlon,

Director, Division of Data Policy.

[FR Doc. 01–22820 Filed 9–11–01; 8:45 am]

BILLING CODE 4151–05–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–2119–N]

Medicare, Medicaid, and CLIA Programs; Continuance of the Approval of the College of American Pathologists as a CLIA Accreditation Organization

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice announces the continuance of the approval of the College of American Pathologists (CAP) as an accreditation organization for laboratories under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). We found that the accreditation process of this organization provides reasonable assurance that the laboratories accredited by it meet the conditions required by CLIA statute and regulations. Consequently, laboratories that voluntarily become accredited by CAP in lieu of direct Federal oversight and continue to meet CAP requirements would meet the CLIA condition level requirements for laboratories and, therefore, are not subject to routine inspection by State survey agencies to determine their compliance with CLIA requirements. However, they are subject to Federal validation and complaint investigation surveys.

EFFECTIVE DATE: This notice is effective for the period September 12, 2001 through September 30, 2007.

FOR FURTHER INFORMATION CONTACT: Val Coppola, (410) 786–3531.

SUPPLEMENTARY INFORMATION:

I. Background and Legislative Authority

On July 31, 1992, we published a final rule in the **Federal Register** (57 FR 33992) that implemented section 353(e)(2) of the Public Health Service Act. Under this rule CMS may approve a private, nonprofit organization to accredit clinical laboratories (that is, an approved accreditation organization) under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) if the organization meets certain requirements. An organization's requirements for accredited laboratories must be equal to, or more stringent than, the applicable CLIA program requirements in 42 CFR part 493 (Laboratory Requirements). A laboratory accredited by an approved accreditation organization that meets and continues to meet all of the accreditation organization's requirements would be considered to meet CLIA condition level requirements as if it was inspected against CLIA regulations. The regulations in 42 CFR part 493, subpart E (Accreditation by a Private, Nonprofit Accreditation Organization or Exemption Under an Approved State Laboratory Program) specify the requirements an accreditation organization must meet in order to be approved. CMS approves an accreditation organization for a period not to exceed 6 years.

In general, an approved accreditation organization must, among other conditions and requirements:

- Use inspectors qualified to evaluate laboratory performance and agree to inspect laboratories with the frequency determined by CMS.
- Apply standards and criteria that are equal to, or more stringent than, those condition level requirements established by CMS when taken as a whole.
- Provide reasonable assurance that these standards and criteria are continuously met by its accredited laboratories.
- Provide CMS with the name of any laboratory that has had its accreditation denied, suspended, withdrawn, limited, or revoked within 30 days of the action taken.
- Notify CMS in writing at least 30 days before the effective date of any proposed change in its standards.
- Notify the accredited laboratories of CMS's decision to withdraw its approval within 10 days of the withdrawal. A laboratory can be accredited if, among other things, it meets the standards of an approved accreditation organization and authorizes the accreditation body to submit records and other information to CMS as required.

In addition to requiring the promulgation of criteria for approving and withdrawing the approval of an accreditation body, CLIA requires CMS to perform an annual evaluation by inspecting a sufficient number of laboratories accredited by an accreditation organization, as well as, by any other means that CMS determines appropriate.

I. Notice of Continued Approval of CAP as an Accreditation Organization

In this notice, we approve CAP as an organization that may continue to accredit laboratories for purposes of establishing their compliance with CLIA. The Centers for Disease Control and Prevention and CMS (hereinafter referred to as "we") have examined the CAP application and all subsequent submissions to determine equivalency with the requirements under 42 CFR part 493, subpart E that an accreditation organization must meet to be granted approved status under CLIA. We have determined that CAP has complied with the applicable CLIA requirements and grant CAP approval as an accreditation organization under 42 CFR part 493, subpart E, September 12, 2001 through September 30, 2007, for all specialty and subspecialty areas under CLIA.

As a result of this determination, any laboratory that is accredited by CAP during this time period for an approved specialty or subspecialty is deemed to meet the applicable CLIA condition level requirements for laboratories found in 42 CFR part 493 and, therefore, is not subject to routine inspection by a State survey agency to determine compliance with CLIA requirements. However, the accredited laboratory is subject to validation and complaint investigation surveys performed by CMS, or any other Federal, State, local public agency, or nonprofit organization under an agreement with the Secretary.

III. Evaluation of CAP

The following describes the process used to determine that CAP, as a private, nonprofit organization, provides reasonable assurance that the laboratories it accredits will meet the applicable requirements of CLIA.

A. Requirements for Approving an Accreditation Organization Under CLIA

To determine whether CMS should grant approval to CAP as a private, nonprofit organization for accrediting laboratories under CLIA for all requested specialty, and subspecialty areas of human specimen testing, we conducted a detailed and in-depth comparison of CAP's laboratory requirements to CLIA laboratory requirements. Our evaluation determined whether CAP meets the following requirements:

- Provides reasonable assurance to us that it requires the laboratories it accredits to meet requirements that are equal to, or more stringent than, the CLIA condition level requirements (for the requested specialties and subspecialties) and would therefore, meet the condition level requirements of CLIA if those laboratories had not been granted deemed status, and had been inspected against condition level requirements.
- Meets the applicable requirements of 42 CFR part 493, subpart E.

As specified in the regulations of 42 CFR part 493, subpart E, our review of a private, nonprofit accreditation organization seeking approved status under CLIA, includes, but is not limited to, an evaluation of the following:

- Whether the organization's requirements for its accredited laboratories are equal to, or more stringent than, the condition level requirements of the CLIA regulations.
- The organization's inspection process to determine the:

—Composition of the inspection teams, qualifications of the inspectors, and the ability of the organization to provide continuing education and training to all of its inspectors.

—Comparability of the organization's full inspection and complaint inspection requirements to the Federal requirements including, but not limited to inspection frequency, and the ability to investigate and respond to complaints against its accredited laboratories.

—Organization's procedures for monitoring laboratories that are out of compliance with its requirements.

—Organization's ability to provide CMS with electronic data and reports that are necessary for effective validation and assessment of the organization's inspection process.

—Organization's ability to provide CMS with electronic data related to the adverse actions resulting from unsuccessful proficiency testing (PT) participation in CMS-approved PT programs, as well as, data related to the PT failures, within 30 days of the initiation of the action.

—Ability of the organization to provide CMS with electronic data for all its accredited laboratories, and the areas of specialty and subspecialty testing.

—Adequate numbers of staff and other resources.

—Organization's ability to provide adequate funding for performing the required inspections.

- The organization's agreement with CMS that requires it, among other things, to meet the following requirements:

—Notify CMS of any laboratory that has had its accreditation denied, limited, suspended, withdrawn, or revoked by the accreditation organization, or any other adverse action taken against it by the accreditation organization within 30 days of such action.

—Notify CMS within 10 days of a deficiency identified in an accredited laboratory if the deficiency poses an immediate jeopardy to the patients of the laboratory or a hazard to the general public.

—Notify CMS of all newly accredited laboratories, or laboratories whose areas of specialty or subspecialty are revised, within 30 days.

—Notify each laboratory accredited by the organization within 10 days of CMS's withdrawal of approval of the organization as an accreditation organization.

—Provide CMS with inspection schedules as requested, for the purpose of conducting onsite validation inspections.

—Provide our agent, the State survey agency, or CMS with any facility-specific data that includes, but is not limited to, PT results that constitute unsuccessful participation in an approved PT program and notification

of the adverse actions or corrective actions imposed by the accreditation organization as a result of unsuccessful PT participation.

—Provide CMS with written notification at least 30 days in advance of the effective date of any proposed changes in its requirements.

—Provide upon the request by anyone, on a reasonable basis (and subject to applicable State law concerning disclosure of confidential information), any laboratory's PT results with the explanatory information needed to assist in the interpretation of the results.

Laboratories that are accredited by an approved accreditation organization, among other things must comply with the following requirements:

• Authorize the organization to release to CMS all records and information required.

• Permit inspections as required by the CLIA regulations at 42 CFR part 493, subpart Q (Inspection).

• Obtain a certificate of accreditation as required by § 493.55 (Application for registration certificate and certificate of accreditation).

B. Evaluation of the CAP Request for Continued Approval as an Accreditation Organization Under CLIA

CMS has examined CAP's assurance that it requires the laboratories it accredits to be, and that the organization is in compliance with the following subparts of part 493:

1. Subpart E—Accreditation by a Private, Nonprofit Accreditation Organization or Exemption Under an Approved State Laboratory Program

CAP has requested continued approval to accredit all specialties and subspecialties, and has submitted the following:

• Description of its inspection process, policies, PT monitoring process, and data management and analysis system.

• List of its inspection team size, composition, and education and experience.

• Investigative and complaint response procedures.

• CMS's notification agreements.

• Procedures for the removal or withdrawal of accreditation from a laboratory.

• Current list of accredited laboratories with announced or unannounced inspection process.

We have determined that CAP has complied with the requirements under CLIA for approval as an accreditation organization under this subpart.

Our evaluation identified areas of the CAP requirements that are more stringent than the CLIA requirements and apply to the laboratory as a whole. Rather than include them in the appropriate subparts multiple times, we list them here:

• CAP requires the directors of its accredited laboratories to sign an attestation that their laboratory(ies) are in compliance with all applicable Federal, State, and local laws.

• CAP lists extensive requirements for the Laboratory Information System (LIS) that include but, are not limited to the following areas:

—Preservation, storage, and retrieval of laboratory and patient data.

—Review of LIS programs for appropriate content and testing before use, when a new program is to be put in place, or when changes are made to existing programming.

—Maintenance of the LIS facility (must be clean, well ventilated, and at proper temperature and humidity).

—Protection of LIS against power interruptions and surges.

—Readily available procedure manuals for LIS operators, adequately trained operators that know how to preserve data and equipment in emergency situations (for example, fire, software or hardware failure).

—Protection of the LIS, its data, patient information, and programs from unauthorized use.

—Entry of data and result reporting.

—Verification and maintenance of LIS hardware and software.

—Routine and emergency service and maintenance of the LIS.

—Evaluation from the laboratory director of the LIS performance as it pertains to patient and clinician needs.

• CAP accredits laboratories that perform testing for any of the following areas and sets specific standards with which accredited laboratories must comply:

—Athletic drug testing (for anabolic steroids, beta-blockers, cannabinoids, narcotics, and stimulants).

—Forensic urine drug testing.

—Parentage testing.

—Reproductive laboratory testing (embryology).

2. Subpart H—Participation in Proficiency Testing for Laboratories Performing Tests of Moderate Complexity (Including the Subcategory), High Complexity, or Any Combination of These Tests

The CAP requirements for PT are in conformance with the CLIA statute that states the standards accreditation organizations must require all laboratories be tested by PT for each examination for which PT is available. The CAP PT requirements are more stringent than the CLIA regulations in Subpart I that lists specific tests in which the laboratory must enroll and participate in a CMS-approved PT program. CLIA exempts waived testing from PT, whereas CAP requires its accredited laboratories to participate in a CMS-approved PT program for all testing, including procedures waived under CLIA.

We have determined that the actions taken by CAP to correct unsatisfactory (one failure) PT performance are equivalent to those of CLIA and that the actions taken to correct unsuccessful (2 in a row or 2 out of 3 failures) PT performance of its laboratories are more stringent than those of CLIA. CAP utilizes an on-going electronic monitoring process that flags both unsatisfactory and unsuccessful results for all PT performance, both CLIA required analytes and all other testing for which PT is available and is required by CAP.

CAP accredited laboratories are allowed 15 days to respond in writing to each unsatisfactory result. The response must indicate how the problem was investigated, the cause of the problem, the specific corrective action that was taken to prevent recurrence, and evidence that the problem was successfully corrected. CLIA regulations state that the laboratory must undertake appropriate training and employ the technical assistance that is necessary to correct problems associated with an unsatisfactory score, take remedial action, and document all steps taken.

Unsuccessful PT performance, when identified by CAP, initiates immediate communication with the laboratory director. A written response must be submitted to CAP, explaining why the adverse results occurred, a description of the problem, and the actions taken to correct the problem. The laboratory must submit this information within 10 working days. If, after review by CAP, it is determined that the laboratory's subsequent PT performance is within acceptable limits, no further action is taken. If the laboratory does not respond, fails to seriously address the problem, or cannot bring performance into acceptable limits, the CAP would evaluate the situation and either request that the laboratory cease testing for the analyte, specialty, or subspecialty in question, or, if warranted, revoke accreditation.

CLIA regulations allow a laboratory to undertake training of its personnel or to obtain technical assistance or both, when the initial unsuccessful PT performance occurs instead of imposing alternative or principal sanctions.

CAP also requires its accredited laboratories performing GYN cytology to participate in its external quality assurance program for PAP smear cytology. The Interlaboratory Comparison Program in Cervicovaginal Cytopathology currently enrolls all of CAP's 2,793 accredited laboratories that perform GYN cytology. This program is a cervicovaginal cytopathology proficiency testing survey, in which all CAP accredited laboratories are required to participate. Currently there is no CMS-approved cytology PT program capable of enrolling all CLIA certified laboratories that perform GYN cytology testing.

3. Subpart J—Patient Test Management for Moderate Complexity (Including the Subcategory), High Complexity or Any Combination of These Tests

The CAP requirements are equivalent to the CLIA requirements at §§ 493.1101 through 493.1111. We have determined that CAP's requirements for an accredited laboratory include on report forms the dates and times of specimen collection (when appropriate), is more stringent than the requirements under CLIA.

4. Subpart K—Quality Control for Tests of Moderate Complexity (Including the Subcategory), High Complexity, or Any Combination of Those Tests

The quality control (QC) requirements of CAP have been evaluated against the phased-in, complexity based requirements of the CLIA regulations. We have determined that the QC requirements of CAP are more stringent than the CLIA requirements, when taken as a whole. Some specific areas of QC that are more stringent are as follows:

• The CAP laboratory safety requirements are specific and detailed.

—Environmental safety requirements address electrical voltage, facility ventilation, lighting, temperature, humidity, emergency power source, and require remedial actions to be taken when necessary.

—Requirements are in place for handling and disposal of biohazardous materials, fire safety and prevention of fire hazards, and OSHA regulations related to laboratories.

• The CAP requires procedure manuals to include the principal and clinical significance for each test, and their procedure manuals must include documentation of initial and annual reviews.

• CLIA regulations allow cytology slide preparations made using automated, semi-automated, or other liquid-based slide preparations that cover half or less of a slide to be counted as one half slide for cytology workload purposes. This allows a maximum of 200 preparations to be examined by an individual in a 24-hour period. The CAP does not recognize these preparations as half slides, but rather as full slides to be included in an individual's 100 slide, 24-hour maximum allowable workload.

• CAP requires its accredited laboratories to use the appropriate reagent grade water for the testing performed, stating which type of water (from type I through type III) must be used in specific tests. Source water also must be evaluated for silicone levels.

• CAP accredited laboratories must verify all volumetric glassware and pipettes for accuracy and reproductability before use, and must recheck them periodically. These activities must be documented.

• CAP accredited laboratories that perform maternal serum alpha-fetoprotein, and amniotic fluid alpha-fetoprotein have specific requirements that must be met. These include a qualitative specimen evaluation, requesting and reporting information necessary for interpretation of results, for example, gestational age, maternal birth date, race, maternal weight, insulin-dependent diabetes mellitus, multiple gestations, median ranges calculated and recalculated yearly, results reported in multiples of the mean.

• The CAP lists specific requirements for newer methodologies. Molecular pathology and flow cytometry standards are presented in separate checklists and immunohistochemistry has specific requirements within histology.

• CAP retention requirements are the same or longer than those of CLIA.

5. Subpart M—Personnel for Moderate and High Complexity (Including the Subcategory) and High Complexity Testing

The Standards for Laboratory Accreditation of the CAP states at Standard I, Director and Personnel Requirements (under item D, Personnel), that all laboratory personnel must be in compliance with applicable Federal, State, and local laws and regulations. This standard is implemented in the general laboratory requirement that there must be evidence in personnel records that all testing personnel have been evaluated against CLIA regulatory requirements for high complexity testing, and that all individuals qualify. CAP holds all technical personnel in its accredited laboratories to the CLIA high complexity personnel requirements. Therefore, we have determined that the personnel requirements of the CAP are more stringent than the personnel requirements of CLIA, when taken as a whole.

6. Subpart P—Quality Assurance for Moderate Complexity (Including the Subcategory) or High Complexity Testing, or Any Combination of These Tests

We have determined that CAP's requirements are equal to, or more stringent than, the CLIA requirements of this subpart. CAP also offers an educational program (Q-Probes) to its accredited laboratories, that provides further information on quality assurance to the large, full service laboratories, that allows peer review and comparisons between facilities.

7. Subpart Q—Inspection

We have determined that the CAP inspection requirements, taken as a whole, are equivalent to the CLIA inspection requirements. CAP has continued its Laboratory Accreditation Programs Inspection Training Seminars program. In the year 2000, there were 8 regional training programs held (hosting 747 participants) and 13 national training programs (hosting 433 participants) with 12 ad hoc training sessions presentations. In addition, 4 audit training conferences were held in which 6,351 inspection team leaders and team members participated.

The CAP will continue its policy of biennial on-site announced inspections. An unannounced inspection would be performed when a complaint, lodged against a CAP accredited laboratory, indicates that problems exist within that laboratory that are likely to have serious and immediate effects on patient care.

CAP requires a mid-cycle self-inspection of all accredited laboratories. All requirements for the mid-cycle self-inspection must be responded to in writing, and the responses must be submitted to CAP within a specified timeframe. CLIA regulations do not have this requirement.

8. Subpart R—Enforcement Procedures

CAP meets the requirements of Subpart R to the extent that it applies to accreditation organizations. CAP policy stipulates the actions it takes when laboratories it accredits do not comply with its requirements and standards for accreditation. As demonstrated during its first period of approval, CAP denies accreditation to a laboratory when appropriate, and reports the denial to CMS within 30 days. CAP also provides an appeal process for laboratories that have had accreditation denied.

Some specific actions CAP takes in response to non-compliance or violation of its requirements or standards for accreditation include:

• When an accredited laboratory is identified as having intentionally referred a PT specimen to another laboratory for analysis, the CAP laboratory will be denied accreditation and be ineligible for CAP accreditation for 1 year. This action is similar to the CMS action of denial of certification for 1 year.

• When a CAP accredited laboratory participates unsuccessfully in PT for an analyte, subspecialty, or specialty, the laboratory must initiate corrective actions. The laboratory must submit to CAP documentation of a detailed investigation of the problem causing the unsuccessful performance with a corrective action plan within 10 working days. Specific educational activity or the retention of the services of a consultant may be imposed. Failure to bring PT performance into acceptable limits or failure to seriously address the PT problem would cause CAP to request the laboratory to cease testing for the procedure(s) in question or, if warranted, revoke the laboratory's accreditation. This action is equivalent to the actions that CMS may take under this section.

• When CAP becomes aware of a problem in an accredited laboratory that is so severe and extensive that it could cause a serious risk of harm (immediate jeopardy) situation, an expedited evaluation is immediately undertaken by the Chair and Vice Chair of the Accreditation Committee, the Regional Commissioner and the Director of the Laboratory Accreditation Program. If it is determined that an immediate jeopardy situation exists, the laboratory is required to remove the jeopardy situation immediately or accreditation would be revoked. An on-site focused re-inspection may be performed to verify that the immediate jeopardy no longer exists. These actions are similar to CMS actions for immediate jeopardy.

• The CAP requires its accredited laboratories to correct all deficiencies within 30 days. CLIA deficiencies that are not condition level must be corrected in a timeframe that is acceptable to CMS, but no longer than 12 months. CLIA deficiencies that are condition level that are not considered immediate jeopardy must be corrected in an acceptable timeframe; however, CMS may impose one or more alternate sanctions or a principal sanction to motivate laboratories to correct these deficiencies. The CAP timeframe for correction of deficiencies, when taken as a whole, is more stringent than CLIA.

We have determined that CAP's laboratory enforcement and policies are equivalent to the requirements of this subpart as they apply to accreditation organizations.

IV. Federal Validation Inspections and Continuing Oversight

The Federal validation inspections of CAP accredited laboratories may be conducted on a representative sample basis or in response to substantial allegations of noncompliance (complaint inspections). The outcome of those validation inspections, performed by our agent, the State survey agency, or us, will be CMS's principal means for verifying that the laboratories accredited by CAP remain in compliance with CLIA requirements. This Federal monitoring is an ongoing process.

V. Removal of Approval as an Accrediting Organization

Our regulations provide that we may remove the approval of an accreditation organization (for example, CAP) for cause, before the end of the effective date of approval. If validation inspection outcomes, and the comparability, or validation review produce findings as described in § 493.573 (Continuing Federal oversight of private nonprofit accreditation organizations and approved State licensure program), CMS will conduct a review of an approved accreditation organization's program. In addition, we will conduct a review, when the validation review findings, irrespective of the rate of disparity (as defined in § 493.2), indicate systematic problems in the organization's processes that provide evidence that the organization's requirements, taken as a whole, are no longer equivalent to the CLIA requirements, taken as a whole.

If CMS determines that CAP has failed to adopt or maintain requirements that are equal to, or more stringent than, the CLIA requirements, or systematic problems exist, CMS may give a probationary period, not to exceed 1 year, to CAP to adopt equal, or more stringent requirements. CMS will determine whether CAP retains its approved status as an accreditation organization under CLIA. If approved status is withdrawn, an accreditation organization such as CAP may resubmit its application to CMS if it revises its program to address the rationale for the denial, demonstrates that it can reasonably assure that its accredited laboratories meet CLIA condition level requirements, and resubmits its application for approval as an accreditation organization in its entirety. However, if an approved accreditation organization requests reconsideration of an adverse determination in accordance with subpart D (Reconsideration of Adverse Determinations—Deeming Authority for Accreditation Organizations and CLIA Exemption of Laboratories Under State Programs) of part 488 (Survey, Certification, and Enforcement Procedures) of our regulations, it may not submit a new application until CMS issues a final reconsideration determination. If circumstances result in CAP having its approval withdrawn, we will publish a notice in the **Federal Register** explaining the basis for removing its approval.

Federalism

We have reviewed this notice under the threshold criteria of Executive Order 13132 Federalism, and have determined that this notice will not have any negative impact on the rights, roles, and responsibilities of State, local, or tribal governments.

OMB Review

In accordance with the provisions of Executive Order 12866, this notice was not reviewed by the Office of Management and Budget.

Authority: Section 353 of the Public Health Service Act (42 U.S.C. 263a).

Dated: July 18, 2001.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 01–22822 Filed 9–11–01; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

Statement of Organization, Functions, and Delegations of Authority

Part C of the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services, Centers for Medicare & Medicaid Services (CMS), (**Federal Register**, Vol. 62, No. 85, pp. 24120–24126 dated Friday, May 2, 1997) is amended to reflect changes to the organizational structure of CMS by replacing the Center for Beneficiary Services and the Center for Health Plans and Providers with the Center for Beneficiary Choices and the Center for Medicare Management. Also, it transfers managed care audit responsibility from the Office of Financial Management to the Center for Beneficiary Choices, and

MAR 0 4 2004

STATE OF MARYLAND

Maryland Department of Health and Mental Hygiene
201 W. Preston Street • Baltimore, Maryland 21201
Robert L. Ehrlich, Jr., Governor • Michael S. Steele, Lt. Governor • Nelson J. Sabatini, Secretary

February 28, 2004

Dr. Philip J. Whalen
Laboratory Director
Maryland General Hospital Laboratory
827 Linden Avenue
Baltimore, MD 21201

Dear Dr. Whalen:

I am enclosing a statement of deficiencies for the Maryland General Hospital Laboratory written as a result of a complaint investigation completed January 23, 2004. The complaint investigation was conducted pursuant to COMAR 10.10.02(B)(2). The survey revealed that for a period of approximately 14 months, the laboratory intermittently reported invalid Hepatitis C and HIV test results due to improper quality control. The OHCQ surveyor conducted an exit conference on January 23, 2004 to discuss the survey findings. Maryland General is directed to submit a Plan of Correction to OHCQ within 10 days of receipt of this letter and attached deficiencies. Please direct the Plan of Correction to my attention.

I understand that Maryland General Hospital Laboratory no longer uses the equipment that produced the questioned results and no longer conducts HIV and Hepatitis C testing. However, we are very concerned at the duration of time where results are questionable and whether patients and providers have been appropriately notified.

Carol Benner, Director of OHCQ has asked me to schedule an administrative conference with you and any other representatives of the Laboratory to discuss the survey and possible sanctions. We would like to schedule the conference during the week of March 15. Please call or e-mail me to set a date. My telephone is 410/402-8101; wendykronmiller@dhmh.state.md.us.

Very truly yours,

Wendy A. Kronmiller
Acting Deputy Director

Cc: C. Benner
P. Getz
Claudia Gray

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OFFICE OF HEALTHCARE QUALITY

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 010	(X2) MULTIPLE CONSTRUCTION A. BUILDING ____ B. WING ____	(X3) DATE SURVEY COMPLETED 1/23/2004
NAME OF PROVIDER OR SUPPLIER MARYLAND GENERAL HOSPITAL LABORATOR	STREET ADDRESS, CITY, STATE, ZIP CODE 827 LINDEN AVENUE BALTIMORE, MD 21201		

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1 00	Comment The following deficiencies were based on a limited State survey of the laboratory that included only the HIV and Hepatitis C testing. The survey, based on a complaint, was conducted on January 9 and January 23, 2004. A summary exit conference was conducted on January 23, 2004 with the laboratory director, the administrative laboratory director, supervisors, testing personnel, a risk management representative, and other clinical consultants and technical personnel. The survey revealed that for a period of approximately 14 months, the laboratory intermittently reported invalid Hepatitis C and HIV test results due to improper quality control.	1 00		
1 84	QA - General COMAR 10.10.06 Medical Laboratories-Quality Assurance .01 General. A. Primary Standards. To obtain or maintain a permit to operate a laboratory, a person or licensee shall ensure that the laboratory: (1) Establishes and follows written policies and procedures for a comprehensive quality assurance program designed to monitor and evaluate the ongoing and overall quality and safety of the total, that is, preanalytic, analytic, and post analytic, testing process; (2) Maintains a quality assurance program that: (a) Continually evaluates the effectiveness of the laboratory's policies and procedures, (b) Routinely revises policies and procedures based on the results of on-going evaluation, (c) Identifies and corrects problems, (d) Assures accurate, reliable, and prompt reporting of test results, (e) Assures adequate and competent personnel, and (f) Documents all quality assurance activities; and	1 84		

HCQ

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE	TITLE	(X6) DATE

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1 84	Continued From Page 1 (3) Establishes and maintains a laboratory safety program. This Condition is not met as evidenced by: Based on record review and interviews with the laboratory director, administrative laboratory director, supervisors and testing personnel, the laboratory did not have a comprehensive quality assurance program that included evaluating its policies for effectiveness, ensuring competency of personnel at all levels and ensuring accuracy of testing. HIV and Hepatitis C records from June 2002 through August 2003 showed that patient test results were reported when laboratory personnel, at all levels, allowed test results to be reported when instrumentation and quality control (q.c.) materials were not used in accordance with manufacturer's instructions (BioRad), when patient testing should have been repeated and was not, and when they did not follow their own internal laboratory policies for using quality control materials. Findings include: 1) Records showed that on August 20, 2003, the end-of-run quality control values were unacceptable (negative control was positive) on a run of HIV testing. Patients' test results were reported from this run even though, according to the laboratory director, the unacceptable q.c. would invalidate the entire run of patients. Both the administrative laboratory director and the supervisor (testing person) allowed patient test results to be reported against the laboratory director's policy for using end-of-run q.c. materials. 2) There were many days of testing where laboratory personnel did not follow the BioRad (manufacturer of the q.c. and reagent materials) instructions for validity criteria and determining negative cut-off values and acceptable patient runs. Review of HIV	1 84		

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1 84	Continued From Page 2 records from June 2002 through August 2003 showed that approximately 10 to 15 percent of the patient runs were invalid because of unacceptable values of the negative controls used for determining cut-off values. In all cases, patient test results were reported. See COMAR 10.10.06.05 citation for examples of days of testing and reporting patient test results with unacceptable quality control. 3) Laboratory personnel did not follow the laboratory's established written procedure for conducting repeat HIV testing in duplicate when the initial test was positive. All records from June 2002 through August 2003 where positive patient samples required repeat in duplicate showed that the repeat was performed in singlet or were run initially in duplicate on the initial test day and not on separate runs. Patients' HIV specimens had not been tested at Maryland General Hospital (M.G.H.) laboratory in the manner described by M.G.H. laboratory's written procedure that required initial testing and then run in duplicate on another run before being sent for HIV confirmation by Western Blot to their off-site reference laboratory. During the exit conference, the administrative laboratory director and a supervisor acknowledged that there has been a history of receiving negative Western Blot (HIV confirmatory) tests back from the off-site laboratory when their Labotech test results had been positive.	1 84		
1 96	QA - QC - General COMAR 10.10.06 Medical Laboratories-Quality Assurance .05 Quality Control-General. A. Primary Standard. A licensee operating under a permit shall ensure that the laboratory establishes and follows written quality control procedures for monitoring and evaluating the quality of the	1 96		

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1 96	Continued From Page 3	1 96		

analytical testing process of each testing method and procedure to assure the accuracy and reliability of patient test results and reports.

This Condition is not met as evidenced by:

I. Based on interviews with the laboratory director, administrative laboratory director, supervisors and testing person, record review and review of procedures from the manufacturer (BioRad) of the reagents and quality control (q.c.) materials used for the HIV testing, the laboratory did not follow manufacturer's instructions for utilizing a quality control program that ensures accurate and reliable patient testing.

Findings include:

Review of HIV instrumentation printouts, containing quality control and patient testing values from June 2002 through August 2003, showed that the laboratory reported patient HIV test results when quality control values were unacceptable and showed that the laboratory did not follow the BioRad instructions that define acceptability and valid performance criteria. Manufacturer's (BioRad) instructions state on page 14 in the BioRad HIV 1 and 2 (Synthetic Peptide) booklet, under "Validity Criteria", that "If two of more negative controls are out of limit, the plate is invalid and must be repeated". Note: The "plate" is the device that has rows and columns of wells that contain all of the quality control and patient samples as a contained run or batch. The instrumentation (Labotech) printouts on many days of patient testing showed edited quality control values. A supervisor stated that these values were from the repeat testing of the quality control materials and that the repeat q.c. values were manually edited into the printout to replace the original values on the initial run. A supervisor stated that patient samples were not repeated. In all cases, there were no records to show

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1 96	Continued From Page 4 the actual repeat run of q.c. materials and no records to show that patients' HIV testing were repeated along with the controls. Repeat testing of the entire plate was not performed in accordance with the BioRad instructions. The following days are examples where patient test runs were invalid and the laboratory reported the patient test results: June 24, 2003 The printout of the plate (the wells that contain quality control and patient specimens) showed that the original negative control values were 0.209, 0.230 and 0.163. The instrumentation printout showed that the negative controls were edited to show three negative control values as 0.129, 0.116 and 0.163. According to the supervisor (testing person), the negative controls were repeated since the original 0.209 and 0.230 were out of range. There were no records to show that the quality control was actually repeated and no records to show that the entire plate of patients' tests were repeated. According to BioRad instructions, this batch of patient testing was invalid, but all of the patients' HIV testing from this plate were reported. July 18, 2003 The printout of the plate showed that the original negative control values were 0.437, 0.562 and 0.550. In this case, all three controls were out of range. The instrumentation printout showed that all three control values were edited to show values of 0.140, 0.137 and 0.128. There were no records to show the repeat testing of the controls and no records to show that the entire plate of patient specimens were repeated. All of the patients' HIV testing from this plate were reported when, according to manufacturer's instructions, the run was invalid. July 1, 2003	1 96		

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1 96	Continued From Page 5 The printout of the plate showed that the original negative control values were 0.300, 0.812 and 0.309. The instrumentation printout showed that all three controls were edited to show values of 0.135,0.140 and 0.138. There were no records to show the actual repeat of the controls and no records to show that the entire plate of patient specimens were repeated. Patient HIV test results were reported. May 14, 2003 May 19, 2003 May 21, 2003 May 23, 2003 On these days of patient testing, 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. Patient HIV test results were reported. July 18, 2003 This run was for Hepatitis C testing where the instrumentation printout showed manually edited acceptable values for the negative control materials, but the plate printout showed unacceptable negative controls. There were no records to show that the controls were actually repeated and no printouts to show that the entire plate of patients were retested. Patient Hepatitis C test results were reported. II. Based on review of procedure manuals and interview with the laboratory director, supervisors and testing personnel, the laboratory had established, but did not have a written policy for using end-of-run positive and negative quality control materials for the HIV and Hepatitis C testing.	1 96		

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196	Continued From Page 6 Findings include: Review of HIV and Hepatitis C instrumentation printouts from June 2002 through August 2003 showed that the laboratory did not follow concrete policies regarding the use of positive and negative control materials at the end of each patient run. Records showed that some days of patient testing had end-of-run quality control and some days did not. On August 20th, 2003, the end-of run quality control values were unacceptable (negative control was positive). On this day and all days where end-of-run quality controls were not utilized, patient test results were reported. According to the laboratory director the use of positive and negative controls at the end of each run is required. According to a supervisor, the use of these controls did not matter. There were no written procedures and policies regarding the use of these control materials. The laboratory director confirmed that the run with unacceptable end-of-run controls was an invalid run and those patient test results should not have been reported. With the requirement of end-of-run controls, all runs without these controls would also be invalid.	196		
1109	QA - QC - Specialty and Subspecialty COMAR 10.10.06 Medical Laboratories-Quality Assurance .07 Quality Control-Specialty and Subspecialty. A. Primary Standard. A licensee operating under a permit shall ensure that the laboratory establishes and follows written policies and procedures for a comprehensive quality control program that includes verification and assessment of accuracy, measurement of precision, and detection of error for all analyses and procedures performed by the laboratory.	1109		

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1109	Continued From Page 7 This Condition is not met as evidenced by: Cross-Refer To "1 96". Based on review of instrumentation and plate printouts for the HIV and Hepatitis C testing, review of procedures, and interviews with the laboratory director, administrative director, supervisors and testing personnel, the laboratory did not ensure accurate and reliable patient HIV and Hepatitis testing. A comprehensive quality control program for HIV and Hepatitis C testing was not established, maintained, monitored properly and followed. There no records to show that correction of errors were made in a timely manner; and no records to show that testing personnel, both past and present, were trained properly and evaluated for competency.	1109		

Mr. SOUDER. Thank you.

Ms. Benner.

Ms. BENNER. Good afternoon, Mr. Chairman and members of the committee. My name is Carol Benner. I am the Director of the Office of Health Care Quality at the Maryland Department of Health and Mental Hygiene. I work for the Secretary of Health, Nelson Sabatini, who was here on May 18th. Secretary Sabatini sends his regrets that he could not be here today. He has asked me to speak on his behalf and to carry his message to you.

I would also like to thank Kristin Turner for coming today and also for coming forward with her complaint to us. I think it's important. Chairman Souder asked how we got the complaint. Kristin Turner sent an e-mail to the Baltimore City Health Department, who in turn sent that to our AIDS administration, who in turn sent that to us. That's how we learned of the issues with the piece of equipment.

In his May 18th testimony, Secretary Sabatini was emphatic that the problem is not Maryland General Hospital. The issue that we need to focus on is the failure of the regulatory and oversight systems to identify the problems and to get those problems fixed. Under Federal and State laws, we, both State and Federal Governments, have turned our regulatory responsibilities over to private accreditation organizations. We have done so with little or no provision for communication, coordination or oversight.

Up until January 2004, in the Maryland General example, there were four different organizations: the State, CMS, CAP and the Joint Commission on Accreditation of Health Care Organizations who were all serving the hospital and its laboratory. Problems were identified and documented, but survey results were not shared. Consumers sent complaints, but these were not shared either.

What resulted was essentially an absence of regulation, a situation that could have had serious consequences. Secretary Sabatini believes, and I share his position that we were fortunate this time. The outcome could have been much worse. It is our responsibility to make sure that a Maryland General situation does not happen again.

Regarding Maryland General, I would like to briefly bring you up to date on our progress since the May 18th hearing. We have visited the hospital on several occasions and we can say with certainty that the hospital laboratory has undertaken and continues to implement corrective action. We will conduct a full survey of the hospital laboratory within the next 60 days to determine overall compliance with all State and Federal regulations.

The Secretary has met with representatives of the College of American Pathologists and we are working together to devise a joint program, one with integrity and reliability that will be effective and will guarantee proper oversight of laboratories in Maryland. We intend to expand this effort to include all health care providers that are presently deemed to meet State licensure programs based on third party accreditation decisions.

The Secretary has also met with legislative leaders in Maryland who have expressed interest in changing our State law so that the State will not be required by law to accept accreditation reports as evidence of meeting State licensure standards. Mr. Sabatini has

also met with Congressman Stark, who shares his concerns. We are hopeful that there will be some movement in this direction on the Federal level.

I understand that time is short, so I will stop here. I assume that you all have a copy of Secretary Sabatini's May 18th testimony. And I'll be happy to answer any questions that you may have. Thank you.

[The prepared statement of Ms. Benner follows:]

STATE OF MARYLAND
DRAFT
Maryland Department of Health and Mental Hygiene
201 W. Preston Street • Baltimore, Maryland 21201
Robert L. Ehrlich, Jr., Governor - Michael S. Steele, Lt. Governor - Nelson J. Sabatini, Secretary

Statement of Carol Benner

July 7, 2004

Good afternoon, Mr. Chairman and members of the Committee. My name is Carol Benner; I am Director of the Office of Health Care Quality at the Maryland State Health Department. I work for the Secretary of Health, Nelson Sabatini, who was here on May 18.

Secretary Sabatini sends his regrets that he could not be here today. He asked me to speak on his behalf and to carry his message to you.

In his May 18th testimony, Secretary Sabatini was emphatic that the problem is not Maryland General Hospital; the issue that we need to focus on is the failure of the regulatory and oversight systems to identify the problems and to get the problems fixed.

Under Federal and State laws, we – both State and Federal governments -- have turned our regulatory responsibilities over to private accreditation organizations, and we have done so with little or no provision for communication, coordination or oversight.

In the Maryland General example, there were four different organizations surveying the laboratory and the hospital. Problems were identified and documented, but survey results were not shared. Consumers sent complaints, but these were not shared either. What resulted was essentially an absence of

regulation, a situation that could have had serious consequences. Secretary Sabatini believes – and I share his position – that we were fortunate this time; the outcome could have been much worse. It is our responsibility to make sure a Maryland General situation does not happen again.

Regarding Maryland General, I would like to briefly bring you up to date on our progress since May 18th 2004. We have visited the hospital on several occasions, and we can say with certainty that the hospital laboratory has undertaken and continues to implement corrective action. We will conduct a full survey of the hospital laboratory within the next 60 days to determine overall compliance with all State and Federal regulations.

The Secretary has met with representatives of the College of American Pathologists (CAP) and we are working together to devise a joint program – one with integrity and reliability -- that will be effective and will guarantee proper oversight of laboratories in Maryland.

We intend to expand this effort to include all healthcare providers that are presently deemed to meet State licensure programs based on third-party accreditation decisions.

The Secretary has also met with legislative leaders in Maryland who have expressed interest in changing State law, so that the State will not be required by law to accept accreditation reports as evidence of meeting licensure standards. Mr. Sabatini has also met with Congressman Stark, who shares his concerns. We are hopeful that there will be some movement in this direction on the Federal level.

I understand that time is short so I will stop here. I assume that you all have copies of Secretary Sabatini's May 18th Testimony. I would be happy to answer any questions you have.

Thank you.

Mr. SOUDER. Thank you. Let me just make this clear for the record. I have national interests at stake, I don't have the similar Baltimore issues at stake. This is the second time, and I want to make it absolutely clear where I stand. That is that I find it a bit cute to have a witness say that they need Federal legislation to share information when my staff shared the information when we got it with the accreditation lab, and they didn't get it from the State. There was no law required for you to share that when you get it into your system with the accreditation association. It shouldn't have been my staff sharing it. We didn't need a Federal law to share it with an accreditation lab.

And while I don't necessarily disagree with the end point that this ought to be, there ought to be some kind of working with the State with this, I don't appreciate twice now getting testimony telling me what we need to do at the Federal level when the State failed. The State could have shared that with the accreditation lab and didn't, and they don't need a Federal law to share that. Like you're doing now, sitting down and working it out is commendable. That ought to be done in every State.

And if it isn't done in every State, maybe we need to look at Federal legislation. But I personally got my dander up now twice on this matter, because of the tone of Mr. Sabatini telling us when he didn't share, and telling us we need a law to share. Because the State in fact did fail as part of this, as did everybody down the line.

Now, a lot of that was structural, and I don't disagree with him that there are structural flaws in this. I also have a question for Mr. Notebaert. You say that it was 99.4 percent accurate when it came back?

Mr. NOTEBAERT. That's correct.

Mr. SOUDER. And 1,800 cases?

Mr. NOTEBAERT. Over 1,800 cases.

Mr. SOUDER. Does that mean there were 12 people who were either told they had AIDS or didn't have AIDS who——

Mr. NOTEBAERT. No, there are individuals who, being mindful of the patient confidentiality issue, whose testing was different on the retesting. There are reasonable explanations for changes in results between the first test and the second test that are related to the specific patients themselves; 99.4 percent is an extremely statistically significant number. In the individual cases, we have looked at them and there are explanations beyond the mechanics of the testing process that explain that deviation.

Mr. SOUDER. And in the validity, is that what we were talking about earlier, about the controls?

Mr. NOTEBAERT. That's correct, yes, sir.

Mr. SOUDER. And that's still being——

Mr. NOTEBAERT. That is substantially fixed, and we believe when we're inspected by the various agencies that inspect us, they will find that the efforts that we have put in to create all of the appropriate quality controls meet the highest standards.

Mr. SOUDER. So it's still the hospital's position that it's not the Labotech machine?

Mr. NOTEBAERT. We have not taken that position. We're not commenting on the Labotech machine except to say that we do not use the Labotech machine in any of our organizations.

Mr. SOUDER. So you've switched?

Mr. NOTEBAERT. Immediately upon the discovery of this event, we discontinued the use of that equipment.

Mr. SOUDER. Thank you. I forgot that. You probably said that last time, and I forgot.

Dr. Kass, why would you do announced inspections?

Dr. KASS. First of all, let me state that the College does both announced and unannounced inspections.

Mr. SOUDER. Let me clarify. We were just looking at the past testimony. But your unannounced inspections were between certain dates where they had the range of the dates.

Dr. KASS. Our unannounced inspections—not quite. Our unannounced inspections are in response to either a complaint, allegation that we have to investigate, it may be in response to deficiencies that we found on a routine inspection that we're not confident have been corrected. We can go in and do an unannounced inspection.

The College retains the right to do unannounced inspections at any time for any laboratory that it accredits. We are required to do a routine inspection every 2 years. That is part of our deemed status from CLIA. We have to do this every 2 years and we have to do it within a certain period of time, so that the lab can get its accreditation redone.

We have always felt, and in fact CMS is the regulatory authority here. CMS in the Federal Register in 1998, "We agree with commenters who recommended announced inspections for all laboratories. We have instituted a policy of announced inspections for all initial and recertification purposes, which allows a laboratory the latitude to include multiple members of the staff in the inspection process for the education value. Announced, routine inspections are more efficient, and that the laboratory can make previous testing records more accessible before the inspection, and these inspections are also less intrusive.

Furthermore, surveys must make every effort to minimize the impact of the survey on laboratory operations, patient care activities, and to accommodate schedules and departmental workloads as much as possible. In facilities providing direct patient care, surveyors must avoid interfering with patient care."

Mr. SOUDER. That all presumes that somebody isn't—it's kind of the reverse of what I commented to Kristin Turner. Because you may have a deeper problem if somebody is manipulating. But I've never heard of announced inspections not causing changes, like she said, getting ready for your Sunday best. I grew up in the retail business. If OSHA's going to come in and give me an announced inspection, I don't care whether I'm in major violation, minor violation, because you always assume something's wrong, and you're going to start scurrying around if you have an announced inspection. Certainly with nursing homes this is a huge issue.

And yes, any unannounced inspection, for example, a retailer with OSHA, on a polluter with EPA, an unannounced inspection means that yes, you're going to have a little more time there, because they don't have all the records ready, you're going to have some disruption of service. But if the goal here is ultimately patient protection, and I presume by commentators you mean the in-

dustry itself commenting on what disruption it would be to the process. Needless to say, I'm very sympathetic to the problems facing all types of people in the medical profession. I believe you ought to take commentary in from those people.

But I'm not sure that I would necessarily take the people who are audited word for what they prefer. Of course they prefer, who wouldn't prefer announced inspections. What I asked was, a philosophical reason why you believe announced inspections would really wind up with better protection for the consumers, not why it would be easier for the lab, which is a different question. Because you gave me reasons that are easier for the lab, because it's less time intrusive, less intrusive for the people involved, all the people will be on duty that day, all things which are beneficial to the lab, but aren't necessarily beneficial to making sure that information is——

Dr. KASS. There are two aspects to your question that I'd like to respond to. First of all, the laboratory is extremely important in patient care; 70 percent of diagnoses now that are made on patients come from laboratory data. So it is extremely important that the laboratory is able to generate accurate results in a timely fashion. When you come into an emergency room or shock trauma unit, you don't want your lab result to take an hour or two to get there. So sometimes speed is of the essence. And to disrupt that process would be extremely difficult if not very adverse to patient care. That's the patient care aspect.

As far as the inspection process, our inspection process is announced. The laboratories know exactly what we expect of them. We have set standards. We have thousands of standards that laboratories have to meet. And they know what they are. The College has always stood for quality in laboratory practice. So we don't feel that an inspection process should be a black box where people have to guess what they're supposed to be doing. Our job is to show them the best laboratory practice, what the standards are for best laboratory practice, and then to see whether or not they are complying with those standards.

So if they tidy up the lab and they clean up a few things, that's fine. But that's not what we're looking at. We're looking at a sustained repetition of the process that's been going on since the last inspection. We are focusing on those deficiencies that they had before to see whether they've really done on a sustained level over a period of time what they said they were going to do.

And we send in a team of individuals. These aren't just pathologists going in and talking to pathologists. There are pathologists on our team, medical technologists, Ph.D.s, clinical laboratory scientists. It is a whole team of individuals with expertise in the areas that they are inspecting. And they have to be in practice now. They cannot be retired, they have to be aware of all the current technologies and the current standard of laboratory practice. If the laboratory does a specialized form of testing, like cytogenetics or molecular pathology or cytology, we send specialized inspectors with special expertise in those areas to inspect those areas of the laboratory. That's how the process works.

I hope I answered your question.

Mr. SOUDER. You did. I want to say for the record that I disagree with your first part. I understand nobody wants to be disrupted in the emergency room or laboratory. But given the choice of making sure that there is accuracy, I will wait a little longer in getting my lab test to know that in fact I didn't get told wrong results for AIDS. That I don't find a compelling argument.

Your second part is similar to what we're working with and is part of the argument over whether we have private agencies or Government agencies. We in fact have taken this position in OSHA. And in fact, if you're getting any whistle blower complaints, and by the way, I wanted to ask Dr. Notebaert, do you see a problem not only at your hospital, but this would be interesting nationally, with why that couldn't be inserted with paychecks every so often, so people have this number where they could call, if they provided something like that, there could be an insertion?

Mr. NOTEBAERT. No. We do payroll inserts regularly. Stuffing another one in is not really a problem.

Mr. SOUDER. We think that would be a great thing nationally, in addition to a poster. Because sometimes, having been in a place and seeing all those posters around there, and you also get things in your envelopes. But the reinforcing would be good.

But as we work through, we don't want to play government gotcha with all these different regulations. The goal is long term to move it forward. I thought that was a very eloquent statement of how you do that. But that is dependent also on occasionally having the uncertainty with it. Because if you have somebody who's altering results, and you wouldn't have a whistle blower if it's unannounced, if it's not unannounced, you'll never catch them. That's the dilemma.

Because the goal here isn't to play gotcha. That's the danger of having people who don't understand the laboratory, who aren't trying to move the full health field forward. And that's what's happened in other agencies of the Government, where in fact the inspectors are so rare, and when they come, it's almost like they have to justify their salary by going and picking at something on the side. That is, I know, what people in the labs are worried about, if we change the control of this system. On the other hand, this is a direct challenge, that if you don't have unannounced visits, you can also have a scurrying around that isn't just fixing at the edges and moving the ball forward, but is in fact deceiving the investigators. And that's a dilemma.

Dr. KASS. I think to ensure good laboratory quality, you need not only the inspection process, and I welcome multiple layers of inspection. I think that's fine, to have State look at it, to have CMS look at it, to have CAP look at it. The more eyes you have looking at it, the less likely anything is to slip through.

We also have proficiency testing. Proficiency testing measures outcomes. We also have Q-pros, Q-trap, PIP and PAP programs which are all programs that are voluntary, but they all measure outcomes of laboratory practice and whether it's good or not.

Whistle blowers, it is extremely important that we create, that hospitals create, that indeed the entire health care industry creates an atmosphere, an environment where employees feel comfortable bringing forth problems that can be not only identified by can be

addressed. This has to be done. This is why this legislation that we are supporting is so important. If it had not been for the whistle blowers in this case, we would not have known of these problems. So it's absolutely essential.

Mr. SOUDER. Thank you. Mr. Cummings.

Mr. CUMMINGS. Dr. Kass, do you think this is happening other places? I mean, the fact that you're getting inaccurate information, it seems from your testimony, I've listened to you very carefully, that if you get inaccurate information you cannot make an accurate assessment.

Dr. KASS. I do not think that this is a pervasive problem throughout the United States. And I say that for several reasons. First of all, the College has been accrediting laboratories, we accredit over 3,000 laboratories a year. We have been doing that since 1961. I think that if there were severe issues with our process that they would have become apparent somewhere along that time line before now.

I think MGH represents an unusual set of circumstances that occurred. Does that mean that our process cannot be improved? Absolutely not. It can be improved. We will learn from this. We will make our process better.

Can we improve communication with the State and with CMS? Absolutely. And we intend to do that. So I do not think this is a pervasive problem, no.

Mr. CUMMINGS. So when Ms. Benner said a moment ago the very chilling words that there is an absence of regulation, I guess you disagree with that?

Dr. KASS. I disagree very much with that.

Mr. CUMMINGS. Why is that?

Dr. KASS. I have worked in laboratories for almost 40 years. I've been a laboratory director. The laboratory is probably the most regulated area of medicine that exists. We have been regulated longer than anyone else. We constantly get more and more regulation, to the point where it's becoming difficult to comply with all the regulations, because there are so many.

I don't think it's a lack of regulation. I think it's a lack of communication, a lack of followup. I don't think we need more. If we don't talk to each other, another layer isn't going to help. So I think that it's extremely important for this communication aspect to be fixed.

Mr. CUMMINGS. Obviously there is an issue, there's a problem based on what you just said and what you've been saying. Just a moment ago you were kind enough to hold up that poster. I was very pleased to see that. And you talk about communication and you talk about, you and Ms. Benner talked about this effort to try to communicate better between the State and your agency.

The problem is this. Obviously there is a communication problem. I want to take it past Maryland, because this is bigger than Maryland. If we are doing this here, in Maryland now, that says to me that it is likely that this problem needs to be solved somewhere else, in other places. In other words, Maryland is not—you cannot convince me that Maryland is that unique that the failure to have cooperation between whistle blowers, and by the way, since these hearings have begun, we've gotten information from various places, people all over the country on these kinds of issues.

And I'm just wondering, Ms. Benner said she wanted the Federal Government to, she wanted to see movement on the Federal level. And that's a quote. But I'm just wondering what movement would you like to see on the Federal level. Let me just make sure you're clear where I'm going with this. You have voluntarily agreed to do this in Maryland with Maryland General Hospital. I guess other institutions in Maryland, too? Just Maryland General or all the hospitals?

Dr. KASS. All the laboratories that are accredited by CAP.

Mr. CUMMINGS. So Maryland—after the hearing, right. So I'm wondering two things. One, has this issue—you're the president, and congratulations, madam president.

Dr. KASS. I don't think they're in order right now. [Laughter.]

Mr. CUMMINGS. I know the feeling.

But I'm just wondering if, has this been an issue before with regard to the College, and two, how do we take what has now become a voluntary situation coming out of these hearings and guaranteeing—I have a feeling that by the time you all finish, it will be like a wonderful, you will have something good going on in Maryland. But that doesn't do anything for Mr. Souder in Indiana.

So I'm just trying to figure out, what do you see the College doing other than the poster and that kind of thing? Is there something that you would like to see happen? Suppose you don't get the cooperation, it's not happening in Hawaii? What happens then?

I'm sure you've thought about these issues, and this is a big issue for the College, I'm sure.

Dr. KASS. Only about 15 percent of our States have State lab licensure laws. And then only a certain percentage of those have the regulatory authority to deem private accrediting organizations. Maryland happens to be one of those.

We do have agreements, formal agreements with three States that are very well crafted and serve the States' needs very well, but most importantly, I think serves our patients' needs very well, that could certainly be used as examples. We do modify our accreditation standards, always raising them or addressing specific complaints or specific needs of certain States. We've done this in Florida, we've done this in Pennsylvania. And we certainly, the College could certainly initiate relationships with all those States that have State lab licensure laws to do a reporting type of communication with them.

I want to emphasize that the College already reports all substantiated complaint allegations to CMS. We report all of those to them. And we get about 70 to 100 complaints a year. We investigate every one of those. We take them very seriously. Those are all handled anonymously. Then if the complaints are substantiated, we notify CMS about them.

Mr. CUMMINGS. So you don't see any further role for Federal Government in all this?

Dr. KASS. I wouldn't know what to recommend to the Federal Government, to be honest with you.

Mr. CUMMINGS. In other words, you know, you don't want a situation where, let's say for example you come up with this agreement that you're trying to work out with the State of Maryland. And it's the greatest thing that ever came about. I guess my concern is that

you may have that agreement in Maryland where, for example, information flows to CAP, CAP doesn't have to find out about it at a hearing and that kind of thing.

But what about the other States? That's where I'm trying to go with this. This is not so much about Maryland. It's beyond that. I'm just trying to figure out, since you all deal nationally, how do you guarantee, how do you make sure you don't have one standard in one State, talking about the cooperation and working together and information flowing so that you can get the best and most accurate results, and then have another whole standard in the next State?

Dr. KASS. It certainly would be helpful if complaints regarding laboratory, from any State, whether or not they have licensure laws or not, could be somehow shared with the College, if that laboratory is CAP accredited. That would be extremely helpful.

Mr. CUMMINGS. Certainly.

Mr. SOUDER. Would you favor also sharing your complaints with the other agencies?

Dr. KASS. Absolutely.

Mr. SOUDER. In other words, there could be, kind of a whistle blower sharing?

Dr. KASS. Absolutely. We would have no problem with that whatsoever.

Mr. CUMMINGS. Did the State fail here? Are you familiar with this case? Have you read all the material?

Dr. KASS. Yes. I am familiar with it. I think that there were several failures here. I've learned in medicine that when bad things happen, it's not that one bad thing happens, it's always multiple bad things. It's always amazing to me.

I think that the State failed to notify the College when it got the complaints. I think that CMS failed to notify us, and I think JCHO failed to notify us. They all knew. They all went in as a result of the complaint to re-inspect the lab, but nobody told us. Nobody told us until we read about it in the newspaper. That's not the way to find out about it.

Mr. CUMMINGS. Let me ask you this. We had the testimony of Teresa Williams. Just listen to what she said. In her testimony, she describes serious problems at Maryland General laboratory that she arrived even prior to the arrival of the Labotech instrument in June 2002. For example, she states, now, listen to this. This is incredible. For example, she states that certain tests were delivered late to other departments of the hospital and that there was a concern among techs that certain tests results, including hepatitis B, were unreliable.

It was also alleged that a refurbished Labotech was purchased for cash, arrived with dry blood on its interior, bypassed the biomedical engineering department, failed the initial validation test, and had to be sent back to the manufacturer for repairs. In what you do, when you all do your inspections, how would that information get to you? Would it only get to you perhaps through somebody whistle blowing?

Dr. KASS. No, we require of all laboratories a complete listing of all the equipment they have and the testing that they're using that for. If we saw that a piece of equipment came in and went out of

a laboratory, it would be our job to ask what happened to this piece of equipment. Most likely the documentation would show that there were problems with it.

I don't know whether any patient results were generated on that piece of equipment or not. It is not uncommon for a piece of equipment to come into a laboratory and for that piece of equipment to be tested by the techs, using extra blood samples, but not reporting out the results, just to see how it works, to see if it's reliable, etc.

But if that piece of equipment were used to generate patient results, then by reviewing the documentation, OK, that was in the laboratory, we would ask why was that piece of equipment pulled out of the laboratory. Hopefully we would be told that there were problems with it. We would ask then, what did you do to validate that the tests that you generated on those patients were indeed valid, that they were accurate.

Mr. CUMMINGS. Ms. Turner, when she was testifying, talked about that she kind of wished that the CAP inspectors could have gone a little further. I take it that you all have certain parameters, only a certain—you go but so far. You talked a little bit earlier about certain things that you do, you come in, you're looking for certain things.

But it seems like still, she talks about what a whistle blower would have been able to reveal to you. I'm just trying to figure out, are there other ways to find out that kind of information that goes perhaps beyond where you would normally go?

Dr. KASS. Right. First of all, when the College goes in to do an inspection, it looks at thousands of things. The checklists are literally thousands of things that we look at. However, and I didn't go into a great deal on this, the College is setting up an entire program to enhance the communication between the laboratory staff and the inspection team when they're there. Not only are we allowing them to communicate with us when we're not there, but also when we are there.

Perhaps setting up small group meetings behind closed doors, without any supervisors, any managers, where we can tell them and hopefully have them believe us that anything they say will be held strictly confidential. Because if you know where to look, if someone specifically describes what is being done, it's a lot easier to detect problems.

Mr. CUMMINGS. What you just said, what you just described, is that something new?

Dr. KASS. Yes, this is a part of the program that the College wants to put in place to improve the environment, the atmosphere in laboratories, so that people are not afraid to speak up. To enhance the ability of people to tell us if there are problems that we might not detect in an inspection.

Mr. CUMMINGS. Is that in part a result of what has happened in this case?

Dr. KASS. Yes, it is.

Mr. CUMMINGS. So I'm just curious. How does the College work? This is a group of people that get together and do what? How are they assigned? How does that happen?

Dr. KASS. How are the inspectors assigned?

Mr. CUMMINGS. Yes.

Dr. KASS. The College has, it's not a bunch of guys that get together, well, it used to be a bunch of guys. Now it is a group of individuals, we have a staff of approximately 450 people, full time professional staff. We have an entire division of laboratory inspection and accreditation. These are all highly trained professional individuals that really have implemented and monitor our inspection and accreditation process.

All of the people in our inspected labs that are eligible to be inspectors are in a data base. These are assigned on a regional basis by the regional and State inspectors, commissioners, to assign people to an inspection team. The inspection, the size of the inspection team is determined by the team leader. It usually varies, anywhere from 10 to 25 people, depending on the size of the laboratory.

For the big system laboratories, we actually get other people from systems laboratories to go and inspect them. But we do have certain rules about who can be inspectors. You can never inspect the same laboratory two times in a row, VA people cannot inspect VA labs, people from commercial labs cannot inspect another laboratory owned by that same entity, and I think there was something said that, this is just a bunch of guys from the neighborhood that come in and inspect our lab.

Mr. CUMMINGS. That was my next question. You go ahead.

Dr. KASS. We looked at our data and actually 57 percent of our inspectors did not require hotel or air travel accommodations, 43 percent did, which means that they're coming from significantly far away. Now, just because they didn't require hotel or air travel doesn't mean that they're from around the block. The people that inspected Maryland General were actually from Andrews Air Force Base. That's not a next door hospital.

And in this Maryland area, people from Silver Spring, people from D.C., people from Cockeysville, people from the Eastern Shore, they could all come in to inspect a Baltimore hospital lab. That's not a hotel stay and it's not an air travel. But it is certainly not a local Baltimore hospital.

Mr. CUMMINGS. Maybe I missed this. Is this like a side job for them or is this what they do all the time?

Dr. KASS. No. Anybody that is inspected by the College is required, if they are asked and able to, to inspect another laboratory. We make all of our inspectees be inspectors. This is the process the College uses, because we want people that are actively engaged in the practice of laboratory medicine and understand the new technology.

Now, for specific types of inspections, as I mentioned before, cytogenetics, molecular path, cytology, we have an entire list of people that have sub-specialty certification in those areas. And we call on them. They do have to fly almost all the time to go and inspect another laboratory. And these are all volunteers. The College does have a cadre of paid inspectors who are all medical technologists. They frequently complement the team or they may go in to inspect a very small, rural hospital that's under 100 beds.

Mr. CUMMINGS. I'm out of time, but I just want to ask you this last question. Can you tell me, you have now said at least two things, maybe even more, of things that you all, the College of Pathologists have done or are doing as a result of the problems that

happened at Maryland General. We in the Congress need to know, in detail, what those things are, are there other things that you are doing. We just need to know, because if we are going to look at legislative remedies, it would be good to know what's already being done. And it's also, I ask you that question for one other reason, too. That is for Kristin Turner, who I'm sure many times has wondered whether, was there a result of what she did.

Dr. KASS. There is absolutely a result of what she did. I can't emphasize that enough. I think that more than doing new things, we're expanding activities to make them more comprehensive. I think that this case has pointed out to us ways that we can improve our program. And I would be happy to share with the members of this committee in explicit detail what those are going to be.

Mr. CUMMINGS. Thank you.

Mr. SOUDER. I want to clarify for the record, Kristin Turner, as you stated, you learned about her through the newspaper. The 2002 lab workers letter, you learned about from the subcommittee staff.

Dr. KASS. That is correct.

Mr. SOUDER. There were multiple sources, none however were done——

Dr. KASS. Not the usual means, yes.

Mr. SOUDER. Second, I want to reinforce the importance, because I know that medical people aren't necessarily, and this is very important to pick up, aren't necessarily trained in management techniques, they're medical people. But if you're going to do management type things, this is pretty basic stuff you're talking about implementing, management by walking around, as a Tom Peters concept, is at minimum 4 years old.

But in most retail businesses, like in my family, that was one of the first things. You walk around the store, you don't just sit in a room and talk to management, you go talk to the people. Sam Walton wrote a whole book about this, because when he goes and calls his associates, he goes in and talks to them first, locks the management out, to try and figure out what's going in first.

So I'm glad you're doing it. It's about time. Hopefully maybe the Federal Government and Defense Department will learn the same thing, maybe to check out a prison before we run into problems. It's not uniform just in private sector agencies. The Government itself has this kind of principle to hole up and not do management by walking around. That's very important, and one of the great outgrowths of this is to listen to the people who are on the front lines, as well as the management, who may have perspective. But then that hopefully will come with whistle blower complaints and other things as well.

Dr. KASS. Couldn't agree with you more.

Mr. SOUDER. Mr. Ruppersberger.

Mr. RUPPERSBERGER. First, I think we've all learned from the hearing, the two hearings we've had, of the importance of oversight coordination and stockholder participation in the whole process of regulatory laboratory testing. I think as far as the stakeholder issue, the stakeholders that I see involved, and I'd like your opinion if you think there are more or less, would be hospitals, patholo-

gists, which is College pathologists, States, FDA is in charge of the equipment, CDS in charge of testing, and employee representation.

Now, I think the next logical question is how the oversight should occur. I do not believe, I think Dr. Kass, as you said, we need more unfunded mandates. That's because I come from a local government, took. And I'm not sure that would solve the problem here. What I'd like the panel to address is what they think, what you think is the best mechanism to bring about a more efficient process of checks and balances of where laboratory quality would be. The mechanism, in my opinion, should be to identify whether changes are needed at the State or Federal level and should be able to report these findings.

Should Congress, and this is the question, should Congress establish a Federal task force or an advisory committee, perhaps reporting to the Secretary of Health and Human Services, made up of the stakeholders that I just mentioned, in laboratory testing, and require that group to come back to Congress on a regular basis? I believe accountability and transparency is very important as it relates to this issue. I think a lot of the issues here are about accountability and in bringing all the stakeholders together.

So could you please comment on my long question, all three? We'll start with Mr. Notebaert.

Mr. NOTEBAERT. Well, there are five or six things that I would comment on from the position of a hospital stakeholder. I think many of the things that I will speak to have become apparent in these rooms during these hearings, and during the work that we've been doing at Maryland General.

First, I think we need better coordination between and among the various surveying entities and the hospitals. I think we need better communication. It's been apparent in the testimony to me that improved communication would go a long way toward helping the respective agencies do the work that's so valuable.

I think uniform standards, I believe right now the standards are not entirely uniform from agency to agency. But equally important, maybe more important, is a uniform interpretation of those standards. Because a standard interpreted by one surveyor can be a different standard if it's interpreted by another surveyor. So I think that there needs to be probably an improved process of interpreting the standards. Or let's say an official interpretation that's uniform among the various surveyors.

I think that it's also become obvious that we can improve the work that's done by removing some of the interagency issues, and that's occurring in Maryland on a voluntary basis. But I think the interagency issues have come out in these hearings and I don't think there's a place for those interagency issues and grandstanding and things of that nature.

Mr. RUPPERSBERGER. By the way, I think a lot of focus has been on the State of Maryland, thanks to Congressman Cummings. I think that we have a wakeup call and there's a lot happening there. But we're doing this from a national perspective. And that's really how I would like you to address the issue, from a national perspective.

I mentioned stakeholders. Is there a better way that all the stakeholders can really come together to work on this issue without

having a congressional hearing? That's kind of where I'm going. And then how do we implement it and what's the accountability factor and let's move forward.

Mr. NOTEBAERT. I certainly think that this hearing has been the impetus for that in Maryland, and maybe Maryland can be the model that can be used. I think that Dr. Kass and——

Mr. RUPPERSBERGER. I've been told that Maryland has two of the best hospitals in the world, is that true?

Mr. NOTEBAERT. It has two of the finest medical centers, academic medical centers, probably in the whole——

Mr. RUPPERSBERGER. I shouldn't have done that. [Laughter.]

Mr. NOTEBAERT. And certainly one that got the top ranking in U.S. News and World Report, which is our neighboring hospital in eastern Baltimore.

In any event, the comments that I was making really were comments from a global perspective. I think the final issue, and I'm not sure how to do this, but I believe that there ought to be, hospitals have accountabilities, very high levels of accountabilities, both through the legal systems, through the accrediting systems. I think there needs to be a form of periodic accountability for the inspecting agencies. I haven't really figured out how to do that. I think that there have been some references to that in the other testimony.

Those are the things that I would think as a general rule would be very helpful from a hospital standpoint.

Mr. RUPPERSBERGER. I will point out, Maryland is rated, considered to have the best trauma system in the world, shock-trauma emergency medical system. I think it's wise for everyone to look at systems in the medical field that are working, and not just because we say they're working, like accreditations that really don't mean anything, but look at really what we do and what the end result is. That's important also.

Dr. Kass.

Dr. KASS. I've been sitting here thinking about what you could do on a Federal level to really enhance this process. Certainly if you got together an advisory group of the stakeholders and they could come up with a plan whereby reporting of complaints between accrediting bodies would be in some way mandated.

Mr. RUPPERSBERGER. On a regular basis.

Dr. KASS. Well, quickly, not next year. But as soon as they are investigated and they are substantiated, you could even have two categories of reporting, those that were investigated that weren't substantiated and those that were.

But if there is some way that could be mandated and people could comply with that, I would see no problem with that at all. I would think that might be helpful.

Mr. RUPPERSBERGER. Ms. Benner.

Ms. BENNER. Mr. Ruppersberger, thank you for your question. As an aside, I might say that I was the director of the laboratory at the shock-trauma center in the mid-1970's.

Mr. RUPPERSBERGER. That's when I was a patient there.

Ms. BENNER. I probably did your lab work while you were there.

I'd like to clarify one thing. And I'm not certain that everyone here fully understands the relationship of CMS to the States. This

is why in Secretary Sabatini's testimony and in my statement today that we said that we hope the Federal Government will follow our lead. Each State has a contract with CMS. And when we go into a hospital laboratory or a hospital or nursing home, we are working on behalf of the Federal Government.

So when we go into one of these regulated entities, we are bound by the Federal rules and regulations. So that is why I said that we hope there are some changes at the Federal level.

Mr. RUPPERSBERGER. But I don't see the groups really communicating as they should.

Ms. BENNER. I couldn't agree more.

Mr. RUPPERSBERGER. And you might have Federal regulations. Again, I meant it when I said, why do we have to have a congressional hearing to bring the parties to the table? I know politics is probably worse in medicine than it is in politics. But notwithstanding that, people's lives are involved here. And thank goodness, Congressman Cummings made it an issue, because it's going to hopefully set standards throughout the country. But you don't have any accountability and communication, and you're saying, well, we're doing it pursuant to Federal rules. That still doesn't solve the ultimate problem to get to the bottom line.

Ms. BENNER. I agree with that. And I think if you go back to Secretary Sabatini's testimony, he says, and Congressman Cummings asked the question, did the State fail, we all failed. We all failed. And what——

Mr. RUPPERSBERGER. I still haven't heard any strong resolution, that's why I asked that question on what we're going to do, or what we should do as Members of Congress.

Ms. BENNER. Perhaps joint surveys, where the State goes on a survey with the CAP inspection team.

Mr. RUPPERSBERGER. But you still need the standards and the accountability. That's something that has to be.

Ms. BENNER. That would automatically bring together the communication. If CAP, before it went in to do its inspection, talked with the State, who knows the hospital laboratory or knows the laboratory and says, are there complaints, what do you know, what do you hear, and we're working together, and we go in and do the survey together. We become far more powerful.

Mr. RUPPERSBERGER. That's a result. Dr. Kass, you said that each State has different accreditation issues, too, correct?

Dr. KASS. A lot of States have special requirements of us. And a lot of States go in with us on inspections.

Mr. RUPPERSBERGER. So would you think there needs to be a Federal standard? Sometimes the Feds get in and they muck it up. We want to make sure——

Dr. KASS. I've heard that happens.

Mr. RUPPERSBERGER. It happens a lot. Unfunded mandates, too. But let me get to the issue. Do you feel, based on what you know about what's happened here, that we need a national standard to hold people accountable, to have the transparency that is needed to resolve the issue?

Dr. KASS. I think to have a standard of reporting, of communication, of complaint investigation, would be helpful. In fact, CMS is holding a meeting next week, and I think CMS, I may be speaking

totally out of turn here, because I'm not an expert on this, but I think CMS probably has the authority to do this. We are asking them to call a meeting of all the stakeholders to discuss these issues. It would seem to me that CMS has the authority to demand this.

If not, though, I'm certain you could give it.

Mr. RUPPERSBERGER. What's the Nike phrase? Just do it.

Dr. KASS. Just do it.

Mr. RUPPERSBERGER. Let me ask you this. What are the implications of having four regulatory agencies simultaneously involved in surveying labs, surveying a lab to discover potential deficiencies, and monitor the implementation of solutions? Right there you have four different agencies involved. What are the implications of that, as it relates to what we know now?

Dr. KASS. Scheduling is difficult. Getting everybody together is difficult. But those are just difficulties that can be overcome.

I think the more people you have looking at something, the better it is. And whether or not State inspectors go with us or don't go with us, CMS frequently can go with us. They frequently follow-up our inspections by their own inspections, unbeknownst to us, and they find anything we've missed let us know. That works very well.

For instance, in Pennsylvania, the State there does, we do an inspection every 2 years. They do an inspection in the intervening year, their own inspection. That's another way to go about it. There are many ways to address this issue which can be worked out. Sometimes what is good for one State isn't necessarily good for another.

Mr. RUPPERSBERGER. My time is running out. I'm looking for solutions. I think we need to develop that. And we want to know, from our perspective, and we'll make an analysis through the chairman or ranking member, where we go with this.

Dr. KASS. I think the solution to this——

Mr. RUPPERSBERGER. We want to make sure we don't create another problem by a Federal program that's not going to work.

Dr. KASS. A solution to this might come out of the stakeholders meeting that CMS I'm sure will call very shortly.

Mr. RUPPERSBERGER. That's very important and very relevant.

Dr. KASS. Right.

Mr. RUPPERSBERGER. Do you agree with the stakeholders that I mentioned? Is there anybody that's missing, hospitals, pathologists, States, FDA, CDC, employee representatives?

Dr. KASS. CMS, obviously, and JCHO.

Mr. RUPPERSBERGER. Anybody else, any other stakeholders?

Ms. BENNER. There are other accreditation organizations that go into laboratories. COLA is one.

Mr. RUPPERSBERGER. But they need to come under one. You have too many in a room, you're not going to get anything accomplished.

Ms. BENNER. The same problems that exist with the CAP accreditation could easily exist with the other laboratory accrediting organizations.

Mr. RUPPERSBERGER. Is there one stakeholder in that group that I mentioned that really might have too much power or too much

influence, that might affect the whole group as a whole coming together?

Ms. BENNER. I don't think so, no.

Mr. RUPPERSBERGER. What do you think, Mr. Notebaert?

Mr. NOTEBAERT. Well, I think simplification and standardization are the goals for any body that's convened.

Mr. RUPPERSBERGER. I agree.

Mr. NOTEBAERT. From the hospital stakeholder point of view, having multiple agencies inspecting, using different standards and different interpretations is burdensome. It's not cost efficient, and it really wastes talented resources of the various agencies. So I'm in favor of them getting together, creating simplification and standardization.

Mr. RUPPERSBERGER. And also, I would think, oversight, coordination and accountability, those five.

Mr. NOTEBAERT. Absolutely.

Mr. SOUDER. Mr. Cummings.

Mr. CUMMINGS. Just one last statement. Whenever we sit in these hearings, I'm often, I often think about what I say to my constituents. A hundred years ago, none of us were here, 100 years from now, none of us will be here. The question is, what do we do while we are here for each other. And I really don't want this issue, at this critical moment, this is a critical moment, thanks to Ms. Turner and Ms. Williams and other people at Maryland General, a critical moment to do something. If we don't do it now, it may not be done, not during our tenure here, anyway.

I just want to make sure, I can see where Mr. Ruppersberger was going, trying to come to some kind of conclusion as to where we go from here, so it is not something that just, we had a hearing, and then 10 years from now, when another Maryland General crops up, hopefully some place else, then we are saying the same things, different set of people, people having suffered, people having gotten wrong results, whatever.

I guess what I'm saying to you, Dr. Kass, it sounds like CAP and CMS seem to be going in the direction of doing some things about it. The question that still remains is how do we, going back to Mr. Ruppersberger's inquiry, how do we make sure that we take advantage of this moment to make things better? I think it would be criminal if we did not take this moment to make things better.

So what do you suggest we do? Mr. Ruppersberger was very clear that not everything, and the chairman was even clear, that everything does not require a Federal solution. But where all else fails and we're dealing with life threatening circumstances, then sometimes I think the Federal Government or government has to step in.

So how do we do that balancing thing? Do we take a look at this, say 6 months from now, and see where we are? What do you suggest? And I direct it toward you because it seems like you've been moving, your organization has been moving in the direction of trying to address it. It doesn't sound like you just stuck your head in the sand and just said, look, this is not a problem. You understand our concerns. And we all have a responsibility to make a difference.

I just don't want to leave here feeling like we had motion, commotion, emotion and no results.

Dr. KASS. Mr. Cummings, I agree absolutely with you. And I know that you've never met me before. However, I can assure you, I will be President of the College for another year and a half. This is my top priority. I will assure you that the College will implement all of the things that I've alluded to today. We will provide you with a detailed description of what those changes are in our process.

I will also promise you that I am absolutely confident that CMS is going to move in the right direction with the stakeholders conference. However, if I run up against a brick wall in making this happen, in getting the kind of oversight and accountability that I think everybody here wants, I can assure you, I know who to call.

Mr. CUMMINGS. Well, since you're into promises and stuff, let me promise you that you can call on us and we will back you up.

Dr. KASS. I would not hesitate one moment.

Mr. CUMMINGS. All right.

Mr. SOUDER. I was concerned you were enjoying this testimony so much you would want to come up here multiple times over the next few years. [Laughter.]

I want to tell Ms. Benner that while I don't agree with Mr. Sabatini's proposal at this time, he's one who can help it remain accountable, if in fact CMS doesn't move to continue to be vociferous in doing that.

I want to say to Mr. Notebaert that first off, it's clear than when confronted with a problem that was clearly at serious proportions in Baltimore, in consumer confidence, you acted decisively, aggressively, across the board, which was to be commended. Because no matter what question it's been, you were dealing with it and realized it was going to be a general threat if you didn't deal with it decisively. That's a strong management praise for how you handled that.

Mr. NOTEBAERT. Thank you.

Mr. SOUDER. The other thing I wanted to say is, your pipe dream that we're going to be clear by surveyor in anything we do in health care is never going to happen. This is in nursing homes, all divisions of hospitals, we try to do this. It's the biggest complaint we get in any related medical field.

But we get it in the business area, we get it in the environmental area, that depending on what inspector you have no a housing site, there's so much variation, it is just very difficult. Even when we apparently write it in clear English, often we're so busy compromising the fudge words in the debate that by the time it gets through, even if they've tried to implement it, it would be confusing.

Nevertheless, it's a goal we ought to have in Government, to make it as clear as possible. Because when we talk about the cost of health care in the United States, we add to that. The less clear we are, the more inspectors you have, even though we're trying to protect the health, that's part of the cost of health. And that's our constant tradeoff.

So I wouldn't hold your breath to have the clarity coming in from each inspector in every agency, all suddenly seeing the light, saying, oh, this is what this particular word means. Nevertheless, it's an admirable goal that we ought to strive for.

Mr. RUPPERSBERGER. Mr. Chairman, may I make one comment?

Mr. SOUDER. Yes.

Mr. RUPPERSBERGER. Mr. Sabatini's name has been mentioned here. I too have not agreed with him on every issue. But I have a lot of respect for him. Unfortunately, he's retiring, I understand. He is one of those individuals that does get to the bottom line when it deals with health issues.

So maybe Dr. Kass or someone else should consult him, now that he's going to be gone, and he can really tell it like it is, to help us with this issue. Because I think he is a true professional and he does usually want to get to the bottom line. I'm sorry he's leaving, but maybe we can use his expertise.

Mr. SOUDER. And he doesn't seem to have much reluctance so far, so I'm sure he'll continue to do so. [Laughter.]

With that, the subcommittee stands adjourned.

[Whereupon, at 5:38 p.m., the subcommittee was adjourned, to reconvene at the call of the Chair.]