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CLINICAL LAB QUALITY: OVERSIGHT WEAKNESSES UNDERMINE FEDERAL STANDARDS

HEARING

BEFORE THE

SUBCOMMITTEE ON CRIMINAL JUSTICE, DRUG POLICY, AND HUMAN RESOURCES

OF THE

COMMITTEE ON GOVERNMENT REFORM

HOUSE OF REPRESENTATIVES

ONE HUNDRED NINTH CONGRESS

SECOND SESSION

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CLINICAL LAB QUALITY: OVERSIGHT WEAKNESSES UNDERMINE FEDERAL STANDARDS

TUESDAY, JUNE 27, 2006

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 2:06 p.m., in room 2247, Rayburn House Office Building, Hon. Mark E. Souder (chairman of the subcommittee) presiding.

Present: Representatives Souder, Schmidt, Cummings, Davis, Watson and Norton.

Staff present: Michelle Gress, counsel; Malia Holst, clerk; Tony Haywood, minority counsel; and Teresa Coufal, minority assistant clerk.

Mr. SOUDER. The subcommittee will come to order.

Good afternoon. I thank all of you for being here.

We're here today to discuss the findings and recommendations of a GAO report requested by Mr. Cummings, the ranking member of this subcommittee, Senator Grassley and myself.

We asked the GAO to investigate oversight of clinical labs and implementation of quality requirements imposed through the CLIA, the Clinical Lab Improvement Amendments of 1988. In particular, we requested that GAO assess quality of lab testing and the adequacy of CLIA oversight.

Lab testing is a vital link in our Nation's healthcare system. Lab tests affect an estimated 70 percent of medical decisions and are one of the most frequently billed Medicare procedures. Accurate results are necessary for determining proper treatment of patients, while erroneous results can lead to the wrong treatment decisions with potentially detrimental effects for the patients, and quite possibly unnecessary mental anguish.

The resulting report by the GAO, "Clinical Lab Quality: CMS and Survey Organization Oversight Should Be Strengthened," is a sobering evaluation of the current state of clinical lab oversight and the quality assessment deficiencies that exist across the country for monitoring the Nation's 193,000 labs.

Our request of the GAO was prompted by problems at the Maryland General Hospital that came to light in 2004. Maryland General Hospital's lab issued more than 450 questionable HIV and hepatitis test results. The College of American Pathologists [CAP], inspected and accredited Maryland General Hospital during the 14-month period that the lab was issuing the questionable results.

CAP's inspections failed to identify the ongoing deficiencies in lab testing at the Maryland General facility.

Maryland General's situation was compounded by numerous problems and deficiencies in reporting and evaluation of the lab, prompting this subcommittee, at the request of Mr. Cummings, to hold two hearings to investigate the issues that led to the deficiencies at Maryland General Hospital and how these problems went undetected and unaddressed for such a long period of time. The subcommittee was concerned then, as it is now, that a similar situation might repeat itself at other hospitals or labs in other parts of the country.

Today's release of the GAO report demonstrates that there are several areas where clinical lab quality oversight by the Centers for Medicare and Medicaid Service is deficient. The problems flagged by the GAO show quite clearly that despite CMS's responsibility for overseeing the quality of our Nation's labs, there is insufficient data for measuring the seriousness or extent of the problems.

While the responsibility for ensuring lab quality ultimately lies with CMS, lab survey and accreditation is handled largely by independent national accrediting organizations. Ninety-seven percent of all accredited labs are surveyed by three accrediting organizations, each of which has three representatives here today to testify, the College of American Pathologists [CAP]; COLA, formerly known as the Commission on Office Laboratory Accreditation; and the Joint Commission on Accreditation of Healthcare Organizations [JCAHO]. Two States, New York and Washington, are CLIA-exempt, but have State survey programs.

Each of the survey organizations measure labs using standards that CMS has determined are at least equivalent to CLIA standards. And the survey organizations are required to conduct complaint investigations and monitor proficiency test results. In theory, this arrangement should ensure that accredited labs have been inspected on a reasonable periodic basis and found to meet CLIA standards. Nonetheless, GAO found that in contemporary practice, it is impossible to get a true picture of lab quality standards.

Among the problems flagged by the GAO and which we will explore today are: Survey organization standards are not standardized with CLIA requirements, making it impossible to measure lab quality nationwide in a standardized manner; lab quality deficiencies may not be reported due to accrediting agencies' emphasis on education or enforcement; whistleblower protections don't exist for all survey organizations, including COLA, which does not have a formal whistleblower policy. Lab sanctions are rarely imposed; in fact, out of more than 9,000 labs that had sanctions imposed, only 501 labs were actually sanctioned by CMS from 1998 to 2004.

Despite the fact that there is a solid framework for what I believe should be a workable system to ensure lab quality, GAO has found that in current practice the oversight by CMS is deficient, making it impossible to accurately measure the effectiveness of independent survey organizations.

Today's hearing will explore the GAO's findings and recommendations and give CMS and survey organizations an opportunity to present ways to improve the current situation so that

what happened at Maryland General Hospital does not repeat itself anywhere else in the country.

Our first witness is Leslie Aronovitz, Director of the Health Division, U.S. Government Accountability Office [GAO]. We will then hear from Mr. Thomas Hamilton, Director of the Survey and Certification Group at the Centers for Medicare and Medicaid Services.

Our last panel will include Dennis O'Leary, M.D., president of the Joint Commission of Accreditation of Healthcare Organizations; Doug Beigel, chief executive officer of COLA; and Thomas Soderman, M.D., president of the College of American Pathologists.

Thank you all for being here today, and we look forward to your testimony and insights.

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

Subcommittee on Criminal Justice, Drug Policy and Human Resources

Opening Statement of Chairman Mark Souder

"Clinical Lab Quality: Oversight Weaknesses Undermine Federal Standards"

June 27, 2006

Good afternoon and thank you all for being here.

We are here today to discuss the findings and recommendations of a GAO report requested by Mr. Cummings, the Ranking Member of this Committee, Senator Grassley, and myself.

We asked the GAO to investigate oversight of clinical labs and implementation of quality requirements imposed through CLIA, the Clinical Laboratory Improvement Amendments of 1988. In particular, we requested that GAO assess the quality of lab testing and the adequacy of CLIA oversight.

Lab testing is a vital link in our nation's healthcare system. Lab tests affect an estimated 70 percent of medical decisions, and are one of the most frequently billed Medicare procedures. Accurate results are necessary for determining proper treatment of patients, while erroneous results can lead to the wrong treatment decisions with potentially detrimental effects for the patients, and quite possibly unnecessary mental anguish.

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Our request to the GAO was prompted by problems at Maryland General Hospital that came to light in 2004. Maryland General Hospital's lab issued more than 450 questionable HIV and hepatitis test results. College of American Pathologists, or CAP, inspected and accredited Maryland General Hospital during the 14-month period that the lab was issuing the questionable results; CAP's inspections failed to identify the ongoing deficiencies in lab testing at the Maryland General facility.

The Maryland General situation was compounded by numerous problems and deficiencies in reporting and evaluation of the lab, prompting this Subcommittee, at the request of Mr. Cummings, to hold two hearings to investigate the issues that led to the deficiencies at Maryland General Hospital, and how these problems went undetected and un-addressed for such a long period of time.

The Subcommittee was concerned then, as it is now, that a similar situation might repeat itself at other hospitals or labs in other parts of the country.

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Each of the survey organizations measure labs using standards that CMS has determined are at least equivalent to CLIA standards; and the survey organizations are required to conduct complaint investigations and monitor proficiency test results.

In theory, this arrangement should ensure that accredited labs have been inspected on a reasonable, periodic basis, and found to meet CLIA standards. Nonetheless, GAO found that in contemporary practice, it is impossible to get a true picture of lab quality standards.

Among the problems flagged by the GAO and which we'll explore today are:

- survey organization standards are not standardized with CLIA requirements, making it impossible to measure lab quality nationwide in a standardized manner;
- lab quality deficiencies may not be reported due to accrediting agencies' emphasis on education over enforcement;
- whistle-blower protections don't exist for all survey organizations, including COLA, which does not have a formal whistle-blower policy;
- lab sanctions are rarely imposed – in fact, out of more than 9000 labs that had sanctions proposed, only 501 labs were actually sanctioned by CMS from 1998-2004.

Despite the fact that there is a solid framework for what I believe should be a workable system to ensure lab quality, GAO has found that in current practice, the oversight by CMS is deficient, making it impossible to accurately measure the effectiveness of independent survey organizations.

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Our first witness is Leslie Aronovitz, Director of the Health Division, U.S. Government Accountability Office; We'll then hear from Mr. Thomas Hamilton, Director of the Survey and Certification Group at the Centers for Medicare and Medicaid Services.

Our second panel will include Dennis S. O'Leary, M.D., President of the Joint Commission on Accreditations of Healthcare Organizations; Doug Beigel, Chief Executive Officer of COLA, and Thomas Sodeman, M.D., President of the College of American Pathologists.

Thank you all for being here today. We look forward to your testimony and insights.

Mr. SOUDER. I now yield to Ranking Member Cummings.

Mr. CUMMINGS. Thank you very much, Mr. Chairman. And I thank you for holding today's hearing to examine findings and recommendations set forth in the GAO report entitled "Clinical Lab Quality: CMS and Survey Organization Oversight Should Be Strengthened."

I want to thank Senator Grassley and you, Mr. Chairman, for joining me in asking GAO to conduct the investigation that led to this eye-opening report.

As you know, Mr. Chairman, the GAO report that we are releasing today cites numerous weaknesses in the operation and oversight of the Federal program for ensuring quality medical testing and labs that seek Medicare reimbursement for performing medical testing.

Enacted in 1988, the Clinical Laboratory Improvements Act established within the Centers for Medicare and Medicaid Services the program for implementing, enforcing and overseeing stringent Federal regulations governing the operation of these labs.

The CLIA statute reflects Congress' recognition of the fundamental role of medical testing and the delivery of medical care and treatment. Plainly, physicians and patients must have accurate medical test results in order to make appropriate medical decisions.

On March 11, 2004, an article in the Baltimore Sun broke the story of a lawsuit filed by Christine Turner, a young lab technician at Maryland General Hospital who 1 year earlier contracted HIV and hepatitis C when the machine used to test blood samples malfunctioned, spraying Ms. Turner with infected blood. After being terminated from employment in December 2003, Ms. Turner reported the matter to State health officials, triggering an investigation by the State health department in January 2004, and followup inspections involving the State health department, CMS and the Joint Commission on Accreditation of Healthcare Organizations.

The College of American Pathologists, a private accrediting organization responsible for accrediting the Maryland General lab under the CLIA program, was not informed of the complaints by the other parties, and conducted a separate investigation after learning of the lab's problems by way of news reports. CAP's inspection resulted in the revocation of the lab's accreditation in two key testing areas. Ultimately the investigations established that between June 2002 and August 2003, more than 2,000 patients were issued invalid HIV and hepatitis C test results by Maryland General Hospital. The investigative report cited numerous deficiencies, indicating the lab had not been in compliance with CLIA standards for a prolonged period of time.

In May and July 2004, this subcommittee held hearings aimed at determining how the serious deficiencies at Maryland General Hospital could have gone undetected for so long despite the safeguards established by CLIA, the CLIA process, to ensure that patients receive accurate and reliable test results. CAP, after all, had conducted an accreditation survey while the deficiencies were ongoing, but having failed to identify the problems during their survey, CAP awarded Maryland General Lab its Accredited with Distinction certificate, certifying the lab as being in compliance with CLIA standards and additional requirements established by CAP.

In addition, the Maryland Health Department had conducted an investigation in response to a July 2002 whistleblower complaint. Later, then-Health Secretary Nelson Sabatini stated that the complaint was too vague to lead inspectors to uncover the problems found during the inspections that followed Ms. Turner's complaint.

During our hearings, witnesses cited the following factors as contributing to the failure of the CLIA process to detect serious deficiencies in Maryland General Hospital laboratory: One, fear of retaliation among lab workers for reporting problems; two, advance notice of accreditation surveys allowing labs to hide deficiencies; three, an emphasis on collegiality and education over aggressive investigation during accreditation surveys; and four, failure to communicate complaint information between the State and the private accreditation organization.

Witnesses from CMS and the College of American Pathologists testified that they had not seen such an extreme case before, and that they believe that the Maryland General Hospital situation was an aberration. They felt this in part because of the lengths to which the lab had gone to purposely cover up problems, efforts that included falsifying quality control readings from a device used to test blood samples for HIV and hepatitis C.

But CMS and CAP could not say with any degree of certainty that what occurred at Maryland General Hospital could not occur elsewhere. At best, Maryland General demonstrated that the CLIA problem was not completely foolproof. Possibly it indicated weaknesses in the program's overall operation and oversight.

In order to understand the extent to which labs across the country were experiencing serious quality problems, Chairman Souder and I asked the GAO to do the following examination. We wanted them to examine the quality of lab testing under CLIA. We wanted them to examine the effectiveness of accreditation surveys, complaint investigations and enforcement actions in detecting and addressing lab problems. And we also wanted them to examine the adequacy of CMS's CLIA oversight.

Disturbingly, the GAO report to Congress concludes that insufficient data exists to identify the extent of serious quality problems at labs. Effective oversight and accountability of any Federal program requires useful and reliable data. The lack of critical data found by GAO is distressing because it undermines the fundamental purpose of the CLIA problem. This is plainly unacceptable and must be remedied.

In addition, GAO found numerous weaknesses in the exercise of oversight by CMS and State and private survey organizations that accredit labs under the CLIA program. According to the report, these shortcomings render CLIA oversight, "inadequate to ensure that labs are meeting CLIA requirements."

In particular, the report underscores three prominent concerns expressed by whistleblowers during the subcommittee's 2004 hearing, namely—and I'm about to close, just a little bit longer, I just want to get all this in—fear of retaliation among lab workers is an obstacle to the reporting of serious lab deficiencies by employees. The strong emphasis of accreditation organizations on education tends to make the masking of deficiencies easier, and the imposition of sanctions for deficiencies that are found less likely. And fi-

nally, the composition of CAP survey teams may undermine their objectivity.

The report also notes that inconsistencies in the imposition of CMS sanctions make it unclear how effective CMS enforcement is at compelling labs to comply with the CLIA requirements, and that CMS is failing to ensure in a timely manner that updated standards by accreditation organizations meet requirements for equivalency with CLIA standards.

To correct these shortcomings GAO reported that CMS take a number of actions including the following: standardizing the reporting of survey deficiencies to permit meaningful comparisons across survey organizations; working with survey organizations to ensure that educating lab workers does not preclude appropriate regulation, such as identifying and reporting deficiencies that affect lab-testing quality; and allowing the CLIA program to fully use revenues generated by the program to hire sufficient staff to fulfill its statutory responsibilities.

My own proposals for congressional action are set forth in legislation that I introduced back in October 2004, and that I reintroduced, along with Congressman Ruppersberger, in the 109th Congress. The Clinical Laboratory Compliance Improvement Act, H.R. 686, will establish whistleblower protections for employees of clinical labs; require labs to post signage to facilitate reporting of lab problems to CLIA entities; require survey organizations to report complaints of deficiencies to the Secretary of HHS; and require lab accreditation surveys to be unannounced. I believe the GAO report underscores the need for enactment of this legislation.

And so, Mr. Chairman, I'm looking forward to hearing from our witnesses today. I think that without a doubt this is a very important subject for all of us. I cannot think of anything that is more significant when you consider that all of us, everybody sitting in this room, everybody sitting in this room has had some kind of test that determined what their status, health status, may have been and were treated or not treated according to those test results. And we in this country simply cannot afford to have anything but the very best in testing.

And again, Mr. Chairman, I thank you for your working with me on this. And we will continue the fight to make sure that all Americans are protected. And with that, I yield back.

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

Representative Elijah E. Cummings, D-MD7
Ranking Minority Member
Subcommittee on Criminal Justice, Drug Policy, and Human Resources
Committee on Government Reform
U.S. House of Representatives
109th Congress

Hearing on "Clinical Lab Quality: Oversight Weaknesses Undermine Federal Standards"

June 27, 2006

Mr. Chairman,

Thank you for holding today's hearing to examine findings and recommendations set forth in the GAO report, entitled "Clinical Lab Quality: CMS and Survey Organization Oversight Should Be Strengthened." I want to thank Senator Grassley and you, Mr. Chairman, for joining me in asking GAO to conduct the investigation that led to this eye-opening report.

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Enacted in 1988, the Clinical Laboratory Improvements Act established within the Centers for Medicare and Medicaid Services the program for implementing, enforcing, and overseeing stringent federal regulations governing the operation of these labs. The CLIA statute reflects Congress's recognition of the fundamental role of medical testing in the delivery of medical care and treatment. Plainly, physicians and patients must have accurate medical test results in order to make appropriate medical decisions.

On March 11, 2004, an article in the *Baltimore Sun* broke the story of a lawsuit filed by Kristin Turner, a young lab technician at Maryland General Hospital who, one year earlier, contracted HIV and hepatitis C when the machine used to test blood samples malfunctioned, spraying Ms. Turner with infected blood. After being terminated from employment in December 2003, Ms. Turner reported the matter to state health officials, triggering an investigation by the state health department in January 2004 and follow-up inspections involving the state health department, CMS, and the Joint Commission on Accreditation of Healthcare Organizations (or JCAHO, "JAY-koh").

The College of American Pathologists, a private accrediting organization responsible for accrediting the Maryland General lab under the CLIA program, was not informed of the complaints by the other parties and conducted a separate investigation

after learning of the lab's problems by way of news reports. CAP's inspection resulted in the revocation of the lab's accreditation in two key testing areas.

Ultimately, the investigations established that, between June 2002 and August 2003, more than 2,000 patients were issued invalid HIV and hepatitis C tests results by Maryland General Hospital. The investigative reports cited numerous deficiencies indicating the lab had not been in compliance with CLIA standards for a prolonged period of time.

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During our hearings, witnesses cited the following factors as contributing to the failure of the CLIA process to detect the serious deficiencies at the Maryland General Hospital laboratory:

- fear of retaliation among lab workers for reporting problems;
- advance notice of accreditation surveys (allowing labs to hide deficiencies);
- an emphasis on collegiality and education over aggressive investigation during accreditation surveys; and
- failure to communicate complaint information between the state and the private accreditation organization.

Witnesses from CMS and the College of American Pathologists testified that they had not seen such an extreme case before and that they *believed* Maryland General was an aberration. They felt this, in part, because of the lengths to which the lab had gone to purposely cover up problems – efforts that included falsifying quality control readings from the device used to test blood samples for HIV and hepatitis C.

But CMS and CAP could not say with any degree of certainty that what occurred at Maryland General could not occur elsewhere. At best, Maryland General demonstrated that the CLIA program was not completely foolproof; possibly, it indicated weaknesses in the program's overall operation and oversight.

In order to understand the extent to which labs across the country were experiencing serious quality problems, Chairman Souder and I asked GAO to examine:

- the quality of lab testing under CLIA;
- the effectiveness of accreditation surveys, complaint investigations, and enforcement actions in detecting and addressing lab problems; and
- the adequacy of CMS's CLIA oversight.

Disturbingly, GAO's report to Congress concludes that insufficient data exist to identify the extent of serious quality problems at labs. Effective oversight and accountability of any federal program requires useful and reliable data. The lack of critical data found by GAO is distressing because it undermines the fundamental purpose of the CLIA program. This is plainly unacceptable and must be remedied.

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In particular, the report underscores three prominent concerns expressed by whistleblowers during the Subcommittee's 2004 hearings – namely:

- fear of retaliation among lab workers is an obstacle to the reporting of serious lab deficiencies by employees;
- the strong emphasis of accreditation organizations on education tends to make the masking of deficiencies easier and the imposition of sanctions for deficiencies that *are found* less likely; and
- the composition of CAP survey teams may undermine their objectivity.

The report also notes that inconsistencies in the imposition of CMS sanctions make it unclear how effective CMS enforcement is at compelling labs to comply with CLIA requirements, and that CMS is failing to ensure in a timely manner that updated standards by accreditation organizations meet requirements for equivalency with CLIA standards.

To correct these shortcomings, GAO recommends that CMS undertake a number of actions, including the following.

- Standardizing the reporting of survey deficiencies to permit meaningful comparisons across survey organizations;

- Working with survey organizations to ensure that educating lab workers does not preclude appropriate regulation, such as identifying and reporting deficiencies that affect lab testing quality; and

- Allowing the CLIA program to fully use revenues generated by the program to hire sufficient staff to fulfill its statutory responsibilities.

My own proposals for *congressional* action are set forth in legislation that I introduced in October 2004 and that I reintroduced along with Congressman Ruppersberger in the 109th Congress.
The Clinical Laboratory Compliance Improvement Act, H.R. 686, would establish whistleblower protections for employees of clinical labs; require labs to post signage to facilitate the reporting of lab problems to CLIA entities; require survey organizations to report complaints of deficiencies to the Secretary of HHS; and require lab accreditation surveys to be unannounced. I believe the GAO report underscores the need for enactment of this legislation.

Mr. Chairman, today's hearing provides an important opportunity for GAO to present its findings and recommendations and to describe the difficulties it encountered in trying to put together a full and accurate picture of the quality of testing in federally regulated medical labs. It is equally important that we hear from CMS and other stakeholders in the CLIA program. CMS and three private survey organizations will appear before us today to respond to GAO's findings and recommendations and to present their perspectives on how to improve lab quality and accountability in the CLIA program. In addition, the Office of Healthcare Quality for the state of Maryland and CLMA, an organization representing lab professionals, are submitting written testimony for the record.

In closing, Mr. Chairman, the issue of clinical lab quality is an issue that has obvious implications for the quality of health care received by all Americans. I am encouraged that the interest this Subcommittee has demonstrated in this issue already has helped to instigate and inform a number of important self-initiated reforms by CMS and CAP, including CAP's decisions to conduct unannounced surveys and to require the posting of complaint signage. Clearly, however, the GAO report underscores the need for further action, and I look forward to our discussion concerning what steps should be taken to ensure that Americans receive the quality of medical testing to which CLIA entitles them.

Thank you, again, Mr. Chairman, for holding this hearing, for joining me in the GAO request, and for your sustained interest in this important issue. I appreciate the cooperation of the witnesses in appearing today and anticipate working with everyone involved to strengthen the CLIA program.

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Mr. SOUDER. Ms. Schmidt, do you have questions?

Ms. SCHMIDT. No.

Mr. SOUDER. Ms. Norton.

Ms. NORTON. Mr. Chairman, I just want to thank you and Mr. Cummings for working together on this issue, which I can only call frightening.

I think this may be the third hearing we've had on this issue. I certainly hope it leads to action.

I know we've been waiting for the GAO report. You know, when you first hear of the Maryland incident—we heard about it perhaps closer than some others because, of course, Baltimore is so close, but what bothered me was knowing Maryland to be a high-quality health State, I couldn't believe that this was an isolated incident. And we talk about life and death, that's a cliche when it comes to lab results.

It does seem to me, Mr. Chairman, that we want Federal standards that were enforceable for the same reason that this committee has been pressing—not this committee, excuse me, Mr. Chairman, that one of the subcommittees has been pressing for, computerized medical records, is because this is no longer a matter of your local hospital. If you get, I don't know, tests done at Washington Hospital Center, they may be used at Johns Hopkins, especially in an emergency.

So this is a real threshold issue, and yet there's been much more focus in the United States on mistakes made in hospitals. Yeah, I want to know about mistakes made in hospitals, but we may never know that the mistake originated in the hospital if we don't have a way of finding out whether the tests themselves, which we assumed, we all assume, have been correct and valid, were not part of the problem.

I was very troubled by what I learned about the GAO report, but perhaps it was to be expected, and that is, you know, we can't even compare; we don't have any data that allows us to compare, much less Federal standards.

Mr. Chairman, what is frightening about this is the only way this came to attention was newspaper reports—thank you, Baltimore Sun—and a catastrophic accident. That's liability.

So essentially, despite all the accreditation paraphernalia—that's what it turned out to be—they were outside institutions, the courts and the newspapers, that alerted us to what we were told would be uncovered by various organizations that deal with the State and with local agencies. So I would think, Mr. Chairman, that at a minimum we would want to begin with the Cummings bill to respond to this situation. We may need more.

I'm impressed—and Mr. Cummings deals in his bill with the whistleblowing notion. It does seem to me that's the one thing everybody in Congress agrees upon. Somebody ought to be able to step forth and tell it without fearing that he would lose his or her position. But it does seem to me that, given the top rating that the Maryland lab received, we have a serious problem with regulation, and we need to attend to it as soon as we can.

Thank you very much for doing the work, it seems to me, that can lead to that kind of action and enforcement improvement.

Mr. SOUDER. Thank you.

I ask unanimous consent that all Members have 5 legislative days to submit written statements and questions for the hearing record, and any answers to written questions provided by the witnesses also be included in the record. Without objection, it's so ordered.

I also ask unanimous consent that all exhibits, documents and other materials referred to by the Members and witnesses may be included in the hearing record, and that all Members be permitted to revise and extend their remarks. And without objection, so ordered.

First panel is Leslie Aronovitz. And so if you will stand and raise your right hand. It's the practice of this committee to swear in each of our witnesses.

[Witness sworn].

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

Thank you for joining us and your work on this study, and we're looking forward to hearing your conclusions.

STATEMENT OF LESLIE G. ARONOVITZ, DIRECTOR, HEALTH CARE, GAO

Ms. ARONOVITZ. Thank you, Mr. Chairman and members of the committee. I'm pleased to be here today as you discuss oversight of clinical labs by CMS and survey organizations.

My remarks are based on a report that was released today that focused on the 36,000 labs that perform moderate or high-complexity testing. Survey organizations are responsible for conducting biennial lab inspections and for investigating complaints, and CMS's role is to ensure the thoroughness and consistency of such inspections, and to impose sanctions when it identifies poor lab performance.

Because of inadequate CMS oversight and limited comparable data, too little is known about the quality of lab testing. In 2004, CMS modified historical State survey agency findings on lab quality and did not maintain a backup file. Moreover, based on interviews with 10 State survey agencies, we found that some surveyors refrained from citing serious deficiencies if a lab worker is new or a lab has a good compliance history.

Due to inconsistent surveys, the percentage of labs with serious deficiencies varied considerably across States in 2004, ranging from none in 6 States, to as much as 25 percent in 1 State.

Additionally, the lack of a straightforward method to link similar requirements across survey organizations makes it virtually impossible to assess lab quality in a standardized manner. Proficiency testing, which measures a lab's ability to consistently produce accurate test results, is the only data set that can be used uniformly to compare lab quality nationwide. Despite the importance of proficiency testing data, CMS requires proficiency testing for labs three times a year, as opposed to the statutory requirement for quarterly testing.

We also found that educating lab workers sometimes precludes appropriate regulation. On more than one occasion, CMS has provided labs with a significant educational period of from 2 to 4 years before enforcing new requirements. We found this long educational

period to be particularly troubling for the regulation of Pap smear testing for cervical cancer. CMS is letting poor performers off the hook for 2 years, even though labs have anticipated the new regulations for more than 13 years.

CMS also rarely uses sanctions to help deter noncompliance. For example, only 30 of the 274 labs with serious repeat deficiencies on consecutive surveys from 1998 to 2004 had sanctions imposed. We also found that there are relatively few complaints about lab quality problems. This may be due to insufficient publicity on how to file a complaint, and privacy complaints resulting from limited whistleblower protections for lab workers.

Some survey organizations have operated without proper authority and have utilized requirements that were less stringent than CLIA because CMS has been an average of over 3 years late in determining whether their inspection requirements are at least equivalent to CLIA's. Nor does CMS always review interim changes prior to implementation. Although officials of CMS attributed these delays to having too few staff, the CLIA program is funded by lab fees and currently has a $70 million surplus.

Finally, validation reviews. One of CMS's most important oversight tools does not provide an independent assessment of the extent to which surveys identify all serious deficiencies because many are performed simultaneously with such surveys.

Moreover, CMS has not required that validations occur in each State. From 1999 through 2003, 11 States had no validation reviews in multiple years. And this is particularly troubling to us because it is the State survey agencies that are responsible for conducting validation reviews of accrediting organization surveys.

Mr. Chairman, this concludes my oral statement, and I'm happy to answer any questions you or other members of the subcommittee may have.

[The prepared statement of Ms. Aronovitz follows:]

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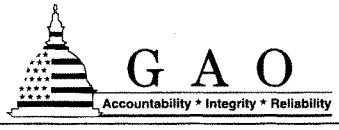
Testimony
Before the Subcommittee on Criminal Justice, Drug Policy and Human Resources, Committee on Government Reform, House of Representatives

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CLINICAL LABS

CMS and Survey Organization Oversight Is Not Sufficient to Ensure Lab Quality

Statement of Leslie G. Aronovitz
Director, Health Care



GAO-06-879T

June 27, 2006

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Highlights

Highlights of GAO-06-879T, a testimony before the Subcommittee on Criminal Justice, Drug Policy and Human Resources, Committee on Government Reform, House of Representatives

CLINICAL LABS

CMS and Survey Organization Oversight Is Not Sufficient To Ensure Lab Quality

Why GAO Did This Study

Today's hearing focuses on oversight of clinical labs. The Clinical Laboratory Improvement Amendments of 1988 (CLIA) strengthened quality requirements for labs that perform tests to diagnose or treat disease. About 36,000 labs that perform certain complex tests must be surveyed biennially by a state survey agency, a state CLIA-exempt program, or a private accrediting organization. CMS oversees implementation of CLIA requirements, which includes determining the CLIA equivalency of the inspection requirements used by exempt states and accrediting organizations. GAO was asked to discuss (1) the quality of lab testing and (2) the adequacy of CLIA oversight. To examine these issues, GAO analyzed data on lab performance and reviewed the procedures used by CMS and survey organizations to implement CLIA and oversee lab performance. This testimony is based on the GAO report, *Clinical Lab Quality: CMS and Survey Organization Oversight Should Be Strengthened*, GAO-06-416 (June 16, 2006).

What GAO Recommends

In a report released today, GAO made numerous recommendations to the CMS Administrator that would strengthen program oversight. CMS noted that the report provided insights into areas where it can improve oversight and said that it would implement 11 of GAO's 13 recommendations.

www.gao.gov/cgi-bin/getrpt?GAO-06-879T.

To view the full product, including the scope and methodology, click on the link above. For more information, contact Leslie G. Aronovitz at (312) 220-7600 or aronovitzl@gao.gov.

What GAO Found

In summary, insufficient data exist to identify the extent of serious quality problems at labs. When CMS implemented revised CLIA survey requirements in 2004, it modified historical state survey agency findings and, as a result, data prior to 2004 no longer reflect key survey requirements in effect at the time of those surveys. The limited data available suggest that state survey agency inspections do not identify all serious deficiencies. In addition, the lack of a straightforward method to link similar requirements across survey organizations makes it virtually impossible to assess lab quality in a standardized manner. Furthermore, CMS does not effectively use available data, such as the proportion of labs with serious deficiencies or proficiency testing results, to monitor lab quality. Proficiency testing is an objective measurement of a lab's ability to consistently produce accurate test results. GAO's analysis of proficiency testing data suggests that lab quality may not have improved at hospital labs in recent years.

Oversight of clinical lab quality is not adequate to ensure that labs are meeting CLIA requirements. Weaknesses in five areas mask real and potential quality problems at labs. First, the balance struck between the CLIA program's educational and regulatory goals is sometimes inappropriately skewed toward education, which may result in understatement of survey findings. For example, even though the initial test failure rates were high, CMS instructed state survey agencies not to cite deficiencies during the first two years of required Pap smear proficiency testing, to allow labs and their staff to become familiar with the program. Second, the manner in which one accrediting organization structures its survey teams raised concerns about appropriate levels of training and the appearance of a conflict of interest that could undermine the integrity of the survey process. Third, concerns about anonymity and lab workers' lack of familiarity with how to file a complaint suggests that some quality problems are not being reported. Fourth, based on the large number of labs with proposed sanctions from 1998 through 2004 that were never imposed—even for labs with the same serious deficiencies on consecutive surveys—it is unclear how effective CMS's enforcement process is at motivating labs to consistently comply with CLIA requirements. Finally, CMS is not meeting its requirement to determine in a timely manner the continued equivalency of accrediting organization and exempt-state program inspection requirements and processes, nor has the agency reviewed changes to accrediting organization and exempt-state program inspection requirements before implementation.

Mr. Chairman and Members of the Subcommittee:

I am pleased to be here today as you discuss oversight of the quality of testing performed by the nation's clinical laboratories. Clinical lab tests are one of the most frequently billed Medicare procedures and, according to the American Clinical Laboratory Association, affect an estimated 70 percent of medical decisions.[1] Ensuring accurate and reliable lab test results is critical because erroneous results may lead to improper treatment, unnecessary mental and physical anguish for patients, and higher health care costs. Concerns about the quality of lab testing resulted in enactment of the Clinical Laboratory Improvement Amendments of 1988 (CLIA).[2] In recent years, despite CLIA, lab quality problems in several states have raised questions about the adequacy of lab oversight.

The Centers for Medicare & Medicaid Services (CMS) is responsible for overseeing compliance with clinical lab testing requirements. As of December 2005, there were approximately 193,000 labs nationwide ranging from very small physician office labs that conduct fewer than 2,000 tests annually, to hospital labs that conduct millions of tests each year. Most clinical labs regulated under CLIA must obtain a certificate from CMS, but only about 19 percent—those that conduct moderate- to high-complexity tests—undergo biennial inspections, which are also referred to as surveys. During the surveys, inspectors assess lab compliance with mandated personnel and testing standards. In addition, surveyed labs must participate in proficiency testing, a program that requires them to test samples with unknown characteristics that are then graded by an external party. Labs with serious deficiencies may be sanctioned. Labs may choose to be surveyed by (1) their state survey agency, under contract with CMS; (2) their state CLIA-exempt program for labs in New York and Washington; or (3) one of six private accrediting organizations. State survey agency inspections use CLIA requirements that are intended to help ensure valid and reliable lab tests; the two state CLIA-exempt programs and six accrediting organizations survey labs using their own requirements that CMS has determined to be at least equivalent to

[1]Medicare is a federal health care program serving elderly and certain disabled individuals.

[2]Pub. L. No. 100-578, 102 Stat. 2903.

CLIA's. Each survey organization is also responsible for investigating complaints about lab quality.[3]

My remarks today will focus on (1) the quality of lab testing and (2) the effectiveness of CMS and survey organization oversight of the CLIA program. My testimony summarizes the findings of a report we released today that examines these issues in more detail and includes numerous recommendations to the CMS Administrator for improving the quality of laboratory testing through closer oversight of clinical labs and the administration of CLIA standards.

To determine what is known about the quality of lab testing, we analyzed data on serious deficiencies identified during surveys by state survey agencies using CMS's On-Line Survey, Certification, and Reporting system (OSCAR). We requested comparable data on serious deficiencies from state CLIA-exempt programs and the three largest accrediting organizations—the College of American Pathologists (CAP), COLA, and the Joint Commission on Accreditation of Healthcare Organizations (JCAHO)—which together survey about 97 percent of accredited labs.[4] We also analyzed proficiency testing data—another indicator of a lab's ability to produce accurate test results. To evaluate the effectiveness of CLIA program oversight, we reviewed the processes used to ensure the quality of clinical lab testing and analyzed available data related to these issues. Based on our review and discussions with CMS and survey organization officials, we focused on several key issues: (1) the balance struck between the regulatory and educational goals of lab surveys, (2) the implications of CAP's use of volunteer surveyors from neighboring labs to conduct inspections, (3) how survey organizations facilitate the filing of complaints, (4) the use of sanctions to encourage compliance, (5) CMS's process for determining that the standards used by state CLIA-exempt programs and accrediting organizations are at least equivalent to those of CLIA, and (6) the results of validation reviews that are intended to assess the adequacy of inspections by survey organizations. In addition, we interviewed officials from CMS, three CMS regional offices,[5] 10 state

[3]We use the term "survey organizations" when referring collectively to state survey agencies, the two state CLIA-exempt programs, and accrediting organizations.

[4]COLA was formerly known as the Commission on Office Laboratory Accreditation.

[5]New York, Philadelphia, and Seattle.

survey agencies,[5] the New York and Washington CLIA-exempt programs, and the three largest accrediting organizations. We conducted our work from January 2005 through May 2006 in accordance with generally accepted government auditing standards.

In summary, insufficient data exist to identify the extent of serious quality problems at labs. When CMS implemented revised CLIA survey requirements in 2004, it modified historical state survey agency findings stored in its OSCAR database and, as a result, data prior to 2004 no longer reflect key survey requirements in effect at the time of those surveys. The limited data available suggest that state survey agency inspections do not identify all serious deficiencies. In addition, the lack of a straightforward method to link similar requirements across survey organizations makes it virtually impossible to assess lab quality in a standardized manner, such as identifying the proportion of labs with condition-level deficiencies, which indicate serious or systemic quality problems. Furthermore, CMS does not effectively use available data—such as the proportion of labs with serious deficiencies or proficiency testing results—to monitor lab quality. Proficiency testing is the one available data source that can be used to uniformly compare lab quality across survey organizations. Although CMS noted that proficiency testing trend data show a decrease in failures for labs as a whole, we found that the data suggest that quality may not have improved at hospital labs in recent years. Despite the importance of, and the statutory requirement for, quarterly proficiency testing, CMS requires proficiency testing for almost all laboratory tests only three times a year.

Regarding oversight of clinical lab quality, we found that it is inadequate to ensure that labs are meeting CLIA requirements. Weaknesses in six areas mask real and potential quality problems at labs. First, the balance struck between the CLIA program's educational and regulatory goals is sometimes inappropriately skewed toward education, which may result in understatement of survey findings. In one instance, CMS instructed state survey agencies not to cite deficiencies for Pap smear proficiency test results during the first two years of required testing, to allow labs and their staff to become familiar with the program. Second, the way one accrediting organization structures its volunteer survey teams raised concerns about appropriate levels of training and the appearance of a conflict of interest. Third, although few labs were the subject of a

[5]California, Colorado, Connecticut, Idaho, Louisiana, Michigan, Nebraska, North Carolina, Pennsylvania, and South Carolina.

complaint each year from 2002 through 2004—significantly less than one complaint per lab per year—concerns about anonymity and lab workers' lack of familiarity with how to file a complaint suggest that some quality problems may not be reported. Fourth, based on the large number of labs with proposed sanctions from 1998 through 2004 that were never imposed—even for labs with the same serious, condition-level deficiencies on consecutive surveys—it is unclear how effective CMS's enforcement process is at motivating labs to consistently comply with CLIA requirements. Fifth, CMS is not meeting its requirement to determine in a timely manner the continued equivalency of accrediting organization and exempt-state inspection requirements and processes. For example, New York's and COLA's reviews were about 4 years and 3 years past due, respectively, as of December 2005. Moreover, CMS allows the implementation of changes to accrediting organization and exempt-state program inspection requirements between periodic equivalency determinations before it reviews the proposed changes. CMS attributed these delays to having insufficient staff. Finally, validation reviews—one of CMS's most important oversight tools—do not provide an independent assessment of the extent to which surveys identify all serious deficiencies because many are performed simultaneously with such surveys.

Accordingly, in the report we released today, we made specific recommendations to the CMS Administrator to standardize survey findings across survey organizations in order to make meaningful comparisons; strengthen survey, complaint, and enforcement processes; and improve oversight of the CLIA program. In its comments on a draft of our report, CMS endorsed our overall conclusion that quality assurance for the nation's clinical labs should be strengthened and said that it would take action in response to 11 of our 13 recommendations. CMS provided an alternative assessment of lab quality, and disagreed with our recommendations concerning the frequency of proficiency testing and the extent of simultaneous accrediting organization validation reviews. CMS also expressed concern about identifying and sanctioning labs with repeat condition level deficiencies. After considering CMS's comments, we believe that implementing our recommendations is necessary to improve oversight of labs and accrediting organizations.

Background

A clinical lab is generally defined as a facility that examines specimens derived from humans for the purpose of disease diagnosis, prevention, and treatment, or health assessment of individuals. Labs conduct a wide range of tests that are categorized as waived tests or as moderate- or high-complexity tests. Approximately 81 percent of all labs (about 157,000) are

not subject to routine biennial surveys because they perform (1) "waived" tests, which are generally simple tests that have an insignificant risk of erroneous results, such as those approved for home use[7] or (2) tests performed during the course of a patient visit with a microscope on specimens that are not easily transportable. CLIA establishes more stringent requirements for the 19 percent (about 36,000) of labs performing moderate- or high-complexity testing, including the requirement for a survey and participation in routine proficiency testing. Surveys examine lab compliance with CLIA program requirements in several areas including: personnel qualifications, proficiency testing,[8] quality control, quality assurance, and recordkeeping.

Survey Organizations

In general, labs have a choice of who conducts their surveys—state survey agencies using CLIA inspection requirements or other survey organizations that use requirements CMS has determined to be at least equivalent to CLIA's. CMS contracts with state survey agencies in most states to inspect labs against CLIA requirements.[9] CLIA established an approval process to allow states and private accrediting organizations to use their own requirements to survey labs. As noted earlier, New York and Washington operate CLIA-exempt programs and CMS has approved six private, nonprofit accrediting organizations to survey labs—the American Association of Blood Banks (AABB), the American Osteopathic Association (AOA), the American Society of Histocompatibility and Immunogenetics (ASHI), CAP, COLA, and JCAHO. The requirements of both state CLIA-exempt programs and accrediting organizations must be reviewed by CMS at least every 6 years to ensure CLIA equivalency, but may be more stringent than those of CLIA. Figure 1 lists the three types of survey organizations and indicates whether they survey labs under CLIA requirements, or use their own CLIA-equivalent requirements. It also shows the percentage of labs performing moderate- to high-complexity

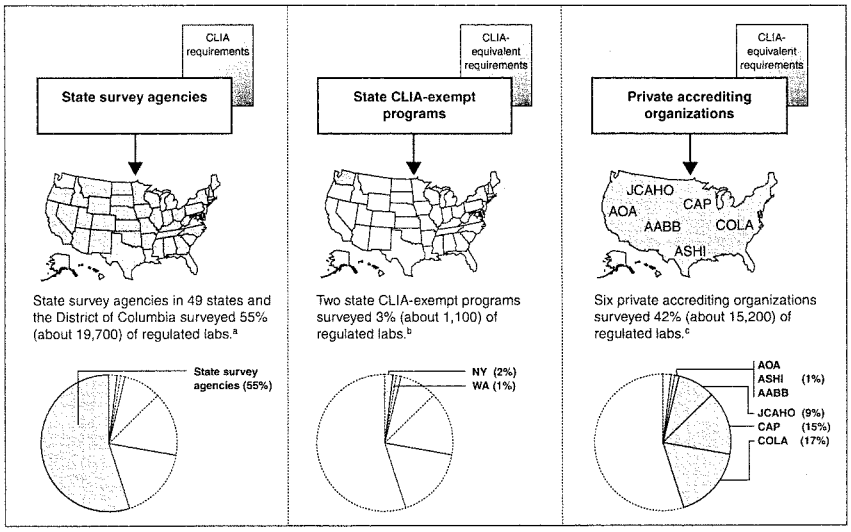
[7]Pregnancy and blood sugar screenings are examples of such tests.

[8]Surveyed labs must participate in an approved external proficiency testing program, which evaluates the accuracy of laboratory testing. Under this requirement, a lab purchases samples with unknown characteristics several times each year from an approved proficiency testing provider. The lab is required to test the samples with its routine patient testing, and the results are returned to the testing provider to be graded. A proficiency testing failure is defined as unsatisfactory performance on two consecutive or two out of three testing events.

[9]CMS contracts with state survey agencies in the District of Columbia and 49 states (including New York but not Washington) to survey labs under CLIA requirements.

testing surveyed by each type of organization. In general, state survey agencies, COLA, and Washington's CLIA-exempt program survey physician office labs, while New York's CLIA-exempt program, CAP, and JCAHO survey hospital labs.

Figure 1: Types of Survey Organizations, Requirements Used to Survey Labs, and Percentage of Labs Surveyed by Each Organization, as of December 2005



Source: GAO.

[a]Washington is not included as it has only a CLIA-exempt program.

[b]New York uses CLIA-equivalent requirements to inspect larger hospital labs under the state's CLIA-exempt program and CLIA requirements to inspect smaller labs, including physician office labs. Only the labs in the CLIA-exempt program are counted here.

[c]Some labs are counted more than once because labs may be accredited by more than one organization. While some labs in New York may be accredited, they are still subject to biennial surveys by the state survey agency or the state CLIA-exempt program, because New York does not authorize accreditation as the basis for lab licensure.

Surveys and Complaint Investigations

Survey organizations (1) conduct surveys and complaint investigations and (2) monitor proficiency test results submitted by surveyed labs three times a year. Surveys are typically conducted by former or current lab workers, who assess lab compliance with CLIA or CLIA-equivalent requirements. Generally, surveyors verify that lab personnel are appropriately qualified to conduct testing, evaluate proficiency test records, check equipment and calibration to ensure that appropriate quality control measures are in place, and determine whether the lab has a quality assurance plan and uses it to, among other things, appropriately identify and resolve problems affecting testing quality. Surveys also include an educational component to assist labs in understanding how to comply with CLIA requirements.

Lab survey requirements are classified as either "standard-" or "condition-" level. Deficiencies are also characterized as standard- or condition-level based on the requirement in which the deficiency occurs. Standard-level deficiencies denote problems that generally are not serious, while condition-level deficiencies are cited when the problems are serious or systemic in nature. When deficiencies are found during surveys or complaint investigations, labs are required to submit a plan of correction, detailing how and when they will address the deficiencies. Additionally, CMS can impose principal or alternative sanctions, or both. Principal sanctions include revocation of a CLIA certificate, cancellation of the right to receive Medicare payments, or limits on testing. Alternative sanctions, authorized by Congress to give CMS more flexibility to achieve lab compliance, are less severe and include civil money penalties or on-site monitoring. For condition-level deficiencies that do not involve an imminent and serious threat to patient health and a significant hazard to public health, labs have an opportunity to correct the deficiencies, which we refer to as a grace period, before the sanctions are imposed. If a lab is unable to correct a deficiency during this grace period, CMS determines whether to impose sanctions.

CMS Oversight

CMS, including its 10 regional offices, oversees state and accrediting organization survey activities. CMS reviews and approves initial and subsequent applications from exempt-state programs and accrediting organizations to ensure CLIA equivalency. Validation reviews are one of CMS's primary oversight tools. Federal surveyors in CMS regional offices are responsible for conducting validation reviews of state survey agency

and exempt-state program inspections, but state survey agency staff conduct the validation reviews of accrediting organization inspections.[10] An objective of these reviews is to determine if all condition-level deficiencies were identified. These reviews are conducted within 60 days of a state's, or 90 days of an accrediting organization's, survey of a lab.

Insufficient Data Exist to Identify Extent of Serious Lab Quality Problems

The extent of serious quality problems at labs is unclear because CMS has incomplete data on condition-level deficiencies identified by state survey agencies prior to 2004. Survey results for 2004 show substantial variability across states, which suggests that state survey agencies do not conduct surveys in a consistent manner. We also found that the lack of a straightforward linkage between CLIA requirements and the CLIA-equivalent requirements of some survey organizations makes it virtually impossible to assess lab quality in a standardized manner. CMS does not effectively use available data, such as the results of surveys and proficiency testing, to monitor and assess lab quality. Although CMS noted that proficiency testing trend data show a decrease in failures for labs as a whole, the data suggest that quality may not have improved at hospital labs for the period 1999 through 2003.

Limited Quality Data for Labs Inspected by State Survey Agencies Suggest Survey Inconsistencies

CMS's OSCAR database contains limited data on the quality of labs inspected by state survey agencies and, as a result, it is not possible to analyze changes in the quality of lab testing over time. In January 2004, CMS implemented revised CLIA survey requirements and modified the existing OSCAR data—state survey agency findings—to reflect the changes. The revisions affected approximately two-thirds of the CLIA condition-level requirements.[11] As a result of the data modifications, the findings for surveys conducted prior to 2004 no longer reflect all key condition-level requirements in effect at the time of those surveys.

[10]Unlike validation reviews of accrediting organization surveys, CMS refers to the validation of state surveys as Federal Monitoring Surveys. Because of their similar objective, we refer to all such surveys as validation reviews in this testimony. We refer to validation reviews that occur at the same time as the lab survey as simultaneous. Conversely, validation reviews that occur after the lab survey are referred to as independent validations.

[11]For example, some condition-level requirements were reorganized and some were consolidated.

Based on the available 2004 OSCAR data (which represent about one half of all labs surveyed by state survey agencies), we found that 6.3 percent of labs had condition-level deficiencies. However, variability in the OSCAR data suggests that labs are not surveyed in a consistent manner. In 2004, the percentage of labs that were reported to have condition-level deficiencies varied considerably by state, ranging from none in 6 states to about 25 percent of labs in South Carolina. Based on interviews with CMS and 10 state survey agencies, it appears that at least some of this variability is due to differences in states' approaches to conducting their surveys as opposed to true differences in lab quality. For example, CMS told us that, because there is not a prescriptive checklist to guide the survey process, the reliance on state surveyor judgment results in variations in the citing of deficiencies. In fact, officials in several states said that there are circumstances under which condition-level deficiencies would not be cited, such as if the lab staff were new or if the lab had a good history of compliance. As a result, available data likely understate the extent of serious quality problems at labs.

Quality of Labs Inspected by Survey Organizations Is Very Difficult to Measure in a Standardized Manner

Differences in the inspection requirements used by survey organizations make it virtually impossible to measure lab quality in a standardized manner. Because exempt-state programs and accrediting organizations do not classify inspection requirements and related deficiencies with the same criteria used by state survey agencies—as either standard- or condition-level—they cannot easily identify the proportion of surveyed labs with condition-level deficiencies.[12]

We asked exempt-state programs and accrediting organizations what percentage of their requirements, and any deficiencies cited for failure to meet those requirements, indicated serious problems that were equivalent to CLIA condition-level deficiencies. CAP and COLA crosswalked their recent survey findings to CLIA condition-level requirements. Although their analysis suggested that from about 56 to 68 percent of labs surveyed during 2004 had a deficiency in at least one condition-level requirement, they acknowledged that these proportions overstated the subset of labs

[12] Although CMS reviews the requirements of exempt-state programs and accrediting organizations to ensure that they are at least equivalent to CLIA's, there is not necessarily a one-to-one match with CLIA requirements. Thus, one CLIA condition-level requirement may equal several accrediting organization requirements or vice versa. For example, CMS's condition-level requirement for successful lab participation in approved proficiency testing corresponds to at least 19 CAP, 3 COLA, and 4 JCAHO requirements.

with serious problems. JCAHO did not crosswalk its inspection requirements to those of CLIA because staff would have had to manually review each survey report to determine which deficiencies were equivalent to deficiencies in CLIA condition-level requirements.[13]

Despite the difficulty of identifying CLIA equivalent condition-level deficiencies, two of the three accrediting organizations we reviewed have systems to identify labs they survey that have serious quality problems. COLA estimated that about 9 percent of labs it surveyed in 2004 were subject to closer scrutiny because of the seriousness of the problems identified. According to JCAHO, about 5 percent of the labs it surveyed in 2004 were not in compliance with a significant number of requirements. The third accrediting organization, CAP, has criteria for identifying labs that warrant greater scrutiny, but CAP officials told us that identifying such labs had to be accomplished on a case by case basis, rather than through a database inquiry.[14]

CMS Use of Data for Monitoring Lab Quality Is Limited

CMS does not effectively use available data, such as the results of surveys and proficiency testing data, to monitor and assess lab quality. Although CMS tracks the most frequently cited deficiencies at labs in an effort to improve quality, it does not routinely track the proportion of labs, by state, in which state survey agencies identify condition-level deficiencies—those that denote serious or systemic problems. As noted earlier, variability in survey findings suggests inconsistencies in how surveys are conducted. CMS also does not require exempt-state programs and accrediting organizations to routinely submit data on serious deficiencies identified at the labs they inspect, unless the deficiencies pose immediate jeopardy to the public or an individual's health.

We also found that CMS does not effectively use proficiency testing data to assess clinical lab quality. Proficiency testing is an important indicator of lab quality because it is an objective assessment of a lab's ability to produce accurate test results and is conducted more frequently than

[13]However, JCAHO officials noted that in 2004, about 90 percent of the labs it surveyed had a deficiency in at least one requirement. JCAHO classifies all of its requirements as serious.

[14]As a result, CAP plans to spend in excess of $9 million during 2006 and 2007 to develop an integrated data system that pulls together multiple factors—survey results, complaints, proficiency testing, findings of other inspection bodies, and changes in lab directors—to enable it to readily identify problem labs.

surveys—three times a year versus once every 2 years. In the absence of comparable survey data, proficiency testing results provide a uniform way to assess the quality of lab testing across survey organizations. Although CMS's analysis of proficiency testing data showed improvements over time, our analysis of proficiency testing data for 1999 through 2003 suggests that there has been an increase in proficiency testing failures for labs inspected by CAP and JCAHO, which generally inspect hospital labs, and a decrease in such failures for labs surveyed by state survey agencies and COLA, which tend to inspect physician office labs.

Importantly, CMS's decision to require proficiency testing for almost all laboratory tests only three times a year is inconsistent with the statutory requirement. CLIA requires that proficiency testing be conducted "on a quarterly basis, except where the Secretary determines for technical and scientific reasons that a particular examination or procedure may be tested less frequently (but not less often than twice per year)."[15] In CMS's 1992 rule implementing CLIA, the agency provided a rationale for reducing the frequency of proficiency testing, but did not provide a technical and scientific basis for reducing the frequency for particular procedures or tests.[16] CMS told us that officials from CMS and the Centers for Disease Control and Prevention had together determined that the reduced frequency was based on technical and scientific grounds and supplied a brief, undated narrative which it attributed to the Centers for Disease Control and Prevention. However, the narrative focused on the relative costs and benefits of proficiency testing at various intervals and did not include an analysis of the technical and scientific considerations with regard to particular tests that presented a basis for reducing the frequency.

CLIA Program Oversight Is Inadequate

Oversight by CMS and survey organizations is not adequate to ensure that labs meet CLIA requirements. For example, the goal of educating lab workers during surveys takes precedence over the identification and reporting of deficiencies, while the use of volunteer rather than staff surveyors by one accrediting organization raises questions about appropriate levels of training and the appearance of a conflict of interest.

[15]Pub. L. No. 100-578, § 2, 102 Stat. 2903, 2907-08, 42 U.S.C. § 263a(f)(3)(2000).

[16]In its rationale, CMS noted that experts were divided on the appropriate frequency of proficiency testing and further justified the change by explaining that fewer events of proficiency testing would give laboratories more time to analyze the causes of test failures, thus enhancing the value of proficiency testing as an educational tool.

The significant increase in complaints since CAP took steps to help ensure that lab workers know how to file a complaint suggests that some quality problems at labs inspected by some survey organizations may not be reported. In addition, sanctions are not being used effectively as an enforcement tool to promote labs' compliance with CLIA requirements, as evidenced by the relatively few labs with repeat condition-level deficiencies on consecutive surveys from 1998 through 2004 that had sanctions imposed. Furthermore, CMS is not meeting its responsibility to determine that accrediting organization and exempt-state program requirements and processes continue to be at least equivalent to CLIA's. Finally, ongoing CMS validation reviews do not provide an independent assessment of the extent to which surveys identify all condition-level deficiencies—primarily due to their timing.

Balance Between Educational and Regulatory Roles by CMS and Survey Organizations Appears to Be Inappropriate

The goal of educating lab workers sometimes takes precedence over, or precludes, the identification and reporting of deficiencies that affect the quality of lab testing.[17] For example, surveyors from one state survey agency told us they do not cite condition-level deficiencies when lab workers are new but prefer to educate the new staff. As a result, data on the quality of lab testing and trends in quality over time may be misleading. CMS also appears to be inappropriately stressing education over regulation. For instance, in its 2005 implementation of proficiency testing for lab technicians who interpret Pap smears, a test for cervical cancer, CMS instructed state surveyors to refrain from citing deficiencies at labs whose staff fail the tests in 2005 or 2006. According to CMS, this educational focus allows labs and their staff to become familiar with the proficiency testing program; however, it is important to note that there was about a 13-year time lag between the 1992 regulations that implemented CLIA and the 2005 implementation of Pap smear proficiency testing.[18] In addition, CMS noted that it was concerned about some of the high initial Pap smear proficiency testing failure rates. An inappropriate balance between the educational and regulatory roles is also evident in

[17]Although CLIA neither requires nor precludes an educational role for surveyors, the preamble to CMS's implementing regulation noted that surveys are intended, in part, to provide an opportunity for on-site education regarding accepted laboratory procedures.

[18]Because of lab testing errors that led to women's deaths, Congress required a specific type of proficiency testing for individuals who interpret the results of Pap smear tests, which requires examining glass slides under a microscope. Although CLIA was enacted in 1988, CMS told us that cost, the inability to find a national testing provider, and other technical issues delayed establishing a Pap smear proficiency testing program until 2005.

some accrediting organization practices. For instance, for COLA, the process of educating labs begins even prior to a survey, when labs are encouraged to complete a self-assessment to identify COLA requirements with which they are not in compliance. A CAP surveyor we interviewed with over 30 years of lab experience estimated that the majority of pathologists—individuals who generally serve as CAP survey team leaders—view surveys as educational, rather than as assessments of compliance with lab requirements.

Use of Volunteer Surveyors by CAP Raises Concerns

The use of volunteer inspectors by CAP raises concerns about appropriate levels of training and the appearance of a conflict of interest. Although state survey agencies, exempt-state programs, COLA, and JCAHO employ dedicated staff surveyors, CAP relies primarily on volunteer teams consisting of lab workers from other CAP-inspected labs to conduct surveys.[19] In contrast to the mandatory training and continuing education programs in place for the staff surveyors of other survey organizations, training for CAP's volunteer surveyors is currently optional.[20] According to data provided by CAP, two-thirds of volunteer surveyors who had recently participated in a survey had no formal training in the 3 to 5 years preceding the survey. While full-time surveyors employed by other survey organizations conduct from 30 to about 200 surveys per year, CAP volunteer surveyors have much less experience conducting surveys because they only survey about one lab each year. CAP officials told us they plan to establish a mandatory training program for survey team leaders beginning in mid-2006.[21] However, the required training will take only 1 or 2 days. In contrast, state survey agency inspectors must complete 5 days of basic training, while COLA staff inspectors participate in a 5-week orientation program and an annual 20 hours of continuing education.

CAP's method for staffing survey teams also raises concerns about the appearance of a conflict of interest. Typically, inspection team leaders are pathologists who direct other labs in the community, and the inspection team is comprised of several employees from the team leader's lab. In the

[19]As of November 2005, CAP also employed 11 full-time surveyors.

[20]Currently, CAP volunteer surveyors are encouraged to participate in surveyor training at least once every 3 years.

[21]Mandatory training for survey team members is targeted to begin in 2007.

event of differing opinions about survey findings, team members who are subordinates to the team leader may feel that they have no other recourse than to follow the team leader's instructions—such as downgrading the record of an inspection finding to a less serious category. Recognizing that team members' objectivity may be compromised in this situation, CAP's revised conflict of interest policy instructs all parties to be cautious to retain objectivity in fact finding throughout the inspection process.

Lab Workers Who File Complaints About Quality Problems in Lab Testing Not Afforded Whistle-blower Protections

Some lab workers may not be filing complaints about quality problems at their labs because of anonymity concerns or because they may not be familiar with filing procedures. Based on OSCAR data and data obtained from exempt-state programs and accrediting organizations for 2002 through 2004, few complaints were received about lab testing relative to the number of labs—significantly less than one complaint per lab per year.[22] We found that lab workers may not know how to file a complaint. CAP experienced a significant increase in the number of complaints it received since October 2004 when it began requiring CAP-inspected labs to display posters on how to file complaints. Specifically, from October through December 2004, CAP received an average of 22 complaints per month, compared to an average of 11 complaints per month in the 9 months preceding the poster requirement.[23]

Because of the difficulty of protecting the anonymity of lab workers who file complaints, whistle-blower protections for such individuals are particularly important. Two of the three accrediting organizations we interviewed have whistle-blower protections—CAP and JCAHO.[24] While officials from New York and Washington's exempt-state programs told us that whistle-blower laws in their states provide some protection for lab workers who file complaints, officials in most of the other 10 states we

[22]Information about complaints is from OSCAR data and data obtained from exempt-state programs and accrediting organizations for 2002 through 2004. The modifications to OSCAR did not affect data on the number of complaints. The complaint information in OSCAR excludes complaints that do not require an on-site survey.

[23]In September 2005, COLA also began requiring labs to display a complaints poster similar to CAP's. Neither CMS nor JCAHO plan to require a similar complaints poster. Effective July 2005, JCAHO required labs to educate staff on how to report concerns about lab quality to the Joint Commission but does not specify use of a poster to do so.

[24]COLA does not have a formal whistle-blower policy. COLA officials told us that they promptly investigate all complaints, many of them from former lab employees, and keep the identity of the complainants anonymous.

interviewed told us that they did not have any whistle-blower protections or were unable to identify specific protections that applied to lab workers in their state. Although there are no federal whistle-blower protections specifically for workers in labs covered by CLIA, legislation was introduced in 2005 to provide such protections.[25]

Lab Sanctions Are Rarely Imposed

Few labs were sanctioned by CMS from 1998 through 2004—even those with the same condition-level deficiencies on consecutive surveys—because many proposed sanctions are never imposed. Our analysis of CMS enforcement data from 1998 through 2004 found that while over 9,000 labs had sanctions proposed during these years, only 501 labs were sanctioned.[26] This equates to less than 3 percent of the approximately 19,700 labs inspected by state survey agencies. Before sanctions go into effect, labs are given a grace period to correct condition-level deficiencies, unless the deficiencies involve an imminent and serious threat to patient health and a significant hazard to public health. Most labs correct the deficiencies within the grace period. CMS officials told us that it was appropriate to give labs an opportunity to correct such deficiencies within a prescribed time frame and thus avoid sanctions.

However, the number of labs with the same repeat condition-level deficiencies from one survey to the next also raises questions about the overall effectiveness of the CLIA enforcement process. From 1998 through 2004, 274 labs surveyed by state survey agencies had the same condition-level deficiency cited on consecutive surveys and 24 of these labs had the same condition-level deficiency cited on more than two surveys.[27] This analysis may understate the percentage of labs with repeat condition-level deficiencies because OSCAR data prior to 2004 no longer reflect about two-thirds of condition-level requirements and associated deficiencies at the time of those surveys. We found that only 30 of the 274 labs with repeat condition-level deficiencies had sanctions imposed—either principal, alternative, or both. With respect to accredited labs, from 1998 through 2004, less than 1 percent of accredited labs (81) lost their accreditation; few of these labs were subsequently sanctioned by CMS and

[25]H.R. 686, 109th Cong. (2005).

[26]Since CMS data list only the number of labs with proposed sanctions by year, this number may double-count labs that had proposed sanctions in multiple years.

[27]Thirty-three states and the District of Columbia had at least one lab with the same repeat condition-level deficiency.

many still participate in the CLIA program. Moreover, CMS did not sanction 3 labs that COLA concluded had cheated on proficiency testing by referring the samples to another lab to be tested.[28] By statute, the intentional referral of samples to another lab for proficiency testing is a serious deficiency that should result in automatic revocation of a lab's CLIA certificate for at least 1 year.[29] Based on our interviews, we found that the 3 labs were allowed to continue testing because they had initiated corrective actions; in effect, these labs were given an opportunity to correct a deficiency that appears to have required a loss of their CLIA certificate for at least 1 year.

CMS Is Late in Ensuring CLIA Equivalency of Exempt States' and Accrediting Organizations' Inspection Requirements and Processes

We found that CMS has been late in determining that exempt states' and accrediting organizations' inspection requirements and processes are at least equivalent to CLIA's. Because CMS has not completed its equivalency reviews within required time frames, accrediting organizations and exempt state programs have continued to operate without proper approval.[30] Equivalency reviews for CAP, COLA, JCAHO, and Washington due to be completed between November 1, 1997, and April 30, 2001, were an average of about 40 months late. In August 1995, CMS determined that New York's next equivalency review should be completed by June 30, 2001, but was over 4 years past due as of December 2005. Similarly, COLA's equivalency review was about 3 years past due. Furthermore, although federal regulations require CMS to review equivalency when an accrediting organization or exempt-state program adopts new requirements, CMS has not reviewed changes in the inspection requirements prior to use by these entities.[31] As a result, such survey organizations may introduce changes that are inconsistent with CLIA requirements. For example, JCAHO made a significant change to its inspection requirements in January 2004; CMS did not begin an in-depth review of JCAHO's revised requirements until early 2005—over a year after they were implemented by JCAHO.

[28]A fourth lab was ultimately sanctioned for proficiency testing cheating by CMS but was allowed to continue testing for almost 2 years after having its accreditation revoked.

[29]Pub. L. No. 100-578, § 2, 102 Stat. at 2911, codified at 42 U.S.C. § 263a(i)(4)(2000).

[30]CMS must verify the equivalency of accrediting organizations and exempt-state programs, and by regulation, CMS requires such survey organizations to seek reapproval at least once every 6 years, or more frequently if deemed necessary. CMS establishes the time frames for when the next reapproval should occur, which have ranged from about 15 months to about 6 years.

[31]*See* 42 C.F.R. § 493.573(a)(3)(2005).

According to CMS, its review has identified several critical areas where JCAHO standards are less stringent than those of CLIA. JCAHO acknowledged the need to make some adjustments to its revised requirements.

CMS officials attributed delays in making equivalency determinations and reviewing interim changes to having too few staff. The CLIA program, located in CMS's Center for Medicaid and State Operations (CMSO), currently has approximately 21 full-time-equivalent positions compared to a peak of 29 such positions several years ago. As required by statute, the CLIA program is funded by lab fees and since its inception the program's fees have exceeded expenses. As of September 30, 2005, the CLIA program had a carryover balance of about $70 million—far more than required to hire an additional six to seven staff members. However, CMS officials told us that because the CLIA program staff are part of CMSO, they are subject to the personnel limits established for CMSO, regardless of whether or not the program has sufficient funds to hire more staff.

CMS Validation Reviews Skip Some State Survey Agencies and Many Lack Independence

CMS validation reviews that are intended to evaluate lab surveys conducted by both states and accrediting organizations do not provide CMS with an independent assessment of the extent to which surveys identify all serious—that is, condition-level or condition-level equivalent—deficiencies. CMS requires its regional offices to conduct validation reviews of 1 percent of labs inspected by state survey agencies in a year.[32] However, CMS does not specifically require that validations occur in each state. As a result, from 1999 through 2003, there were 11 states in which no validation reviews were conducted in multiple years. Without validating at least some surveys in each state, CMS is unable to determine if the states are appropriately identifying deficiencies.

Many validation reviews occur at the same time a survey organization conducts its inspection and, in our view, the collaboration among the two teams during these simultaneous surveys prevents an independent evaluation. Seventy-five percent of validations of state lab surveys were conducted simultaneously from fiscal years 1999 through 2003.[33] According to CMS officials, the large proportion of simultaneous validation reviews

[32]In contrast, validation reviews of 5 percent of labs inspected by accrediting organizations during a year are conducted by state survey agency personnel.

[33]These validation reviews include both exempt-state and state survey agency lab surveys.

provides an opportunity for federal surveyors to share information with state surveyors, monitor their conformance with CLIA inspection requirements, and identify training and technical assistance needs. However, we found that such reviews do not provide an accurate assessment of state surveyors' ability to identify condition-level deficiencies. Of the 13 validation reviews that identified missed condition-level deficiencies, only 1 was a simultaneous review. Regarding validation reviews of accrediting organization's survey of labs, CMS officials were unable to tell us how many of the roughly 275 validation reviews conducted each year from fiscal year 1999 through fiscal year 2003 were simultaneous.[34] However, JCAHO estimated that 33 percent of its validation reviews were conducted simultaneously. CMS officials told us that the agency's intent in instituting simultaneous reviews was for state and accrediting organization surveyors to share best practices, to promote understanding of each other's programs, and to foster accrediting organization improvement. In contrast, most of the state survey agency officials we interviewed told us that simultaneous validation reviews do not provide a realistic evaluation of the adequacy of accrediting organizations' inspection processes.

Concluding Observations

Clinical labs play a pivotal role in the nation's health care system by diagnosing many diseases, including potentially life-threatening diseases, so that individuals receive appropriate medical care. Given this important role, lab tests must be accurate and reliable. Our work demonstrated that the oversight of clinical labs needs to be strengthened in several areas. Without standardized survey findings across all survey organizations, CMS cannot tell whether the quality of lab testing has improved or worsened over time or whether deficiencies are being appropriately identified. Using data to analyze activities across survey organizations can be a powerful tool in improving CMS oversight of the CLIA program, yet CMS has not taken the lead in ensuring the availability and use of data from survey organizations to help it monitor their performance. Furthermore, the agency is not requiring that labs participate in proficiency testing on a quarterly basis, as required by CLIA. More broadly, CMS and survey organization oversight of the lab survey process is not adequate to enforce CLIA requirements. Educating labs to ensure high-quality testing should complement but not replace the enforcement of CLIA inspection requirements. Labs with the same serious deficiencies on consecutive

[34]CMS did not begin tracking this information until August 2003.

surveys often escape sanctions, even though Congress authorized alternative sanctions to give CMS more flexibility to achieve lab compliance. Without the threat of real consequences, labs may not be sufficiently motivated to comply with CLIA inspection requirements. By allowing validation reviews to occur simultaneously with surveys and permitting some states to go without validation reviews over a period of several years, CMS is not making full use of this oversight tool. Moreover, independent validation reviews of accrediting organization surveys are critical because CMS has not conducted equivalency reviews within the time frames it established. The recommendations we have made would help CMS to consistently identify and address lab quality problems.

Mr. Chairman, this concludes my prepared remarks. I would be happy to answer any questions that you or other Members of the Subcommittee may have.

Contact and Acknowledgments

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Mr. SOUDER. Before I start my questioning, I wanted to—because these hearing records are a kind of a permanent record for people to go back through, and I have no prepared questions, I have no agenda with this, it's more of a generic question. And I know that you could provide more specific data if we want later, but I just wanted a general idea. When you do a study like this—you head the Health Division at GAO?

Ms. ARONOVITZ. I'm one of six Directors that work with the Director of our Health Division.

Mr. SOUDER. And then do you have—then when you decided to go ahead with this study, did you have some people on staff, and then you contracted with others? Could you kind of walk through a little bit what you do to prepare a survey like that?

Ms. ARONOVITZ. Sure. We sometimes do use contractors or other experts when we do a study of this enormity, but we actually did this study in house. We used experts to consult with to make sure we understood the meaning of different terms and terminologies, but because we were looking at oversight mechanisms and different administrative and other types of logistical and regulatory requirements, which is more within our bailiwick, and not scientific or clinical requirements, we did not need, in our minds, to go with specific medical or clinical experts. In other words, we did not independently assess the quality of any labs. That would have been well beyond our expertise. What we did is try to see who is responsible for overseeing the quality of labs and what types of activities they were involved in.

Mr. SOUDER. So in the process here you would have talked with each of the individual groups?

Ms. ARONOVITZ. Absolutely. We spent quite a bit of time working with CMS, the two exempt State CLIA program representatives, and the accrediting organization representatives.

Mr. SOUDER. And with CMS themselves?

Ms. ARONOVITZ. Absolutely, extensively with CMS.

Mr. SOUDER. And you referred to—did you say you had 10 States respond in a survey?

Ms. ARONOVITZ. What we did is, in addition to working with CMS, we also separately, independently interviewed 10 State survey agencies to get their perspective.

Mr. SOUDER. Did you see anything as glaring as what we saw in the Maryland General Hospital or cases like that?

Ms. ARONOVITZ. No. I think a lot of what we saw really has to do with the regulatory structure and also the potential for problems to occur. But we saw no specific cases that were quite—that came to us.

Mr. SOUDER. When we look at the national CLIA requirements, do you think there is an efficient and effective way to have some sort of a national standard that would give us a clearer picture and at the same time allow these different organizations to have additive standards? One of the problems we have in housing in all sorts of flood standards and everything else is the Federal standards become the minimum—I should say they become the maximum and drive everybody to one standard which is not necessarily as high as some. Do you see how to reconcile that question?

Ms. ARONOVITZ. It's a difficult one to reconcile. We think the fact that the CLIA requirements give the accrediting organizations the opportunity to have requirements that are equivalent or even more stringent really goes far to really push labs to try to have high quality. We're impressed with how hard the accrediting organizations work, and the State exempt programs, to develop standards that they feel, based on their own clinical knowledge, are needed and required to do a good job in a lab.

The problem we have is not with the types of requirements that accrediting organizations develop, but the fact that when they develop their own set of requirements, it becomes very difficult for CMS to translate their findings and State findings into one common language, and therefore it becomes very difficult to look at the quality of labs across different types of survey organizations. We think there has to be a solution of some way that all the different organizations that are serving labs could come to some type of language where they could communicate to CMS what the serious deficiencies they're finding are and how they translate.

For example, we actually asked the accrediting organizations to supply us with a crosswalk to say if you find serious deficiencies based on your requirements, how does that translate to CLIA requirements? And COLA and CAP spent an enormous amount of effort to try to provide us with a crosswalk, which ended up really not being a good enough common language. And JCAHO tried very hard to do that, but it would have had to go through each individual case file to come up with that information, which we thought was not fair to that organization to have to do that. So right now it really leaves CMS in a position where it cannot look at lab quality in terms of the findings of these different survey organizations across organizations.

Mr. SOUDER. One other question I wanted to raise. When I was first elected to Congress and served on one of the oversight committees, we were spending a lot of time with OSHA. And one of the concerns in OSHA was how much they played gotcha, put fines on, versus how much they spent educating and working with different companies.

Here we have kind of the reverse question going on, and it's a struggle of how we do this in government, because, in fact, the oversight process, if it's not an egregious risk, I think the way we worked through it in OSHA is now more than half the funding they're to be given time to work through something and educate through the process unless there is an imminent health and life question.

Could something be worked through here? Because, in fact, a lot of the oversight should be an education process, not a gotcha process, because, in fact, often that drives more complaints underground, less whistleblower because of fear of retribution as opposed to cooperation; yet at the same time if it's all just talk and nobody—there is never a sanction, it doesn't leave much leverage either.

Do you have, as we work through this, a refined suggestion of how we might balance this education and penalty sanction question? And maybe it's pointed to by your just previous answer,

which is if it's egregious, it's one thing; if it's not egregious, it's another; if we can agree on what's egregious.

Ms. ARONOVITZ. I think that's true, if we could agree on what is egregious. The languages that different organizations use really look at serious deficiencies, but their definition of serious doesn't also translate to a CLIA definition of a serious deficiency, so from that standpoint we still need a common language.

But we've been wrestling a lot with this whole issue of education versus regulation, and we in no way discount the importance of having an educational component. What we worry about is that an educational component, if it precludes a regulatory one, and there is a slippery slope, there would come to a point where you would never really know what the state of lab quality is, and that's what really concerned us. Specifically in certain cases where there were deficiencies in consecutive surveys and the lab wasn't sanctioned, or in a case where the quality control standards that CMS applied in 2003 that became effective in 2004, the labs had 2 years before a deficiency would be noted, and now that has been extended 2 more years.

So what we worry about is by giving the labs every benefit of the doubt and to try to train them and to try to make sure that lab workers understand the requirements, we might be leaning over so far to give them every educational opportunity that we're really losing track of what the quality of labs are so that we could react when there are serious deficiencies noted.

Mr. SOUDER. Thank you.

Mr. Cummings.

Mr. CUMMINGS. Yes. First of all, I want to thank you very much for a very thorough report. And we truly appreciate the role that GAO plays in providing us with the information we need to do our jobs.

I want to just kind of go back just a moment. I know that was not your focus, necessarily, the Maryland General case, but it had some elements in it that I would just like for you to comment on.

The chairman and I mentioned—and I think it was Ms. Norton, too—the whole idea of the whistleblower and the significance of the whistleblower. In your findings there was some findings, if I recall—as I recall that there was an issue of whether there was an open environment for people to feel comfortable telling about what they see in these labs. And I just want you to comment, if you can, on the significance of the whistleblower and how that might—having a kind of closed environment might hurt our efforts to make sure that our labs are doing what they're posed to do.

Ms. ARONOVITZ. Yes. We did talk to several surveyors and some lab workers, and also the 10 survey agencies at the State level, and we heard that it was not that uncommon for two things to happen, for lab workers not to be aware of how to file a complaint, and also, when they were aware, that they were worried about retaliation to the extent that the law or the legal structure didn't really protect them or their privacy.

It became very clear to us that a lab worker who would file a complaint would probably have the best information and the most specific information for an oversight entity to decide whether this was a serious complaint and whether it warranted further inves-

tigation. On the other hand, lab workers felt that if they gave very specific information, they could easily be associated with the labor, the type of equipment or the department where the complaint came from, and therefore, without very strong protections, and a really good understanding of how to file a complaint, they were very reluctant to do so, at least among the people we talked with.

When we went to the State survey agencies, we found that some States possibly have whistleblower protections that would protect lab workers, but many States said that they did not have, even at the State level, the kind of protections that lab workers would need. Obviously you know that at the Federal level, there is no Federal statute, whistleblower statute, that protects lab workers that are covered under CLIA, and not all accrediting organizations have that either.

Mr. CUMMINGS. And I would take it that, when you have a situation where—when you answered Mr. Souder's questions about how to—this fact that we have insufficient information to accomplish what we need to accomplish here, I would take it that the whistleblower, under those circumstances, becomes even more significant, although we don't know, once they blow the whistle, exactly what standards they might be using; is that a fair statement?

Ms. ARONOVITZ. Right. I think once they would have to—once they would file a complaint, it would have to be investigated immediately—well, actually there would be a consideration as to whether the complaint warranted an investigation, and then it would have to be investigated, and the standards or the CLIA requirements that would apply would then be looked at very, very closely.

Mr. CUMMINGS. Going back to the Maryland General case, one of the problems was that there was a lack of sharing of information. You could have one organization come in and say, we've got problems; you could have a whistleblower out there saying there are problems; then you have another organization that comes in and says, my, you're doing a great job.

Can you comment on the sharing of information? Because I think that's a very significant thing that has not been happening, but I'm sure we'll hear from some of our representatives on things they may be doing now.

Ms. ARONOVITZ. Yeah, I think you will. I think—this is—excuse me, this is one of the areas that—another area that's a very, very critical one, and one we're just beginning to see some progress.

CMS has mentioned that it is establishing something called performance reviews both with State agencies, but also with the accrediting organizations. And with the accrediting organizations, one of the most important performance areas will be the extent to which accrediting organizations are able to communicate with CMS and within its organization to make sure that it understands what types of complaints and results of proficiency testing have occurred, and to make sure that CMS is aware of that also. So communication among entities is critical, and it's one of the areas that CMS is going to be focused on.

Mr. CUMMINGS. Now, under these circumstances, going back to the—one of the things that you have said in your report is that even when CMS has the information, that they are not necessarily

effectively using the information that they have; is that correct? Is that what you said?

Ms. ARONOVITZ. That is correct.

Mr. CUMMINGS. Do you want to get some water?

Ms. ARONOVITZ. No, I'm fine. Thanks.

Mr. CUMMINGS. All right. Can you explain that for us, please? I mean, so they get the information, they get information—maybe not all the information that they should have, but they get it. But then the information that they do have is not used effectively and efficiently.

Ms. ARONOVITZ. Well, this information is in several different areas. One of the areas has to do with proficiency testing. First of all, CMS requires proficiency testing for every lab three times a year. We think the statute really requires four times a year. So they're getting less information than they should. And CMS justifies this and feels very strongly that they have followed the law. And I could elaborate on that if you'd like. I don't want to get into too much detail if it's not relevant here.

But also on sanctions, for instance, as the chairman was saying, there should be an ability for labs to be able to take corrective action. There is a grace period for a lot of labs to fix the problems that are noted in surveys; however, CMS has sometimes bent over backward to give labs an opportunity to fix problems where they just crop up again at the next survey, and nothing more than that has happened.

So in some cases where there have been serious deficiencies, there have not been sanctions, and it's because the labs have been given an opportunity to correct the problem without it really being noted.

Mr. CUMMINGS. Speaking of correcting problems, I heard just an incredible argument when we held hearings before with regard to why unannounced visits would be a problem; it was almost shocking to the conscience.

What we were told was that if there were unannounced visits, they would be so disruptive to the lab that it would just—the benefit just far outweighs the disruption. Did you hear any of that as you talked to folks?

Ms. ARONOVITZ. We actually did hear that. We feel very strongly that, to the extent possible, surveys should be unannounced. Now, we do note that in small physician labs where patients are coming in and seeing the doctor and getting lab tests during those visits, it could be somewhat disruptive if you have a team come in and pretty much take over the lab. So we do understand that. We would expect some smaller labs to, in fact, need an announced survey. However, the hospital labs where there's people, there is many people that could work with the surveyors, and there's always people onsite, it would be much less necessary. And, in fact, some of the accrediting organizations are beginning to do unannounced surveys.

The big issue that we have really has to do with the amount of time that accrediting organizations or different survey organizations are giving in terms of notifying labs ahead of time. CMS's policy, when State survey organizations notify labs, their policy is to give labs 2 weeks' notice. They feel that's the right amount of time

for a lab not to be able to go back and react and change everything or fix everything, but, at the same time, make sure that the proper people are there and that it won't be too disruptive. On the other hand, there are some survey organizations that give up to 12 weeks' notice. We think this is excessive, and we think it's unnecessary.

So if, in fact, it's necessary to give labs some notice, we think a 2-week unannounced—a 2-week notice period in conformance with CMS's guidelines would be much more appropriate.

Mr. CUMMINGS. I'm just going to ask you a few more questions because I know we've got to move on. But I want to just go to the College of American Pathologists and some of the things that they're trying to do. And the more I look at some of the things that they're trying to do, the more I'm convinced that maybe they—first of all, I believe they've apparently seen the light, and the light is shining brightly, and that perhaps it can shed some role modeling, at least so far, for some of the other survey organizations. But I just want to get your comments on some of the things that they're doing and how what they are doing there fits into what you all found and what you all are recommending, OK?

One of the things that they have moved to are these unannounced visit surveys, so I take it that's something that you think is very good?

Ms. ARONOVITZ. Yes. I'm wondering if I could just make a comment before we do.

Mr. CUMMINGS. Please, please.

Ms. ARONOVITZ. We worked extensively with the accrediting organizations, and we are absolutely convinced that they are doing a lot to try to improve the quality of lab testing. We think that each of the accrediting organizations have a lot of strengths and areas of improvement. So while we do applaud CAP for some of the things it's doing, we also note that there are other areas where it really is working to improve and maybe is even as up to speed as some of the other accrediting organizations.

So we're very proud of how all of the organizations are moving forward, but we think all of them have their strengths and weaknesses. I just wanted to say that because I think that we all can learn from each other from that standpoint.

The unannounced surveys we think are very much a definite positive step, and I believe JCAHO is also going toward unannounced surveys.

Mr. CUMMINGS. And I just to want go through a few things——

Mr. SOUDER. Can I ask something? By unannounced, do you mean 2 weeks, or just completely unannounced?

Ms. ARONOVITZ. In some cases completely unannounced, maybe a day or two, or just enough in terms of logistics, but at a maximum we're hoping it will be 2 weeks.

Mr. CUMMINGS. And I'm not just highlighting CAP, it's just that I'm more familiar with what they're doing than other organizations. I'm sure you're going to tell us about them, but we won't hear from you, they're going to come up, and I just want to get your comments, that's all.

Ms. ARONOVITZ. Absolutely.

Mr. CUMMINGS. And if there are things that really impress you about some of the things that they're doing, please let us know.

Ms. ARONOVITZ. OK.

Mr. CUMMINGS. One of the things I know CAP is doing or moving to do is having an organization—the group of pathologists who actually do the examination of the lab present their findings, and then another group, totally independent group, then does the accreditation issue, deals with that. What do you think of that? I mean, is that significant?

Ms. ARONOVITZ. Sure. Any time you have a separate independent group overseeing the work of a different group, you're getting another set of expertise, and we think that's very positive.

Mr. CUMMINGS. OK. And with regard to whistleblowers, the fact that they're having these signs put up in the lab to encourage people to call in to our hotline number, and it sounds like they are maintaining some kind of high level of confidentiality so that we don't have a situation where the whistleblower feels as if they are going to get in trouble with their employers, because that was a big deal at the Maryland General Hospital case. In that case, as a matter of fact, there were two whistleblowers, both of whom—one of whom I had met in my office, and literally she just broke down in tears because she was so fearful. And sadly, a lot of the things that she feared came to be true. So how is—you go ahead.

Ms. ARONOVITZ. No, I'm sorry.

Mr. CUMMINGS. No, you go ahead.

Ms. ARONOVITZ. I think any effort to try to educate lab workers on how to file complaints is very, very positive. CAP, when it started requiring posters to be placed in labs to explain just that, found that it had, instead of about an average of 11 complaints a month, had about 22 complaints per month for the 3 months after it started putting up posters.

Now, JCAHO, in responding to our report, thought that while that might be a good idea for us being so proscriptive, it could limit what other ideas accrediting organizations had to maybe encourage lab workers to report complaints.

We think what CAP did was an excellent effort, and we think that it really paid off. If accrediting organizations have different approaches, as long as the principle of making sure that lab workers feel like they know where to go and also they feel protected, that's really all we care about.

Mr. CUMMINGS. And finally, the collegiality issue. You know, a lot of people were concerned—are concerned that when people are in the same region or they know each other, it's—you know, you scratch my back, I scratch yours. Maybe we were just playing golf last week, and I'm going to run in and take a look at your lab. And I think a lot of what we deal with here is not only the actual validity of a testing process, but even the appearance of the fairness and impartiality of the testing process. And so I understand that CAP is moving toward more of a regional kind of a situation, and I'm just wondering, trying to get it so that we neighbors are not looking at each other's labs.

Ms. ARONOVITZ. Yeah, I think that is an area that we have been talking to CAP about. It pointed out that about 42 percent—and I might have that number wrong, but it's about half of the surveys

that it actually does is someone has to go on an airplane, so there wouldn't be people who were at the next lab.

But the other half really do look at labs that are in the community, if not right next door. We worry a little bit about that. We think that any type of structure you could put in place where there would be not just a perception, but a real sense, of independence is very, very important.

Along that line, we've been talking to CAP about the construction of their—or the structure of their survey teams. Right now they have a volunteer program where lab workers and supervisors in one lab would actually look at a different lab. And the structure of those teams usually include the supervisor and the team that work in a particular lab because they work well together, and they could accomplish a lot together.

The thing we do worry about in that structure is if you're my boss in my real job, and you're telling me that we should downgrade or we should, in fact, not write up a deficiency, and I have a different judgment, and I think it's serious enough to write up, we do have a question. And we don't have any evidence that this has happened, but we do have a strong perception that this could be a real dilemma for a lab surveyor. So we're working with CAP to try to figure out how they could construct their teams, but write their conflict of interests and independent standards so that lab workers feel like they do have a way out or they have a place to go if they don't agree with their supervisor in a particular situation.

Mr. CUMMINGS. A little bit earlier at a press conference we were talking about this, and Mr. Souder and I answered a question with regard to legislation, and this is the reason why I spent so much time on this part. So often it's hard to get the legislation that we want through here on the Hill, but you said something that was very interesting. You said that you were very encouraged and very impressed with the efforts that the agencies have been making. And I've mentioned a few things. Are there other things that you see that you would like to see continue? In other words, there is more than one way to skin a cat sometimes, so we're trying to figure out how do we make sure that we get to the result that we want, because we don't like the way it is right now.

Ms. ARONOVITZ. Right. I should, unfortunately, qualify what I said just a little bit. We've had great discussions with CMS and two exempt—CLIA-exempt States, and also the accrediting organizations, they all do seem to be very anxious to move forward, but that's just the first step. We have 13 recommendations, and that doesn't even include your legislation, which we think is important, and we would like to see how CMS responds to our recommendations.

We have a provision in GAO where we followup on open recommendations, and it's on our Web site, where anyone in the public could see what recommendations—what the agency has done to take action on our recommendations. So while I'm very encouraged in terms of our conversations, there have been quite a few disagreements with some of the things we've said along the way. We're hoping that we'll be able to negotiate or come to terms on some of these. But ultimately it's the actions that CMS takes that

will really tell whether we're going to have improvements in this area.

Mr. CUMMINGS. Do you feel comfortable whether a person in Mr. Souder's district, a rural district, going into a hospital lab today can feel comfortable that they are getting accurate results with regard to tests that might be lifesaving, determine what kind of treatment they get? I mean, do you feel comfortable based upon what you've seen?

Ms. ARONOVITZ. I think that the CLIA amendments have been one of the most important positive approaches to getting us closer to ultimately where we want to be, and I'd rather be getting a lab test now than maybe even 5 years ago. However, until it's airtight, until it will be 100 percent, I would not feel comfortable if it were someone in my family.

So, no, I think we all need to keep working very, very hard to get even better. We're not there yet.

Mr. CUMMINGS. Thank you very much.

Mr. SOUDER. Ms. Watson, do you have any questions?

Ms. WATSON. I really want to thank the Chair for this hearing, and I believe you probably have responded to my query.

I do know mistakes and inaccuracies happen—it's a whole movie I just saw recently starring Queen Latifah that illustrates that; and I think what you're doing is right.

You know, I think all inspections ought to be unannounced. We ought to say the year of 2007 is a year that we might happen into your laboratory, because as I read the summary of what happened at the Maryland General Hospital, most everybody involved was fired. So we don't know if the problem rests with the personnel, we don't know if it's cronyism, we don't really know. So I would think that you would want to pick a period of time and see if you can get to the factors and offer dissenting reports so we can pin down what happens in these laboratories. Are the pathologists moonlighting? Are they doing other things, they're not really focusing? And what is the background experience of the lab technicians and so on?

I think this is a serious problem. It affects all humanity, particularly here in this country, and I think that maybe you want to do a study in a given year to find out where the problems really are. That's a comment, and you can respond.

Ms. ARONOVITZ. Yeah, I think that's a really important comment. And I think you hit on some of the very essence of what a survey really involves. It really looks at the quality of the personnel, and the qualifications of the personnel, and the quality assurance system, and the quality control systems that are in labs, and how a lab monitors itself, and how it makes sure that it fixes some of the problems that are identified.

Right now I think that the structure, the framework, exists for us to go into a lab—not us personally, but accrediting organizations and other survey organizations—to go into a lab and identify problems. It's what happens when those data are then communicated or not communicated in the aggregate to other oversight organizations where things could break down.

Mr. WATSON. Let me just probe that a bit. Let me just probe that a bit. After you go in, and you get—and you do a report, is there

another step that could be taken, you know, it's like getting multiple opinions. Is there another step that could be taken to be assured of the accuracy?

Ms. ARONOVITZ. When lab surveys are finished, the survey organizations do discuss and make sure that they were done properly, but in addition to that CMS has a very important tool. It's called a validation survey, and the validation survey really goes in behind the survey organization to make sure that those surveyors did a good job and reported all condition level deficiencies. Now, we do have some concerns about the way validation surveys happen because we think too many of them happen simultaneously instead of independently. But the validation survey I think is the quality step that you are referring to.

Ms. WATSON. Thank you so much, and I yield back the rest of my time.

Mr. SOUDER. I wanted to ask you briefly a clarification question. My impression is that, how the labs—who owns the labs and how they're managed is not uniform. Could you kind of just give me a brief snapshot, are most of these labs owned by a private entity, are they owned by the hospital? Are they owned by a group of doctors? And I have a followup question to that.

Ms. ARONOVITZ. I don't know exactly what the breakdown is. I do know that there are hospital labs that do millions of tests a year and then there are also on the other end labs that get CLIA certificates that are physician labs that also do 2,000 tests in a year that would be owned by the physicians themselves. We could get you a breakdown, which would be much more appropriate than for me to try to estimate.

Mr. SOUDER. I'd appreciate at least some kind of a rough—because in any kind of review strategy, if the primary reviewer isn't going to be a uniform—single, uniform organization, and I myself would like to see how to make a flexible system work, but one thing in limiting conflict of interest is it's important to know who the ownership groups are. In other words, part of this, if you're not going to say, you have to be so far away to be a reviewer, that you have to get on an airplane, I think that was one standard that you put forth that 40 percent had to fly in or something in that order, 40 percent didn't, would be to say that certainly you don't want a doctor who's a partner, who may have another lab at another unit be the reviewer. You don't want a hospital who has a hospital system be a reviewer of their own hospital system and that would be a start, would it not, for some sort of conflict of interest? Does that exist currently?

Ms. ARONOVITZ. I'm not sure. I don't know, and I think we could find out for you and supply you with a breakdown and more of a rationale.

Mr. SOUDER. Because nobody who I would think at minimum reviewers, nobody that has a financial stake that overlaps with the person they're reviewing should be doing the reviewing.

Ms. ARONOVITZ. I know that each survey organization does have certain conflict of interest requirements and standards, but to the extent that they would cover or be sufficient, we would have some questions.

Mr. SOUDER. Thank you.

Mr. CUMMINGS. I have just one question. You know, I'm just curious, you made throughout your testimony, you have talked about how you interacted with all—interacted with the various agencies and whatever. And I'm just wondering, have you seen—is there—can you see a difference that has been made as a result of the Maryland General case? Are you following what I'm saying?

Ms. ARONOVITZ. Yes.

Mr. CUMMINGS. In your discussions with folks, in this case, is this a major incident that happened? And if so, if it's a major incident, how has it affected, from what you could see, other labs and enforcement of the CLIA policies or what have you?

Ms. ARONOVITZ. Yeah. I think we believe that the Maryland General situation did have a traumatic effect on making labs and survey organizations understand again how important it was to do the kinds of things we're talking about today and to assure lab quality. Given that, though, I personally was surprised at how much still needs to go to happen, that we found some of the things we did that the communication lines aren't as strong as they should be, that the sanctions aren't used as much as they could be, that proficiency testing failures occur without a whole—often without a lot of sanctions or followup occurring. We were surprised that CMS still doesn't have a way to understand across survey organizations the extent to which condition-level deficiencies occur in the aggregate. We think it's so important because then you could look at trend data and you could look and you could answer the question that you're asking, not what kind of impression I have, but with real hard data, and that's where we think we need to be, and we're surprised that we're not there.

Mr. CUMMINGS. Do you believe from what you have seen that Maryland General is an aberration?

Ms. ARONOVITZ. I can't answer that. I don't know, but I do know that it's important that labs have the potential for having problems if they're not well overseen, and we think that there are still gaps in the oversight process. So we worry about the potential. We don't know whether there's a lab out there right now that's on the verge.

Mr. CUMMINGS. Right. Thank you. Thank you very much.

Mr. SOUDER. I thank you for your testimony and appreciate your report, and we'll be looking forward to additional followups.

Ms. ARONOVITZ. Thanks very much.

Mr. SOUDER. Our next panel is Mr. Thomas Hamilton. If you will come forward and remain standing, I will give you the oath. Mr. Hamilton is the Director of Survey & Certification Group, the Centers for Medicare and Medicaid Services, U.S. Department of Health and Human Services. Raise your right hand.

[Witness sworn.]

Mr. SOUDER. Thank you. Let the record show that the witness responded positively. I thank you for coming today and we look forward to your testimony.

STATEMENT OF THOMAS HAMILTON, DIRECTOR, SURVEY & CERTIFICATION GROUP, CENTERS FOR MEDICARE AND MEDICAID SERVICES, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Mr. HAMILTON. Thank you. Chairman Souder, Representative Cummings, Representative Watson, distinguished members of the subcommittee who may appear yet, thank you for the opportunity to discuss CMS's efforts to assure quality testing in all laboratories in the United States as required under the clinical laboratory improvement amendments. Thank you.

CLIA established nationally uniform quality standards for all clinical laboratory testing to ensure the accuracy, reliability and timeliness of patient test results regardless of the setting in which the test was performed. Under CLIA, three categories of laboratory tests have been established, waived tests, tests of moderate complexity, including the subcategory of provider-performed microscopy, and tests of high complexity. CLIA specified detailed quality standards for the latter two categories.

For laboratories that perform moderate or high-complexity tests, those laboratories must be surveyed biannually to maintain certification. They may choose whether they wish to be surveyed by CMS or by a private CMS-approved accrediting organization. Laboratories that conduct only waived tests are subject to surveys if a complaint is alleged.

The CMS survey process focuses on outcomes. That is, we focus on the test results in the actual or the potential harm that may be caused to patients due to inaccurate testing. Education and enforcement are both used and both are important. An educational approach permits a surveyor to provide resources and an explanation of the applicable requirements to the laboratory. This facilitates the laboratory's ability to correct deficiencies prior to the imposition of enforcement actions.

However, if the laboratory cannot or will not correct the problems within a reasonable and specified amount of time, sanctions are imposed that are commensurate with the history, seriousness, and pervasiveness of the deficiencies.

Fulfillment and enforcement of CLIA standards is CMS's primary focus. When CMS finds problems during a survey, the lab is generally provided an opportunity to correct those problems prior to enforcement actions unless there is actual or potential harm to patient safety or there are recurring deficiencies. Over the past 5 years CMS has initiated enforcement action in more than 5,000 cases. These proposed sanctions carry a clear communication, problems must be fixed promptly and effectively. I am pleased to say that in approximately less than 10 percent of the time have we needed to implement the sanctions because of laboratory failure to take effective and timely remedial action.

In a moment I will discuss the challenges that we face, and Ms. Aronovitz did an excellent job describing the findings of the GAO and some of those challenges. But first I wish to emphasize that the Clinical Laboratory Improvement Amendment enacted by Congress and faithfully implemented by CMS has substantially improved the reliability and accuracy of laboratory testing in this country. The first onsite surveys of laboratories conducted right

after CLIA implementation in 1992, for example, revealed that up to 35 percent of laboratories had significant quality control and quality assurance problems. Currently less than 7 percent of the laboratories surveyed by CMS each year evidence such quality control problems. More recently, the percentage of laboratories that meet our proficiency testing standard has increased from about 88 percent in 1998 to about 93 percent in 2003.

CMS continues to improve our survey and certification system. For example, in 2003 we strengthened quality control standards through new regulations. In 2004, we established performance standards for State organizations. Also in 2004, we initiated national meetings with all accrediting organizations to strengthen the national system and enter into better information sharing agreements, as Representative Cummings has so eloquently described is needed.

In 2005, we implemented national annual cytology proficiency testing for all people who examine pap smears. For the first time, more than 12,000 people took individual exams to test and demonstrate their ability to make accurate readings of pap smears.

In 2006, we implemented a national electronic tracking system for all complaints and all complaint investigations received by CMS and State survey agencies. These advances, however, do not mean that further improvements are not possible or desired. They are. To such an end, we appreciate the subcommittee action to make resources of the Government Accountability Office available to study what we are doing and make a number of very useful recommendations.

The GAO made 13 recommendations. We committed ourselves to 21 action steps in response to those 13 recommendations from GAO, and we are putting in place the plans necessary to do even more. For example, the GAO recommended that CMS standardize criteria used by accrediting organizations. Recognizing that the law permits accrediting organizations to have standards that are different than CMS's standards so long as they are equivalent, we will improve the crosswalks of our different standards to make them more comparable. But in addition, we will work with the accrediting organizations to create a taxonomy of deficiency findings to promote consistent enforcement of standards on the back end.

We've also convened a work group of accrediting organizations and CMS representatives to develop data-driven performance indicators similar to those used to monitor State survey agencies' performance, as Ms. Aronovitz described. These performance measures will complement the validation surveys that we now conduct to check on the accuracy of accrediting organization surveys. The GAO also recommended that we ensure that lab workers know how to submit a complaint to the proper entity. We will do so. Complaints from lab workers represent an important source of information about potential problems. We are working with surveying entities to increase awareness of the ways of lab workers and others may submit complaints, including how to get their complaints to the right place confidentially.

In addition, in March 2006 we implemented a new, more sophisticated data system to receive and track such complaints. This tracking system will enable all surveying entities eventually to sub-

mit access information that is collected on any lab. The GAO also recommended that CMS establish an enforcement data base to monitor actions taken by State survey agencies. We will definitely do so. We have developed such a data base for nursing homes and other providers, and it has been extremely useful. I have directed that the timetable for inclusion of clinical laboratories in this data base and electronic system be moved up as soon as possible.

In conclusion, we in CMS are dedicated to ensuring the accuracy of test results from our Nation's laboratories. I thank the subcommittee for your interest in improving clinical laboratory testing in the United States. There is no substitute for objective, trained personnel examining the quality of health care. That is the purpose of CMS's survey and certification system, and that is the function served by GAO in examining CMS's oversight.

We are putting the results of the GAO study to good and prompt use, and I thank you for directing their energies toward our common purpose of improving the quality of health care in the United States. I look forward to answering any questions you may have about our efforts.

[The prepared statement of Mr. Hamilton follows:]

TESTIMONY OF

THOMAS HAMILTON
DIRECTOR
SURVEY & CERTIFICATION GROUP
CENTER FOR MEDICAID AND STATE OPERATIONS
CENTERS FOR MEDICARE & MEDICAID SERVICES

ON
CLINICAL LABORATORY QUALITY

BEFORE THE
SUBCOMMITTEE ON CRIMINAL JUSTICE, DRUG POLICY,
AND HUMAN RESOURCES
OF THE
HOUSE COMMITTEE ON GOVERNMENT REFORM

June 27, 2006

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

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June 27, 2006

Chairman Souder, Representative Cummings, distinguished members of the Committee: I thank you for your invitation to appear here this morning to discuss efforts to ensure quality testing results in all laboratories in the United States. The Centers for Medicare & Medicaid Services (CMS) works with a number of different entities, including state government agencies, professional associations and independent survey groups, to ensure that entities receiving Medicare payments comply with established conditions of participation for their provider type and that all laboratories in the U.S. meet Clinical Laboratory Improvement Amendments (CLIA) standards. This morning I would like to first discuss CMS' general efforts at ensuring laboratory quality and then the specifics of the GAO Report: "Clinical Lab Quality: CMS and Survey Organization Oversight Should Be Strengthened."

CLIA Background

In 1988, Congressional hearings concerning deaths of women from erroneously read Pap smears, and the proliferation of bench top laboratory technology into non-traditional testing sites, led to passage of CLIA. CLIA established nationally uniform quality standards for all clinical laboratory testing to ensure the accuracy, reliability and timeliness of patient test results regardless of the setting in which the test was performed. A laboratory subject to CLIA is defined as any facility that performs laboratory testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention, or treatment of a disease or

impairment, or to assess the patient's health. CLIA is user fee funded; therefore, all costs of administering the program must be covered by the regulated facilities, including certificate and survey costs.

Final CLIA regulations were published on February 28, 1992 and are based (as required by statute) on the complexity of the test method; thus, the more complicated the test, the more stringent the compliance and oversight requirements. Three categories of tests have been established: waived; moderate complexity, including the subcategory of provider-performed microscopy (PPM); and high complexity. CLIA specifies detailed quality standards for the latter two categories. Laboratories performing only waived tests must enroll in CLIA, pay the applicable fee and follow manufacturers' testing instructions.

CMS is charged with the implementation of CLIA, including laboratory registration, fee collection, surveys, surveyor guidelines and training, enforcement, and approving entities that test laboratory proficiency, accrediting organizations and exempt states with appropriate requirements. The Centers for Disease Control and Prevention (CDC) is responsible for CLIA research studies, convening the Clinical Laboratory Improvement Advisory Committee (CLIAC) and providing scientific and technical support/consultation to DHHS/CMS. The Food and Drug Administration (FDA) is responsible for test categorization.

Laboratory Enrollment and Performance Standards

To enroll in the CLIA program, laboratories must register by completing an application, pay fees, be surveyed, if applicable, and receive a CLIA certificate. CLIA fees are based on the certificate requested by the laboratory (that is, waived, provider performed microscopy (PPM), accreditation, or compliance) and, for moderate and high complexity laboratories, the annual volume and types of testing performed. Waived and PPM laboratories may apply directly for their certificate as they aren't subject to routine inspections, unless there is a complaint. Laboratories that must be surveyed routinely (i.e., those performing moderate and/or high complexity testing) may choose whether they wish to be surveyed by CMS or by a private accrediting organization. The biennial CMS survey process is outcome (test result) oriented and

utilizes a quality assurance focus to assess compliance. An educational approach is employed in which the surveyor may provide resources and an explanation of the requirements to the laboratory that allow the laboratory to correct deficiencies prior to imposition of enforcement actions. However, if the laboratory cannot correct the problem(s) within a reasonable amount of time, sanctions are imposed that are commensurate with the history, seriousness and pervasiveness of the deficiencies.

Labs subject to routine biennial surveys must comply with a number of CLIA requirements, including:

- Personnel: CLIA sets minimum qualifications, experience and training requirements for all persons performing or supervising moderate or high complexity lab tests. These individuals must also meet specific responsibilities that correspond to all of the CLIA quality standards.
- Proficiency testing: Many labs must also participate in an approved proficiency testing program that provides an external evaluation of the accuracy of the lab's test results. Under this requirement, three times per year, labs purchase samples from an external source (the proficiency testing provider), whose characteristics are not disclosed to the lab. The lab tests the samples along with their routine patient testing and the results are returned to the testing provider to be graded. If the lab passes, they have met the CLIA standard. The results of proficiency testing for all labs in CLIA are transmitted to CMS and are routinely monitored and maintained in a database. If a laboratory repeatedly fails proficiency testing during successive testing challenges, then action is taken to limit the laboratory's ability to continue performing the test(s). Proficiency testing providers are private companies, or state lab departments, that must meet certain CLIA requirements to provide testing samples to labs, and are approved by CMS annually.
- Quality control: Labs must have a process for monitoring personnel, testing equipment and the lab's environment to ensure proper operation and accurate results each day.
- Quality assessment: Labs must have and follow a plan to monitor, on an ongoing basis, the overall operation of the laboratory, provide communications, and resolve problems that affect the quality of their testing.

- Cytology testing: CLIA sets special rules for cytology testing including workload limits, individualized proficiency testing, personnel standards, and quality control.
- The lab must maintain a recordkeeping system for the entire testing process.

Data show that these regulations are helping to improve testing quality. Since CLIA was implemented in 1992, quality deficiencies cited against clinical labs have decreased significantly. The first onsite surveys of labs revealed that up to 35 percent of labs had quality issues. Currently less than 7 percent of 11,000 labs surveyed by CMS in a year have quality problems. We believe that our educational rather than punitive approach has facilitated improvement in lab quality. Data from our Survey Evaluation Form show that most laboratories respond very positively to the educational, information-sharing approach to oversight and correct their problems prior to imposition of enforcement actions. The quality assurance approach encourages labs to develop a plan to monitor their entire operation to identify and resolve their quality-related problems on an ongoing basis. Survey data and proficiency testing data reflect improvement in lab performance over time, thus demonstrating labs' accountability in knowing the regulatory requirements and preventing and correcting identified issues. When CMS finds problems during the survey, the lab is generally provided an opportunity to correct these problems prior to enforcement actions, unless there is actual or potential harm to patient safety or there are recurring deficiencies. Over the past five years, CMS has proposed enforcement action in 5,361 cases, and carried out such action in 395 instances.

Oversight and Surveys

CMS contracts with State Departments of Health to perform lab surveys. CMS' objective in developing an outcome oriented survey process is primarily to determine the laboratory's regulatory compliance, but also to assist laboratories in improving patient care by emphasizing those aspects that have a direct impact on the laboratory's overall test performance. CMS promotes the use of an educational survey process. The surveyor determines, based on observation of the laboratory's (past and current) practices, interviews with the laboratory's personnel and review of the laboratory's relevant documented records, whether the laboratory is meeting the requirements of the CLIA regulations to produce accurate, reliable and timely (quality) test results. The surveyor meets the objectives by employing an outcome-

oriented/quality improvement type of survey process or approach, the intent of which is to focus the surveyor on the overall performance of the laboratory regarding the applicable standards and the way it monitors itself, rather than on a methodical evaluation of every standard level regulatory requirement.

The quality assessment (QA) requirements of the laboratory regulations (42 CFR Part 493, Subpart K) are the appropriate guide that surveyors use for organizing their review. The surveyors select a cross-section of information, tour the facility and observe testing, and review quality records and all aspects of the laboratory's operation to assess its capability to produce quality results as well as its ability to identify and correct problems and communicate with its clients. Emphasis is placed on overall laboratory performance and the structures and processes contributing to the reliability of the testing. Since it would be impossible to review every test and every document in the laboratory, the surveyor reviews the selected cross-section of information to see if the laboratory has established and implemented appropriate mechanisms for monitoring and evaluating its practices and solving its problems. The surveyors investigate further any test areas identified as a problem but not addressed by the laboratory's QA program, ensure permanent resolution of previous deficiencies and review any new tests and personnel since the last visit. If the laboratory is failing to monitor (or effectively monitor) its own systems, the surveyor may direct the laboratory to the requirements and the relevant regulatory sections for its particular setting, thereby accomplishing the educational aspect of the survey process.

If, however, problems identified during the survey, or as the result of a complaint, are not remedied in a reasonable amount of time, CMS has authority to impose sanctions against the lab from an array of available actions. These may range from onsite monitoring, fines, or loss of Medicare reimbursement, to revocation of their CLIA certificate, depending on the seriousness and pervasiveness of the problem. Most laboratories correct their problems as a result of the education they receive following the survey, prior to having sanctions imposed. Only about one percent of laboratories surveyed each year have had enforcement actions taken against them. The names of these labs and the laboratory director are compiled annually and this list is placed on the CLIA web site at: www.cms.hhs.gov/clia. The 2005 registry lists 240 entities. The

percentages of each laboratory type experiencing enforcement actions are proportional to the total number of labs of that type enrolled in the CLIA program.

As mentioned previously, labs that are subject to biennial surveys can choose to obtain CLIA certification by the State agency, as an agent of CMS, or by an approved private accreditation organization. Accrediting organizations with standards that are equivalent to, or more stringent than CLIA, currently approved by HHS for this purpose include:

- the Joint Commission on Accreditation of Healthcare Organizations (JCAHO);
- the College of American Pathologists (CAP),
- COLA (formerly Commission on Office Laboratory Accreditation);
- the American Association of Blood Banks (AABB);
- the American Society for Histocompatibility and Immunogenetics (ASHI); and
- the American Osteopathic Association (AOA).

States that have lab licensure program standards equivalent to, or stricter than those of CLIA can apply for "approval" or "exemption." Then the labs in those states that meet state licensure requirements are deemed to be in compliance with CLIA. There are currently only two exempt states – New York and Washington. In other states that have a state laboratory licensure program, laboratories within the state must comply with both CLIA and their state requirements.

On an annual basis, CMS, through the state agencies, surveys approximately 2.5 percent of accredited and exempt laboratories using CLIA standards to validate that these laboratories are in compliance with CLIA by meeting the accrediting organization's standards and to ensure that the organization is enforcing its own equivalent standards. After surveying the accrediting organization's laboratories, CMS compares the results of the state survey to the accrediting organization's, to determine the level of disparity. The rate of disparity is the percentage of all sample validation surveys for which a State survey agency finds non-compliance with one or more CLIA conditions and no comparable condition level deficiency was cited by the accreditation organization. As set forth in regulation at 42 CFR 493 Subpart E, an accreditation program with a disparity rate of 20 percent or more is subject to a review to determine if that

organization has adopted and maintains requirements comparable to those of CMS. No accrediting organization has even approached the maximum threshold of 20 percent disparity.

Complaints alleged against accredited laboratories from any source are either addressed by the accrediting organization or by the State agency in conjunction with the CMS Regional Office. CMS has recently implemented an automated complaint tracking system to capture all complaints to ensure timely and complete follow up and investigation. Ultimately the approved accrediting organizations and exempt States will enter their complaint data into this system to provide national data for CMS to monitor for program effectiveness.

CMS Responds to GAO Draft Report

As you are aware, this Subcommittee requested that the GAO assess the effectiveness of CMS' oversight of clinical laboratories, and our enforcement of CLIA. We have been given an opportunity to examine and comment on a draft of that report and I would like to take some time to respond to each of the recommendations the GAO made in that document.

GAO Recommendation #1: *Work with exempt state-programs and accrediting organizations to standardize their categorization and reporting of survey findings in a way that tracks to CLIA inspection requirements and allows for meaningful comparisons across organizations, such as the analysis of trends in the citation of condition-level deficiencies.*

CMS Response: We endorse this concept but will be cautious as to its scope. In our experience, a straightforward linkage of accrediting organization requirements to CLIA condition-level requirements is limited by our authority under the statute, and still may not make it fully possible to assess labs in a standardized manner.

First, the law permits each accrediting organization to have different requirements compared to CMS, so long as their requirements are at least equivalent to CMS requirements.

Second, accrediting organization requirements may exceed CMS requirements (so their standard may not have a CMS equivalent).

Third, standardization of requirements does not automatically provide a total picture of the adequacy of an accrediting organization's survey and will not reduce the need for CMS to analyze in-depth those accrediting organization surveys that are subject to validation review[1].

Fourth, after multiple review cycles, CMS has verified that the accrediting organization's published standards are at least equivalent to, if not more stringent than the CLIA regulations. We believe the more important issue in accrediting organization oversight is the accrediting organization's *enforcement* of their standards. Demonstrating that an accrediting organization is enforcing its standards through comprehensive policies, procedures and internal monitoring processes is vital to the effectiveness of a program. An accrediting organization can have the highest standards, but if not enforced appropriately, these standards hold little value in ensuring laboratory quality. Toward that end, CMS has re-focused its approval and oversight of accrediting organizations to concentrate on outcomes. This re-focusing is not only a more efficient use of CMS resources, but also a more effective approach overall in overseeing accrediting organizations.

To supplement the validations and other information about accrediting organizations, CMS, through the Partners for Laboratory Oversight process, has convened a workgroup of accrediting

[1] For example, we might equate an accrediting organization's requirement for proficiency testing enrollment with CMS' CLIA condition-level requirement for proficiency testing enrollment. Beneath the surface, however, we must be aware that proficiency testing enrollment applies to the laboratory's enrollment in proficiency testing for a great many potential analytes. If an accrediting organization-to-CLIA linkage is based only on lack of enrollment in testing, regardless of how many analytes were omitted, the assessment of quality would be woefully incomplete. Such an incomplete picture of quality would represent an inadequate assessment of quality since it would not capture all the serious deficiencies that have occurred. In our CLIA validation review of accreditation organizations, a CMS team manually reviews and compares the entire narrative findings of the CLIA validation inspections to those of the accrediting organization inspections. The entire narratives are compared and not limited to whether or not the accrediting organization found a deficiency in proficiency testing enrollment. Otherwise, the picture would be incomplete and our review would be inadequate. We need to know more about the analytes involved. If the CLIA validation inspection found that the laboratory failed to enroll in proficiency testing for 2 analytes, e.g., prothrombin time and glucose, but the accrediting organization inspection found that the laboratory failed to enroll in proficiency testing for only 1 of those 2 analytes, prothrombin time, the review identifies an inadequacy on the part of the accrediting organization —the accrediting organization inspection has failed to identify a serious flaw in the laboratory's practices that can negatively impact the quality of the laboratory's testing and the outcome can be death. In a worst case scenario, the laboratory's lack of enrollment in proficiency testing for the analyte glucose can result in inaccurate and unreliable testing results, which could affect the health status of a diabetic patient. The flawed testing results could directly result in patient fatality from diabetic shock. If the laboratory performs thousands of tests each year under those circumstances, thousands of patients are at risk.

organizations and CMS representatives to develop data-driven performance indicators similar to the State Agency Performance Review (SAPR) program that CMS utilizes to monitor State agency performance of CLIA responsibilities and adherence to policies. The accrediting organization indicators would monitor routinely, for example, whether biennial surveys were conducted timely, and whether laboratories that failed proficiency testing or incurred serious deficiencies corrected their problems promptly or had sanctions imposed. The Partners for Laboratory Oversight effort engages an exceptional collection of expertise and experience in laboratory oversight. By organizing the "best of the best" in a collaborative endeavor involving all accrediting organizations, we hope that accrediting organizations will make further improvements as well as advance the state of the art for laboratory quality.

CMS Action:

1(a) Categorization of Findings: CMS will work with exempt state-programs and accrediting organizations to promote greater standardization of categorizing and reporting survey findings in a way that enables improved tracking to CLIA inspection requirements and allows for more meaningful comparisons across organizations, such as the analysis of trends in the citation of condition-level deficiencies.

GAO Recommendation #2: *Ensure that the advance notice of upcoming surveys provided to physician office labs is consistent with CMS' policy for advance notice provided by state survey agencies.*

CMS Response: We agree. CMS will require any accrediting organization using announced surveys to reduce its lead time to be consistent with CMS policy governing actions of State survey agencies.

CMS Action:

2(a) Advance Notice in Small Labs: CMS will ensure that the advance notice of upcoming surveys provided to physician office labs is consistent with CMS' policy for advance notice provided by State survey agencies.

2(b) Consistency: CMS will work with accrediting organizations and State survey agencies to promote unannounced surveys in larger labs and achieve greater consistency among all oversight organizations.

GAO Recommendation #3*: Ensure that regulation of labs is the primary goal of survey organizations and that education to improve lab quality does not preclude the identification and reporting of deficiencies that affect lab testing quality.*

CMS Response: We agree that education to improve lab quality should never preclude the identification of deficiencies that affect lab testing quality, and that regulation of labs is the primary goal of survey organizations. In the case of significant new requirements, and only within certain areas for the time period specified by CMS, the educational approach may include the possibility of identified deficiencies being communicated to laboratories without a concomitant citation. Currently, such allowance primarily applies to two situations:

- Quality control requirements that were new in the 2003 regulation for labs conducting moderate complexity testing;
- Cytology proficiency testing that was newly implemented on a national basis in 2005.

For the reasons explained previously, we do not anticipate a change in this policy.

CMS Action:

3(a) Consistency Action Plan: CMS will ensure that a CMS Consistency Workgroup comprised of Regional Office and Central Office CLIA staff formulates an action plan to increase consistency.

3(b) Guidance: CMS will develop protocols or refinements to surveyor guidance to ensure an appropriate balance between the enforcement and educational functions of the survey process.

3(c) Training: CMS will provide additional training for surveyors and management on the differences between the "educational approach" and the "outcome oriented survey process", including concentrated training on which survey findings require citation without any variation.

3(d) Performance & Consistency Review: CMS will ensure Central and Regional Office data review of key identified data sets, on a periodic basis, to determine if observed variations are truly significant and to identify any significant trends. This increased communication between Central Office, Regional Offices, & State agencies as they work to explain and understand the variations will lead to decreased variability and enhanced consistency over time.

GAO Recommendation #4: *Impose appropriate sanctions on labs with consecutive condition-level deficiencies in the same requirements.*

CMS Response: This recommendation is already CMS policy; the issue is our approach to implementation of the policy. CMS' policy of progressive enforcement involves the imposition of sanctions for laboratories failing to correct deficiencies that impact on the quality of laboratory testing, increasing in severity in the event of continuing failures. By looking only at the category of failure (the "conditions"), however, it is not possible to determine whether a laboratory has consecutively failed in the same requirement.

For example, the laboratory could fail in proficiency testing in one year for neonatal testing, and fail in proficiency testing in a completely different division of the laboratory the next year (e.g., virology). In regard to laboratories with consecutive condition-level deficiencies, the data presented by GAO would not permit us to assess whether there is a serious problem because the underlying failures could have been different in the two consecutive surveys for those

laboratories that the GAO included in its report. Nonetheless, we agree that the issue is important and that labs that consistently fail to assure quality must be subject to consistently stronger remedial action.

CMS Action:

4(a) Monitoring & Data Analysis: CMS will carefully monitor citations of repeat deficiencies as part of the overall redesign of the CMS information system (converting from the Online Survey and Certification Reporting System (OSCAR) database to the ASPEN information system).

4(b) Follow-up System: CMS will review the data with State survey agencies and accrediting organizations for the purpose of ensuring that the laboratories with true repeat deficiencies have accelerated and progressive enforcement actions imposed, if the deficiencies are not corrected expeditiously and effectively[2].

GAO Recommendation #5*: Require all survey organizations to develop, and require labs to prominently display, posters instructing laboratory workers on how to file anonymous complaints*[3].

CMS Response: Complaints from clients or laboratory workers can be an extremely important vehicle for identifying problems. For that reason, CMS follows up on all complaints. Information about filing complaints has already been included in the updated Surveyor and

[2] CMS provides laboratories with an opportunity to correct its problems prior to the imposition of sanctions. If the problem represents a threat to patient health and safety, then the time frame for correction is either very short or the laboratory is required to cease testing. Most laboratories find the threat of sanctions to be an enormous incentive and quickly correct their problems. The desired outcome in CLIA is regulatory compliance, high quality, and prompt and effective remedy of problems. For CMS certified laboratories, 396 laboratories received a notice of a proposed sanction and of those, 93 failed to take prompt corrective action and had sanctions imposed in 2005. The 2005 Laboratory Registry contains 236 laboratories listed for all oversight entities as having sanctions imposed. The number of cases in which sanctions were threatened is approximately four times the sanction level, indicating that in the vast preponderance of cases the laboratories responded quickly to the potential for sanctions. CMS also assessed $4.4 million in civil monetary penalties.

[3] CMS data consistently indicate approximately 200 complaints alleged per year. This relatively low number may alternatively suggest either that quality is good, or that clients and workers do not know the avenues by which to lodge a complaint.

Laboratory Interpretive Guideline document and most States already have a Hotline for the receipt of complaints.

In March 2006, CMS also implemented a new, more sophisticated data system to receive and track complaints. The system will significantly facilitate State agency documentation and follow-up of complaints to their conclusion.

CMS Action:

5(a) Filing Complaints: CMS will take action to promote greater awareness of the opportunity and methods to file a complaint with CMS, State survey agencies, and accrediting organizations regarding the quality of laboratory services. Such actions may include:

- Providing a complaint filing "fact sheet" and model complaint poster on our website;
- Issuing a CLIA brochure regarding complaint filing;
- Encouraging State agencies and partners to publicize the complaint process through their websites and publications; and
- Working with the laboratory industry to use publications to highlight the importance of complaint filing by laboratory workers to promote laboratory excellence.
- Consideration of requirements for all laboratories to display posters instructing laboratory workers on how to file anonymous complaints.

5(b) Complaint Information Sharing: CMS will work with accrediting organizations and States to increase the sharing of information regarding complaints and complaint investigations.

5(c) Complaint Tracking and Response: CMS will seek to augment its complaint tracking system to build in the capability for accrediting organizations to transmit their complaint data to that system, thereby enabling a national complaint information database

(or repository) for the first time. Along with CMS' monitoring its own follow-ups of complaints, such a system would assist the accrediting organizations to follow up timely on complaints they receive.

GAO Recommendation #6: *Consistent with CLIA, require quarterly proficiency testing, except when technical and scientific considerations suggest that less frequent testing is appropriate for particular examinations or procedures.*

CMS Response: CMS already made this determination. While the public explanation emphasized limiting the burden on laboratories, CMS, in conjunction with the Centers for Disease Control and Prevention, concluded on both technical and scientific grounds that proficiency testing three times per year was appropriate.

GAO Recommendation #7: *Ensure that evaluations of exempt State and accrediting organization inspection requirements take place prior to expiration of the period for which they are approved in order to ensure the continued equivalency of their requirements with CLIA.*

CMS Response: We recognize the need to complete timely reviews. However, we must manage the work within available resources and assessment of priorities. Initially, we deemed accreditation organizations and exempt States for periods of less than 6 years. This allowed us to perform multiple assessments to evaluate their programs and assure their standards were consistently equivalent to those of CLIA. Over the years we have found that the accrediting organizations have been consistent in regard to equivalency of standards. To ensure continued equivalency or more stringent requirements than those of CLIA, we are refocusing our approval process and oversight on evaluating how exempt States and accrediting organizations are enforcing their standards and assessing patient testing outcomes through the validation survey process. We are managing the risk appropriately. For accrediting organizations, we are developing performance measures through our partners, and are using the validation process to monitor the outcomes of their survey processes, as well as CLIA compliance. The CMS-convened Partners' for Laboratory Oversight group has already raised the bar by collaborating to

facilitate increased effectiveness, knowledge and consistency for all participating entities, with the aim of improving their application and assessment of compliance for CLIA purposes.

CMS Action:

7(a) Timely Review of Accrediting Organization Standards: CMS will ensure, within available resources and priorities, that evaluation of exempt State and accrediting organization inspection requirements takes place prior to expiration of the period for which they are approved in order to ensure the continued equivalency of their requirements with CLIA.

GAO Recommendation #8: *Ensure that changes to the inspection requirements of exempt states and accrediting organizations are reviewed prior to implementation, as required by regulation, to ensure that individual changes do not affect the overall CLIA equivalency of each organization.*

CMS Response: It is correct that the accreditation organization must submit changes to CMS 30 days prior to their implementation [42 CFR 493.557(a)(13)]. However, the regulatory language does not specify a time period for the review of this information by CMS. Additionally, State exemption has no similar requirement. Since accreditation organizations' requirements may be more stringent than CLIA, changes to requirements do not necessarily impact CLIA equivalency determinations.

The approval of accrediting organizations is only one portion of CMS' oversight responsibilities. While we appreciate the value of timely review, we reserve the right to manage the work within available resources and assessment of priorities. Due to the potential for concerns about accrediting organization performance (versus equivalency of standards), CMS increased the percentage of validation surveys performed per year from an initial 1% to the current level of 2.5%. CMS also receives anecdotal information regarding accrediting organization performance from State agencies and specific concerns through the complaint process.

CMS Action:

8(a) Timely Review of Accrediting Organization Changes: CMS will, with available resources and priorities, ensure that changes to the inspection requirements of exempt states and accrediting organizations are reviewed prior to implementation, as required by regulation, to ensure that individual changes do not affect the overall CLIA equivalency of each organization.

GAO Recommendation #9: *Allow the CLIA program to utilize revenues generated by the program to hire sufficient staff to fulfill its statutory responsibilities.*

CMS Response: CMS is fulfilling its statutory responsibilities.

CMS Action:

9(a) CLIA Staffing: CMS continues to consider adjustments to CLIA staffing in CMS Central and Regional Offices to meet statutory requirements and priorities.

GAO Recommendation #10: *Ensure that Federal surveyors validate a sufficient number of inspections conducted by each State survey agency to allow a reasonable estimate of their performance, including a minimum of one independent validation review for each State survey agency surveyor.*

CMS Response:

In its recommendation to perform a sufficient number of surveys "to allow a reasonable estimate of their performance," GAO quotes the CLIA statute (at section 353(e)(2)(D) of the Public Health Service Act), which pertains only to the evaluation of approved laboratory accreditation organizations, not the State agencies. There is no statutory requirement regarding the number of surveys to be performed in each State to assess surveyor competency. Nevertheless, we agree that oversight of State agency and surveyor competency is important and that Federal surveyors

should conduct a sufficient number of Federal Monitoring Surveys to allow for a reasonable estimate of State agency performance. In CY 2004, CMS instituted the CLIA State Agency Performance Review, a more comprehensive State agency oversight mechanism. The CLIA State Agency Performance Review includes indicators that measure the mechanisms for improvement in response to findings of our Federal Monitoring Surveys concerning individual surveyor competency assessments.

Types of Federal Monitoring Surveys include:

> **Comparative.** The Regional Office surveyor(s) survey the laboratory after the State agency surveyor(s). This type of survey (called a "Look-Behind") would be considered by GAO to be an "independent" validation survey.
>
> **Observational.** The Regional Office surveyor accompanies the State agency surveyor(s) during the laboratory survey and interacts as necessary to provide guidance to the State agency surveyor(s) at appropriate times.
>
> **Participatory.** The Regional Office surveyor and State agency surveyor(s) identify deficiencies during the laboratory survey.

The Federal Monitoring Survey is a powerful educational tool for surveyor training. Observational and participatory Federal Monitoring Surveys are balanced by the comparative surveys. We estimate the comparative surveys accounted for about 15% of all CLIA oversight surveys during the period GAO studied.

We agree that the comparative survey or "independent validation review" offers a truer assessment of surveyor competency than the observational or participatory Federal Monitoring Survey, and for that reason continue to have the comparative survey as a tool available to Federal surveyors for their oversight responsibilities. We are convinced that Federal surveyors exercise appropriate judgment as to when to select or not select the comparative survey to fulfill their responsibilities for surveyor competency assessment. One must also consider that comparative

Federal Monitoring surveys can be disruptive to laboratories as they require two separate surveys conducted during different time frames to separately determine laboratory compliance for CLIA.

CMS Action:

10(a) Validating State Agency Performance: CMS will increase its efforts to ensure that the Federal Monitoring Surveys are performed annually in each State in numbers sufficient to allow a reasonable estimate of State agency performance, including increasing the number of "independent" reviews.

10(b) Independent Validation Review: CMS will ensure that at least one comparative Federal Monitoring Survey is performed for each surveyor every year.

10(c) Strengthen Training: CMS will strengthen its training focus and application of the outcome-oriented approach to surveying for laboratory compliance with 42 CFR §493 by incorporating additional specific examples and case studies of deficiencies that demonstrate non-compliance in current and future training of laboratory surveyors.

GAO Recommendation #11: *Require that almost all validation reviews of each accrediting organizations' surveys be an independent assessment of performance.*

CMS Response: We reviewed the statistics provided by GAO regarding the numbers of validation surveys performed simultaneously with the laboratory accreditation organizations, as well as our statistics regarding validation surveys. The numbers given for CAP (11%), COLA (9%) and JCAHO (33%) equate to the numbers of simultaneous validation surveys per year for each organization that are shown here in Figure 1.

FIGURE 1: SIMULTANEOUS VALIDATION SURVEYS (Annual Nationwide Data)

Accrediting Organization	Number
CAP	9
COLA	15
JCAHO	23
TOTAL	**47**

Forty-seven is consistent with the number historically recounted by the staff in the CMS regional offices that authorize the validation surveys—an average of about 1 simultaneous validation survey per State per year. It is also consistent with statistics in the CLIA data system for calendar year 2005 (45 simultaneous validation surveys).

The number of validation surveys performed nationwide has increased in recent years to almost 400 validation surveys to ensure that CMS is adequately overseeing accrediting organization performance. At the present level of 1 simultaneous validation survey per State, simultaneous validation surveys constitute about 12 percent of the total number of validation surveys performed. Conversely, about 88 percent of the total validation surveys are performed independently, which equates to the recommendation that almost all validation surveys be an independent assessment of performance. We believe 12-15% is a reasonable proportion to reserve for the opportunities afforded by simultaneous validation surveys, such as:

- promoting understanding of each other's programs;
- sharing of best practices; and
- fostering improvements in accreditation organizations' survey processes.

CMS Action:

11(a) Ensure Validation Surveys: CMS will continue to monitor and ensure that the vast preponderance of validation surveys for accrediting organizations takes the form of independent assessments.

GAO Recommendation #12: *Collect and routinely review standardized survey findings and other available information for all survey organizations to help ensure that CLIA requirements are being enforced and to monitor the performance of each organization.*

CMS Response: We strongly endorse the value of collecting and reviewing survey findings and other available information to monitor, sustain, and improve performance. For this reason we instituted standardized mechanisms for State survey agency performance through the State Agency Performance Review (SAPR) protocols. Those protocols utilize standard indicators of

performance and data. More recently we initiated development of a similar system for application to the performance of accrediting organizations. We believe that the accrediting organization Performance Measures under development will effectively enhance current methods to fulfill our oversight responsibilities for accrediting organizations.

With regard to the "standardized" aspect of this recommendation, we will put emphasis on improving our methods of standardizing interpretations of survey outcomes, even though the standards of each accrediting organization may be different[4].

CMS Action:

> **12(a) Collection & Review of Accrediting Organization Survey Findings:** CMS will explore methods to expand its collection, review, and analysis of survey findings and the follow-up actions of accrediting organizations in order to monitor, sustain and improve performance of accrediting organizations.

GAO Recommendation #13: *Establish an enforcement database to monitor actions taken by state survey agencies and regional offices on labs that lose their accreditation.*

CMS Response: We agree that laboratories losing accreditation due to CLIA quality issues require close attention to ensure they are not erroneously deemed CLIA compliant. Our development efforts for enforcement management, and planned future system enhancements,

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[4] The CLIA regulations do not require that an accreditation organization's or exempt State's standards be the same as CLIA. Rather, the accreditation organization and exempt State's requirements, taken as a whole, must be equivalent to or more stringent than those of CLIA. The majority of the deemed organizations and exempt States' requirements are at a level that elevates the quality of testing and the standard of practice. CLIA, on the other hand, represents minimum requirements, and is sometimes less rigorous than the routine standard of clinical laboratory practice.

Because their standards can be more stringent than CLIA, the accrediting organizations and exempt States can hold the labs to higher quality requirements. For example, CAP requires proficiency testing for all analytes, not just those that are specified at Subpart I, and the JCAHO has quality standards for waived tests. Standardization would make our reviews easier, but would weaken the accreditation organization standards that are more stringent than CLIA, restrain marketplace-enriching standard development, and change their unique corporate identity and organizational autonomy.

will assist us in tracking and monitoring such cases. We will also be working closely with our state agencies, regional offices and accreditation organizations to review present procedures to ensure that actions taken are appropriate and timely.

CMS Action:

> **13(a) CMS Enforcement Database.** Complete the development of the CMS CLIA enforcement database to track and monitor labs that necessitate any potential federal enforcement actions.

Conclusion

As you can see, CMS has either taken steps already to address the GAO's recommendations, or is responding to their analysis in a positive manner. We anticipate that the actions we have laid out above will result in continued improvements in our oversight and enforcement of the provisions of CLIA.

I thank the Subcommittee for its time this morning and would be pleased to answer any questions you might have.

Mr. SOUDER. On the GAO recommendation No. 9, that you utilize your revenues generated by the program to hire sufficient staff to fulfill its statutory responsibilities, your response was CMS is fulfilling its statutory responsibilities. My understanding was—is that the fees collected, that you've had a reduction in staff from 29 to 22 and you have carryover balances of $70 million. What happens to that $70 million? Does that go to other agencies to use as a cash-flow? Why would you have reduced your staff from 29 to 22? Have the number of labs reduced? What would be the reason?

Mr. HAMILTON. CMS has been very careful to ensure that the burden placed on laboratories through the user fees are managed very conservatively. Those lab fees are set in advance and only infrequently adjusted, and what happens in the early years is that there is a surplus and then over time expenditures exceed the revenues that are generated and that surplus is diminished to the point where the fees then need to be raised again. We are over the tipping point, so at the current point the expenditures for the Centers for Disease Control, for the States, for CMS and the FDA, who all work in combination to achieve the results of CLIA, the expenditures at this point in time are just beginning to exceed the incoming revenue. So that $70 million is going down.

What has happened overall in CMS in terms of the staffing is that as the agency diminished staffing somewhat, the CLIA staff had been subjected to that diminishment as well. And we have had a request in to re-examine that practice, and that examination has been completed, and I am pleased to say that we are in the process of separating out the CLIA staffing into its own set of controls where the staffing will be governed not so much by what's happening in the rest of the agency but what's happening precisely in the way of the CLIA workload and the user fees.

Mr. SOUDER. Yeah. Because you're different than the rest of the agency. In a sense, you have a fee that's collected to do the enforcement. Is that correct?

Mr. HAMILTON. That is correct.

Mr. SOUDER. How is the $70 million counted in the budget? Do you automatically—are you automatically guaranteed what is at a maintenance level? I mean, it's like a postage stamp. In other words, we always have more income at the beginning of the postage stamp than we do at the end and then you raise the fees. That's basically what you describe there, but you are not a frozen agency. In other words, HHS, is this fund subject to the general HHS appropriations?

Mr. HAMILTON. It is. Your analogy is perfect in terms of postage stamps. Those funds that are received from the user fees are held in trust and used exclusively for the Clinical Laboratory Improvement Act amendments.

Mr. SOUDER. Wouldn't you have been able then to hire, not reduce, staff if you had the funding and in fact if you had 29 and you said we wanted to keep 29 because it's necessary for our mission, that would have meant you would have raised the fees?

Mr. HAMILTON. That is the way it could work in the future. In the past, the overall personnel controls in terms of the number of people that could be devoted to this function have been treated separately without regard to budget. Now we're separating those out.

Mr. SOUDER. In the sanctions question, in one of your responses you said that in fact a lab—part of the reason you didn't agree that if you had multiple failures that they would automatically be sanctioned was—is that it could be in different subsections of the same lab for a different task. That implies that you believe the reasons for failure are specific as opposed to generic. In other words, that a lab is lax in their processes, therefore if they have a failure in one area, then they have a failure in another area. It isn't a failure of the management or the general commitment. It's a failure of whatever happened in that particular area. Am I correct in articulating that and why would such an assumption be made? And let me make one other followup with that. In the sanctions process, I mentioned in the first panel about egregiousness. I kind of look at this as a little bit like restaurant violations. In other words, it's one thing if you don't have the ketchup bottle top on. It's another if you have salmonella in your meat. Do you have some sort of a standard here that dependent on the egregiousness there's an immediate automatic sanction? Do you have tiered levels in that—how are you dealing with this? Because one type might just be a lax management that's why you would have repeated areas of different departments or more staff turnover than would be normal so staffers weren't as highly educated, therefore they're more likely to make an error, which is once again a management question, to some degree a pay question, to some degree whatever other management questions there is, and some are just like making an error, some which we've heard in Maryland General are just catastrophic, putting pressure on the process where somebody gets AIDS and is fired, and then you have others that they couldn't for a fairly long period of time even tell us whether they had misidentified whether somebody had AIDS or not. So you have a whole bunch of people hanging in balance as to whether they have AIDS or not or whether the surveys are accurate. That seems to be fairly egregious, that kind of—how do you work through that sanctions standard?

Mr. HAMILTON. The problems in Maryland General were indeed egregious, and in that kind of situation we need very prompt sanctions and very effective remedy. We need also the ability to distinguish that kind of situation from minor problems, and our point in our reply was simply to say if we found, for example, a problem in proficiency testing in general, then we need to look beneath the surface to discern whether or not this is a systemic problem of the overall management or is isolated.

We have found situations, for example, where the problem was concentrated in a neonatal testing area of the laboratory and not generalized to other parts of the laboratory. In that case we really need to focus on what's happening in the neonatal testing area. Now, if we looked back and saw that the previous year that the proficiency—the lab had a proficiency testing problem, but that it was in a completely different area and there seemed to be no common systemic problems, then we need the ability to make appropriate judgments with regard to the strength of the sanctioning and enforcement action.

So that was the only point we were trying to make there. We may need to make refinements in our data system to be able to pick up on some of these nuances because when we run the reports

we might just find that the data indicate the frequency of problems in the overall deficiency area rather than getting beneath the surface. So for us to do effective monitoring of our States and accrediting organizations, we may need to adjust the data base to be able to do so.

Mr. SOUDER. I have one more question, and I ask this somewhat with fear and trembling that in the—because in listening to the doctors of our areas and Medicare-Medicaid reimbursement questions all the time, when we charge a fee for these labs, for the oversight, if that goes up, how is that factored in in reimbursement questions in Medicare and Medicaid? Is it irrelevant? Do they just have to absorb it?

Mr. HAMILTON. The fees range from a low of $150 for say a physician office lab that's doing a few tests to on the other extreme $8,000 for a lab that may do a million or more tests a year.

Mr. SOUDER. So if it went from $150 to $170, it's not going to have a huge impact?

Mr. HAMILTON. [Yes indicated.]

Mr. SOUDER. OK. Thank you. Mr. Cummings.

Mr. CUMMINGS. The GAO found that CMS is not meeting its requirements to determine in a timely manner the—continue the equivalency of accrediting organization and exempts States inspection requirements between periodic equivalency determinations before it reviews the proposed changes. And I was wondering, what was your opinion on that? Because apparently there's a time when you all are trying to figure out whether the surveyors' standards meet CLIA standards, and one of the complaints has been—and you heard it, you heard it a few minutes ago—that there sometimes has been a kind of long delay. What is that about? Is that a personnel issue?

Mr. HAMILTON. It has been primarily a personnel issue and a prioritization issue. But let me first clarify the circumstance. Let us take, for example, the situation where an accrediting organization changes its standards. The accrediting organization is obliged to notify us of the changes. What hasn't been happening in a timely manner is our formal response back to the accrediting organization. That's not to say we don't take a look at the change. We do take a look at the change as it comes in and make a triage decision as to whether or not this seems to be a significant change, serious change, or it could be an accrediting organization adopting something that is more stringent than the minimum requirements that are specified in law and regulation.

So we make that initial review. What we haven't been doing is making the formal determination, sending the letter back to the accrediting organization, saying this is a problem or not a problem because generally we haven't found that those changes have been problems. The priority decision has been—as we look at all of the work that we've had to do, some things are much more important than others, and frankly, during the past year one of the most important things we have done, I think, believe, is to implement the cytology proficiency testing requirement. And that has been a major accomplishment, and we devote considerable energies to that effort and to responding to the concerns from the field that we have had about that testing.

So in light of that kind of priority comparison, we have elected in the past to simply take a look at the accrediting organization changes to their standards, but not immediately issue a response back. We're going to respond in a more timely manner in the future, but we will always need to take a look at our workload and make determinations with regard to priorities, some things being more important than others.

Mr. CUMMINGS. Going back to the Maryland General situation, how has that affected your agency? I mean, I know it's affected the people who are sitting right behind you, but I'm wondering how has that affected you all because basically while they are the folks who do the surveys, you are the folks who kind of oversee them. So what if any—effect has it had?

Mr. HAMILTON. I would say for CMS its effect was similar to the effect of Hurricane Katrina. I think only Rip Van Winkle could have slept through the wake-up call that was presented by the Maryland General situation.

Mr. CUMMINGS. So this is major stuff, huh?

Mr. HAMILTON. It was of significant concern to us not only in terms of the immediate events and findings but also of great concern to us in terms of how long it took the hospital system to accept the problems that it had and engender systemic corrections, and so there were two aspects to that problem, and I think, as Representative Watson pointed out, there were significant personnel changes subsequent to that, and I think those personnel changes had more to do with the slowness of the response and not just the immediate problems that they faced.

Mr. CUMMINGS. Now, the recommendations that were made by the GAO, you talked about things that you felt pretty good about. I was just reviewing some of your, you know, responses and what have you. What did you disagree with?

Mr. HAMILTON. We appreciate the caution that GAO communicated with regard to ensuring that we have a balanced approach between education and enforcement, and we appreciated their worry because we worry about it in terms of constant vigilance. However, the two instances that they cite we very much disagree with. Consider, for example, the cytology proficiency testing. This was a new requirement. While the law had been passed by Congress some time ago, the conditions requiring laboratories to ensure that all of their affected workers were individually tested did not apply until 2005. That was a new requirement for the laboratories. We told the laboratories that if they failed to enroll all of their affected workers in the testing, we would provide sanctions. We told them that if they failed to ensure that their workers were retested should they fail, we would apply sanctions. The only thing that we said that we wouldn't do is to levy sanctions if a laboratory had failed to ensure that 100 percent of its workers in that year achieved a passing score. So we think that we did a very responsible job.

On the other hand, I appreciate the GAO concern because on one hand while they're saying that we've been too lenient, I have stacks of correspondence from professional societies and others saying that we were too stringent and that we ought to slow things down.

So we think that we have crafted and implemented the perfect Goldie Locks solution, something neither too lenient nor too stringent but one that got the job done, and the end result is that 100 percent of the pertinent labs participated in the proficiency testing and ensured that their workers were tested. So the American public has a much greater assurance today that the people who are reading pap smears are doing so accurately and reliably.

Mr. CUMMINGS. Did you listen to—I'm sure you did—to the previous witness and particularly the last question that may have been next to the last question that I asked her, whether she would feel comfortable with labs, and did you hear what she said?

Mr. HAMILTON. I believe she didn't give you a direct reply but expressed her concern. I thought it was a very good answer. We likewise are concerned about any lapse in the accuracy, reliability or timeliness of testing, and we would like to see continuous improvement in all laboratories in such testing. To that end, we dedicate ourselves and will use the GAO report as effectively as possible to make those improvements.

Mr. CUMMINGS. You said a little bit earlier that you all were working on trying to bring all these standards together so you have—everybody's pretty much reading from the same page in the same handbook. Is that pretty much accurate?

Mr. HAMILTON. That is correct.

Mr. CUMMINGS. What is your timetable with regard to that?

Mr. HAMILTON. We will accomplish that in the next calendar year. I asked before coming here for one of our staff to bring me the latest set of standards and correspondence back and forth between one of the accrediting organizations, and they wheeled in a very large cart, and I can tell you that when we've got not just one accrediting organization but multiple accrediting organizations, each of which has a different process instead of criteria, it's a substantial undertaking, but it is high on our agenda, and we are regularly meeting now with all of the accrediting organizations to figure out ways in which we can improve our information sharing, our red alerts, our communications and our compatibility in our processes. But I would point out that GAO recommendation pertained to the front end; that is, are the standards comparable? We are perhaps even more concerned with making further improvements on the back end, which is after the survey is done, are we able to agree on what the most serious findings are and ensure that there is appropriate followup action and correction for any problems that are identified. To that purpose, we would like to construct with the accrediting organizations a taxonomy of deficiency findings so that we can have greater comparability and followup to ensure that remedial action is promptly and effectively made when such action is called for.

Mr. CUMMINGS. Now, see, you are taking me back to my days as a lawyer. Did you answer my question?

Mr. HAMILTON. I don't know if that was a compliment or not.

Mr. CUMMINGS. Sounded nice, but I mean it——

Mr. HAMILTON. I was—your question had to do——

Mr. CUMMINGS. With timetable. I said——

Mr. HAMILTON. In the next year, yes.

Mr. CUMMINGS. Is it next year?

Mr. HAMILTON. Yes.

Mr. CUMMINGS. Oh, OK, next year.

Mr. HAMILTON. Perhaps I said it under my breath.

Mr. CUMMINGS. I missed it. Did you actually say that?

Mr. SOUDER. Yeah, he said it. He explained why it was going to take him a year.

Mr. CUMMINGS. OK. Just one other question, Mr. Chairman. I want to go back to some questions that the chairman asked about the $70 million. And I'm trying to figure out, if you have a Maryland General situation, and let's say you had—you felt that the problem was just there were probably maybe a lot of Maryland Generals out there, and you said, wait a minute, we've really got to do something different here. In other words, had you had a true emergency, what happens then? And you know you need more personnel, you know it. You just can't get around it, and it would be almost negligent if you failed to take money that you have to deal with the emergency and then figure out how to collect more dues in the future or whatever. I mean, what happens under that circumstance?

Mr. HAMILTON. Under a circumstance such as the one that you described, we would mobilize national resources to make them available and we would deal with the fiscal consequences later, whether or not that meant that we needed to increase the table—timetable or speed up the timetable for fees or whatever.

Mr. CUMMINGS. All right. I don't have anything else.

Mr. SOUDER. Ms. Watson.

Ms. WATSON. Thank you.

Mr. SOUDER. Let me briefly followup because my understanding to your first answer when we compared to postage stamp revenue and the latter part you draw down, now my understanding was, as you said, HHS will no longer put you under an arbitrary uniform shared cost reduction if budgets are squeezed, which they are everywhere in personnel because of our increases, aren't meeting the increased cost of living demands is the bottom line. Do you have control over—does your subagency have control over your revenue that comes in independently or is that decided by OMB or HHS headquarters?

Mr. HAMILTON. The fees are established through the publication and the Federal Register process pursuant to the regulations that have been previously established. So we go through a process of publishing any change in the fees.

Mr. SOUDER. So that generates the revenue. Who controls the expense side?

Mr. HAMILTON. The expense side, CMS controls. From the user fees then we work out a budget for the Centers for Disease Control, one of our partners in this effort, and the budget for the Food and Drug Administration, and then ourselves.

Mr. SOUDER. So do you have an internal—like for the postage stamp, would you have projections and say when we increase it to 39 cents we will have this much revenue at the beginning, making these assumptions, and then it will draw down by X year? Do you have an internal budget like that?

Mr. HAMILTON. Yes. We have internal budget controls and as we look at the personnel needs here, we are going through our own

process of examining the workload and then ensuring that any position that we have is fully justified in terms of the priority and the workload.

Mr. SOUDER. Would you have the flexibility if you felt an increased workload to accelerate that plan and kick in an increase earlier? Would that be something your department would—would you have automatic flexibility? Would you have to run that up through the Secretary and then through OMB?

Mr. HAMILTON. Definitely. We would go through the Federal Register process with Health and Human Services and OMB.

Mr. SOUDER. So it's not a dedicated fund per se like the gas tax or the inland waterway, airport tax where those agencies would have control over their budget; they would still have to have it reviewed. You, while you have a dedicated fee, in fact have to go through traditional budgeting inside the——

Mr. HAMILTON. Inside the agency and within the executive branch. That is correct, and through the Federal Register process. But it is a dedicated fund in the sense that it cannot be used for any purpose other than CLIA.

Mr. SOUDER. Well, thank you very much for your testimony, and we're looking forward to hearing how the followup goes over the next year and the implemented standards. Thank you for coming today.

Mr. HAMILTON. Thank you very much, and thank you for all the time that you have put into this issue.

Mr. SOUDER. Our third panel could come forward and remain standing for the oath.

Dr. Dennis O'Leary, president of the Joint Commission on Accreditation of Healthcare Organizations; Dr. Thomas Sodeman president, College of American Pathologists; and Mr. Beigel, chief executive officer of COLA.

It is the practice of this committee to swear in all witnesses.

[Witnesses sworn.]

Mr. SOUDER. Let the record show that all the witnesses responded in the affirmative. We thank you for participating in the hearing today. And we'll start with Dr. O'Leary.

STATEMENTS OF DENNIS S. O'LEARY, M.D., PRESIDENT, JOINT COMMISSION ON ACCREDITATION OF HEALTHCARE ORGANIZATIONS; THOMAS SODEMAN, M.D., PRESIDENT, COLLEGE OF AMERICAN PATHOLOGISTS; AND DOUG BEIGEL, CHIEF EXECUTIVE OFFICER, COLA

STATEMENT OF DENNIS S. O'LEARY, M.D.

Dr. O'LEARY. Thank you. Good afternoon. I'm Dr. Dennis O'Leary, president of the Joint Commission on Accreditation of Healthcare Organizations. We thank the subcommittee for taking a leadership role and urging improvements on laboratory services in this country. We would also like to commend the GAO for its detailed review of the quality of testing in our Nation's clinical laboratories.

The Joint Commission accredits more than 3,000 laboratories that hold varying numbers of CLIA certificates. Some of these laboratories are hospital based while others are independent. Assuring

that accredited laboratories are providing safe, high-quality services is one of the Joint Commission's highest priorities. Joint Commission laboratory surveys are conducted by experienced medical technologists and pathologists who have passed a rigorous certification examination and participate in training exercises on an ongoing basis.

Recognizing the critical importance of laboratory services, the Joint Commission has designated the laboratory as an essential hospital service. This designation has elevated the importance of the laboratory's compliance with established requirements in determining the overall accreditation status of the hospital that it serves. This policy underscores the patient care implications of laboratory quality and the need for hospital leaders to pay particular attention to laboratory performance.

The Joint Commission's close working relationship with CMS on laboratory issues demonstrates the value of public-private sector partnerships in improving health care and to serve laboratories and Medicare beneficiaries well. The Joint Commission makes a special effort to assure open communications and coordination of efforts with the State and Federal agencies and other private accrediting bodies responsible for the quality oversight of laboratory services.

The Joint Commission welcomes the GAO report on the oversight of quality in laboratories. We emphasize, however, the need to strike a balance between timely identification and resolution of performance issues and laboratories and the education and improvement objectives inherent in the accreditation process. Simply pointing out deficiencies in laboratory performance does not automatically translate to effective resolution of those identified problems.

While the Joint Commission generally concurs with the GAO findings and conclusions in this report, we wish to highlight several areas of concern with respect to its recommendations. First, while the GAO recommendation that CMS standardize the categorization reporting of survey findings may simplify administrative oversight of the laboratory program, it may also stifle innovation in evaluation approaches and thereby ultimately compromise the safety of patient care. This recommendation assumes that CLIA requirements and categorizations are a gold standard rather than a set of basic expectations for laboratories and that more advanced performance standards do not exist. In fact, the rationale for relying on private sector accreditation is that this makes possible the timely setting of higher standards on an ongoing basis. This GAO recommendation basically fails to acknowledge that the Joint Commission and others use different contemporary approaches to assessing laboratory performance. We suggested the recommendation to standardize a categorization and reporting a survey findings be set aside in the favor of directing CMS to develop a common taxonomy that could be used by all laboratory quality oversight bodies that would track serious deficiencies.

Second, the Joint Commission believes that GAO has misinterpreted its validation of survey data. Based on this analysis, the GAO concludes that independent surveys are more effective than simultaneous surveys in identifying condition level deficiencies that were missed by accrediting bodies. However, the data presented in

the report do not support this assertion. In fact, the proportion of condition level findings was generally equivalent in both types of surveys. Further, there are significant benefits to simultaneous surveys because they allow dialog between CMS and Joint Commission evaluators and staff that leads to enhanced understanding of how each entity conducts its evaluation process.

Finally, while GAO's detailed review addresses a number of laboratory quality issues, it does not address a long-acknowledged shortcoming of CLIA requirements, the qualifications of laboratory personnel. We believe that the personnel standards currently required by CLIA are insufficient to adequately protect patients in the public health. Today the problems underlying failures in laboratory performance are the growing shortage of laboratory technologists and the inadequacy of their training. These shortcomings become especially glaring in the face of the expanding array and increasing complexity of laboratory tests in hospitals today.

In conclusion, the longstanding positive working relationships among CMS, the Joint Commission and its colleague accrediting bodies has benefited the public through assuring continuous access to and application of state-of-the-art methods for evaluating quality and safety in laboratories. The Joint Commission remains firmly committed to working with all of its partners in both the public and private sectors to ensure continuous improvement of laboratory services.

Thank you.

[The prepared statement of Dr. O'Leary follows:]



Joint Commission
on Accreditation of Healthcare Organizations

Setting the Standard for Quality in Health Care

Hearing on

Clinical Laboratory Quality: Oversight Weaknesses Undermine Federal Standards

Before the

Committee on Government Reform
Subcommittee on Criminal Justice, Drug Policy and Human Resources
June 27, 2006

Testimony by

Dennis O'Leary, M.D.

President
Joint Commission on Accreditation of Healthcare Organizations

I am Dr. Dennis O'Leary, President of the Joint Commission on Accreditation of Healthcare Organizations. We appreciate the opportunity to present testimony on the subject of today's hearing, "Clinical Laboratory Quality: Oversight Weaknesses Undermine Federal Standards."

I would first like to thank the Subcommittee on Criminal Justice, Drug Policy, and Human Resources for taking a leadership role in urging improvements in laboratory services in this country in the wake of the highly-publicized laboratory testing problems that were identified in the Baltimore region. The problems found at Maryland General Hospital's laboratory underscore the importance we all should place on fostering cultures of safety within health care organizations that encourage voluntary reporting of staff concerns to organization leaders, and ultimately to responsible quality oversight bodies. Absent such cultures, critical information may go unreported or surface too late to avoid harm to patients.

The Joint Commission would also like to congratulate the Government Accountability Office (GAO) for its efforts to study the quality of testing in our nation's clinical laboratories; the effectiveness of quality oversight body assessment of laboratory performance; and the Medicare program's oversight of the implementation and appropriate application of the Clinical Laboratory Improvement Amendments (CLIA) of 1988.

Background

Founded in 1951, the Joint Commission is a private, not-for-profit entity dedicated to improving the safety and quality of health care. Its member organizations are the American College of Surgeons; the American Medical Association; the American Hospital Association; the American College of Physicians; and the American Dental Association. In addition to representation from these organizations, the 29-member Board of Commissioners includes an at-large nursing representative and six public members whose expertise spans such diverse areas as ethics, public policy, insurance, academia, and patient advocacy.

The Joint Commission currently accredits approximately 15,000 health care organizations in the United States. These include hospitals (both general acute care and specialty), critical access hospitals, clinical laboratories, ambulatory care organizations, office-based surgery providers, assisted living facilities, behavioral health care programs, home care agencies, hospices, home medical equipment suppliers, and long term care organizations.

Among the Joint Commission accredited entities are more than 3,000 laboratories that hold CLIA certificates of various types; these include independent laboratories and those that are integral to other health care organizations, such as hospitals. Laboratory surveys are conducted by experienced medical technologists and pathologists who have passed Joint Commission's rigorous certification examination. The Joint Commission surveyors are distinguished from other accrediting body surveyors in that they are not volunteers, but rather are dedicated employees who have extensive knowledge of the full range of laboratory services that are provided in a variety of settings, and are required to participate in ongoing training exercises.

Ensuring that its accredited laboratories are providing high quality and safe services is one of the Joint Commission's highest priorities. Many clinical diagnoses and most patient clinical management are based on the results of laboratory tests, yet attention to the level of quality in hospital laboratories is often eclipsed by other quality concerns within the larger organization. Recognizing the critical

importance of laboratory services, the Joint Commission has designated the laboratory as an "essential" hospital service. This designation has elevated the importance of the laboratory's compliance status in determining the overall accreditation status of a hospital. This policy underscores the patient care implications of laboratory quality, and the need for hospital leaders to pay particular attention to laboratory processes and outcomes.

Keeping Patients Safe

Joint Commission efforts to improve patient safety in all types of health care organizations are based upon a fundamental recognition of the need for organization leaders and health care practitioners to adopt a "systems approach" to managing risk and keeping inevitable human error from reaching patients. The systems approach idea is borrowed from both the field of engineering and from quality control principles which have been successfully applied in manufacturing and other industries to mitigate the effects of human error. This approach to safety—"systems thinking"—requires the application of tools such as retrospective root cause(s) analysis when adverse events occur. It also requires prospective failure mode and effects analyses to identify and eliminate risks in identified vulnerable processes before actual adverse events can occur. Improving systems within laboratories requires attention to the entire testing process—starting with proper sample preparation and continuing with the appropriate selection of tests, application of proper analytics, correct and understandable portrayal of results, and utilization and timely reporting of these results.

This approach also requires a "blame-free" environment in which errors and "near misses" are systematically identified, rather than hidden, so that they regularly become learning experiences for the organization and its staff. A safety-focused learning environment is one in which safety is always top of mind; in which the identification and reporting of errors and unsafe conditions is rewarded, not punished; in which a commitment to honesty, transparency and where appropriate apology and if necessary re-testing, characterize the relationship with patients who have been unintentionally harmed; and in which there is constant vigilance for emerging risks. This type of organizational environment only develops when the organization's managerial and clinical leaders work collaboratively and deliberatively to create it.

The Joint Commission's standards, survey process, and other quality and safety improvement initiatives are designed to stimulate and facilitate the creation of cultures of safety within accredited organizations.

Specific Joint Commission Efforts to Improve Quality in Laboratories

With the fore noted framework in mind, the Joint Commission has created a substantial portfolio of initiatives, practical tools, and solutions to further enhance the value and reliability of accreditation. These efforts include:

- The recent transition to unannounced surveys which underscores that the laboratories be in continuous compliance with all accreditation standards.
- The expanded use of data to focus and drive the onsite assessment.
- Continuing attention to reduce the risk of adverse events.
- The tracing of patients and their specimens through the continuum of laboratory services during the unannounced survey to determine compliance with each applicable standards.

- Ready public access to a robust complaint process, availability of a toll-free complaint hotline, confidentiality for those who report concerns about an accredited organization, and use of compliant data in the onsite evaluation process.
- The use of an annual self-assessment tool and process to identify continuing opportunities for improvement and support continuous standards compliance.

The Joint Commission also works closely with accredited laboratories that have been cited for standards deficiencies by requiring specific corrective actions and monitoring these laboratories to ensure that substandard patterns of performance are actually remedied and do not recur. Combining this rigorous evaluation and monitoring approach with the educational dimension of the Joint Commission's accreditation process is critical in the ongoing efforts to achieve lasting improvement in laboratory performance. Simply pointing out deficiencies in laboratory performance does not automatically translate to effective resolution of those identified problems.

Partnerships to Enhance Laboratory Quality

The Joint Commission believes that its close working relationship with the Centers for Medicare & Medicaid Services (CMS) on laboratory issues demonstrates the value of public-private partnerships in improving health care, and has served laboratories and Medicare beneficiaries well. The Joint Commission makes a special effort to work with state and federal agencies and other private accrediting bodies to assure effective oversight of laboratories and is committed to continuous efforts to improve communication and coordination among these parties. These efforts are critically important because a number of oversight bodies have roles in overseeing the quality of laboratory services. The responsible oversight bodies have forged relationships that make the system work to reduce unnecessary duplication, control costs, and leverage improvement when deficiencies are found to exist, but these relationships also create significant communication challenges. The Maryland General laboratory issues starkly illustrate the need to more tightly weave together the oversight fabric so that it identifies and addresses performance problems in a timely fashion. Because the focus of the oversight process must always be the patient, it is incumbent on each oversight body to share significant complaint information—
that it alone may receive—with all of its oversight partners in a timely manner, so that effective remedial action can be thoroughly leveraged.

The initial public/private sector partnership in the oversight of laboratories began when the Congress granted the Joint Commission deemed status for Medicare hospital requirements in 1965. Under this deeming provision, the Congress determined that Joint Commission hospital accreditation provides an assurance of compliance with the Medicare Conditions of Participation. One of the Medicare Conditions identifies laboratory services as a basic hospital function and required service. As part of its hospital accreditation program, the Joint Commission verifies that the hospital laboratory has a valid CLIA certificate and that the laboratory services are adequate to meet the needs of the hospital's patients.

Following enactment of the CLIA legislation, the Joint Commission was one of several accrediting bodies to receive recognition from CMS for approval of laboratories to receive CLIA Certificates of Accreditation. Under its laboratory program, the Joint Commission accredits laboratories in hospitals and other health care facilities as well as independent laboratories.

When a hospital (or any other) laboratory elects accreditation by the Joint Commission, a biennial laboratory surveys are conducted to determine compliance with the applicable CLIA Condition-level requirements. When a hospital elects to have its laboratory accredited by another CMS-approved accrediting body with which the Joint Commission has a partnership agreement, the Joint Commission relies upon the findings of its partner. In all cases where a hospital laboratory fails to demonstrate compliance with either the CLIA requirements (as determined by the Joint Commission or by another CMS-approved accrediting body) or the hospital Conditions of Participation for laboratory services, the hospital and the laboratory are both subject to the possible loss of their respective accreditation awards.

The Joint Commission maintains partnership agreements with other nationally-recognized accrediting organizations in order to reduce the cost and duplication of survey and inspection activity experienced by hospitals and other health care organizations. These specifically include partnerships with the College of American Pathologists (CAP) and COLA. Before becoming a Joint Commission partner, each organization must undergo extensive review of its standards and standards development process; survey process; selection, training and monitoring of surveyors; and accreditation decision process.

Following upon the intensive review of the Maryland General situation, the Joint Commission has negotiated an enhanced information-sharing mechanism with CAP to assure the exchange of important information. For example, CAP now provides the Joint Commission reports on CAP-accredited laboratories in Joint Commission-accredited hospitals for all laboratories that exceed a certain threshold of deficiencies. The Joint Commission then reviews this information and determines appropriate courses of action on a case-by-case basis. These actions may include special for-cause unannounced surveys and, where appropriate, a change in the hospital's accreditation status.

The Joint Commission also continues to enhance the communication of information it provides to the states regarding its accredited organizations. For example, to assist the states in fulfilling their licensure function, forty-five state hospital licensing agencies recognize the Joint Commission's hospital accreditation program as an element of the state's licensure process. The most common form of recognition involves the state's acceptance of a hospital's accreditation in lieu of the conduct of its own routine state licensure inspection. The Joint Commission pays specific attention to effective and timely sharing of information not only with state licensing bodies but also with CMS.

As part of another collaborative effort to improve the quality of laboratories, the Joint Commission, along with state agencies and other accrediting bodies, is involved in the CMS Partners in Laboratory Oversight project. The goal of this partnership is to encourage communication and coordination and promote more effective oversight of our nation's laboratories, and therefore drive continuous improvement in quality and patient safety in these laboratories.

Comments on the GAO Report

The Joint Commission welcomes the GAO report on the oversight of quality in laboratories. This report, *Clinical Lab Quality: CMS and Survey Organization Oversight Should Be Strengthened*, calls on Congress to give CMS greater power to monitor the accreditation of laboratories. The Joint Commission supports the emphasis on achieving a balance between timely identification and resolution of performance issues in laboratories and the education and improvement of objectives inherent in the accreditation process. While the Joint Commission commends the GAO for its efforts, we would like to highlight several issues with respect to the GAO recommendations.

Standardizing Categorization and Survey Findings

The GAO recommendation that CMS standardize the categorization and reporting of survey findings, may theoretically have the potential to simplify the administrative oversight of the laboratory program, however it may also stifle innovation in the creation of patient safety evaluation approaches and thereby ultimately compromise the safety of patient care. This recommendation assumes that CLIA requirements and categorizations are a "gold standard" rather than a set of basic expectations for laboratories, and that more advanced performance standards do not exist. In fact, the rationale for relying on private sector accreditation is that it provides a level of flexibility in the timely setting of higher standards not readily available in a regulatory environment. When Congress established the accreditation option—with the caveat that the relevant standards "meet or exceed" federal regulations—it recognized that other approaches to quality improvement can be more innovative and effective in ensuring quality and patient safety, and that the private sector can be more nimble than the government in developing and applying state-of-the art performance expectations and assessment techniques. This GAO recommendation fails to recognize that the Joint Commission—like its colleague accrediting bodies—use different and more sophisticated approaches to assessing laboratory performance. Compliance with this recommendation would require a complete revamping of our laboratory process.

Notwithstanding the foregoing, the Joint Commission believes that CMS could and should play a lead role in developing a common, agreed-upon taxonomy that could be used by all laboratory oversight organizations to track serious deficiencies. As the GAO report notes, state survey agency determinations that Condition-level requirements are out of compliance are highly subjective and, by their nature, inconsistent. If all oversight organizations were to agree on criteria as to what constitutes a serious deficiency, this would create the desired comparability without requiring accrediting bodies to change their standards or the ways in which they categorize and document findings. We believe that this GAO recommendation to standardize the categorization and reporting of survey findings should be set aside in favor of direction to CMS to take the lead in coordinating a joint effort to develop common definitions of what constitutes serious deficiencies that should be reported to CMS.

Sanctions on Laboratories with Repeat Condition-level Deficiencies

The Joint Commission questions the GAO recommendation that CMS arbitrarily impose more frequent sanctions on laboratories with repeat Condition-level deficiencies. First of all, more information respecting such citations is essential because a variety of standards contribute to each Condition of Participation. Therefore, the "Condition" may be found to be out of compliance on two different occasions for very different reasons. Further, the laboratory may lack the expertise to fix the identified problem. Determining when to employ a punitive versus an educational or collaborative approach to promoting compliance is a difficult judgment and should not be an automatic determination.

The most appropriate way to manage reckless behavior is through sanctions or other disciplinary action. However, we contend that most laboratories with consecutive Condition-level deficiencies are actually exhibiting behavior that they mistakenly believe to be justified. Quality experts call this "at-risk" behavior to differentiate it from reckless disregard. The best way to manage at-risk behavior is to increase situational awareness, create incentives for healthy behaviors, and provide tools and solutions. Highly regarded patient safety studies overwhelmingly support the conclusion that punishment

encourages organizations to cover up problems. Thus, the Joint Commission believes that GAO's call for CMS to simply impose more sanctions on laboratories with repeat Condition-level deficiencies is likely to be counterproductive.

Validation Surveys

We also believe that GAO has misinterpreted its validation survey data. It concludes that "independent" surveys—more commonly referred to as "look-behind" surveys—are more effective than simultaneous surveys in identifying Condition-level deficiencies that were missed by accrediting organizations. However, the data presented in the report do not support this assertion. The Joint Commission found that in re-evaluating the same data, the proportion of Condition-level findings was generally equivalent in both types of surveys. We would like to emphasize that there are significant benefits to simultaneous surveys in that they allow dialogue between the CMS and the Joint Commission that leads to enhanced understanding of how each entity conducts its evaluation process. This approach can also reduce confusion regarding sometimes seemingly different findings from two oversight bodies and can optimize opportunities for leveraging change in laboratories.

Qualifications and Supply of Laboratory Personnel

Finally, while the GAO's lengthy and detailed review addresses many issues associated with laboratory quality, it does not address a long-acknowledged shortcoming of CLIA requirements—the qualifications of laboratory personnel. The Joint Commission believes that the personnel standards currently required by CLIA are insufficient to adequately protect patients and the public health. For example, CLIA requires only an Associate Degree and minimal laboratory training to perform tests of high complexity, and lacks personnel requirements for waived tests which account for 81 percent of the testing that takes place in the nation's laboratories. Today, the problems underlying failures in laboratory performance most commonly cited by experts in the field are the growing shortage of laboratory technologists and the inadequacy of their training. These shortcomings become especially glaring in the face of the expanding array and increasing complexity of laboratory tests in hospitals. By not addressing this serious shortcoming in the scope of its review, GAO has missed an important opportunity to leverage potential improvements in laboratory performance and protect the public interest.

Concluding Remarks

In conclusion, the long-standing, positive working relationship among CMS, the Joint Commission, and its colleague accrediting bodies has benefited the public through assuring continuous access to and application of state-of-the-art methods for evaluating quality and safety in laboratories. These efforts to continuously improve health care quality and patient safety not only serve to protect the interests of patients and the public, but they also ensure that the Medicare program and other payers are making sound purchasing decisions. The Joint Commission's leadership role in this area is evidenced by the fact that many private insurers and employers, including employee health plans, require that hospitals and laboratories serving their plan members be accredited by the Joint Commission.

The Joint Commission thanks the Subcommittee for its ongoing interest in the quality and safety of services provided in our nation's clinical laboratories. We are firmly committed to working with all of our partners—public and private—to ensure continuous improvement in these services.

Mr. SOUDER. Thank you for your testimony. Dr.—is it Sodeman?

STATEMENT OF THOMAS SODEMAN, M.D.

Dr. SODEMAN. Sodeman, yes.

The College of American Pathologists is pleased to appear before the subcommittee for this hearing of issues related to the GAO report on clinical laboratory quality. I am Dr. Thomas Sodeman, president of the CAP, a medical specialty society of nearly 16,000 board certified pathologists who practice clinical and anatomical pathology.

The CAP inspects and accredits more than 6,000 laboratories worldwide under its laboratory accreditation program. I am here today to provide our perspective on the GAO report and to update the committee on CAP's recent initiatives to improve its laboratory accreditation program. We are pleased to work with the GAO on this report and appreciated the opportunity to provide comments and testify before this subcommittee.

As an organization dedicated to improving laboratory medicine and patient care, we take seriously the findings and recommendations of the GAO. The CAP will analyze the report to assess if there are additional steps that CAP needs to take to address the issues identified as areas of concern regarding our accreditation program.

Beginning in 2004, the CAP initiated its own evaluation of its laboratory accreditation program. The testimony we presented to this committee on May 18th and July 7, 2004 included information on changes that we implemented. Since those hearings, the CAP has announced and implemented additional initiatives designed to strengthen our program. In its report the GAO acknowledges many of the new initiatives, including moving to unannounced inspections by July 3rd, nearly 100 percent of all CAP inspections will be unannounced.

We enhanced and require training for all CAP inspectors. This training will supplement the inspectors' years of professional experience with specific guidance on inspection techniques.

We implemented mandatory signage to facilitate the reporting of quality complaints. The CAP policy also includes whistleblower protections that shield the reporting laboratory worker from employee retaliation.

We strengthen conflict of interest policies by making the policies more comprehensive and explicit.

We are spending $9 million on the development of integrated data systems to better assess laboratory quality that will provide early detection of potential problems in our accredited laboratories.

The GAO report provides valuable insight for the College to consider as it strives to continuously improve its program. There are also portions of the report that we have a different perspective. The CAP believes that the GAO underestimates the value of utilizing laboratory professionals in the inspection process. We believe the combination of current professional experience in the laboratory and training in advanced inspection technique make the CAP inspectors uniquely qualified to ensure compliance with the CLIA standards. Proficiency testing data indicates that the CAP system is comparable to other models. We also have to keep in mind that

CAP accredited laboratories voluntarily choose CAP accreditation, which includes requirements that are more stringent than CLIA. We believe this dedication to enhanced quality by laboratory professionals demonstrates a commitment to the quality of patient care that goes beyond that is required by CLIA.

With respect to the regulatory and educational functions of CLIA, the CAP believes that these dual objectives are not mutually exclusive and that education is an inherent and important outcome to the inspection process of identifying and correcting deficiencies. The CAP believes that the dual objectives should be complementary. However, we recognize the primary purpose of the CLIA statutes are to ensure minimum standards.

The GAO also was charged with examining the quality of laboratory testing and was unable to make a determination about this issue. Proficiency testing is one of the areas for which there is a dated measure of quality. Laboratory quality as measured by the CMS aggregate PT data for all enrolled laboratories showed mark improvement in performance since 1996. Much of the report is devoted to examining Federal oversight of CLIA. In general, we believe that CLIA provides appropriate Federal oversight for ensuring accuracy of laboratory testing and promoting ongoing quality improvement.

We are pleased with the CMS partner initiative, which provides a forum for sharing information among all accrediting entities and provides a forum for discussion of best practices in the laboratory inspection and accreditation. We believe this enhanced CMS initiative is a strong indication of the commitment of the agency and all of the accrediting and oversight entities to improve our communication and strengthens the collaboration necessary to ensure laboratory quality.

CAP thanks the subcommittee for its interest in assuring the highest quality laboratory testing and is firmly committed to working with Congress, CMS and other oversight entities and accreditation organizations on a way to ensure laboratory quality.

Thank you, sir.

[The prepared statement of Dr. Sodeman 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 Clinical Lab Quality: Oversight Weaknesses Undermine Federal Standards

Statement Presented by
Thomas M. Sodeman, MD, FCAP
President,
College of American Pathologists

June 27, 2006

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Hearing on Clinical Lab Quality: Oversight Weaknesses Undermine Federal Standards

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

June 27, 2006

The College of American Pathologists (CAP) is pleased to appear before the Subcommittee on Criminal Justice, Drug Policy and Human Resources for its hearing of issues related to the Government Accountability Office (GAO) report on Clinical Lab Quality. 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.

I am Thomas M. Sodeman, MD, FCAP, president of the CAP, 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 CAP 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).

We are here today to provide our perspective on the GAO report on Clinical Lab Quality and to update the committee on the CAP's recent initiatives to improve its Laboratory Accreditation Program (LAP). We were pleased to work with the GAO on this report and appreciate the opportunity to provide comments and testify before this subcommittee. As an organization dedicated to improving laboratory medicine and patient care, we take seriously the findings and recommendations of the GAO. The CAP will analyze the report to assess if there are any additional steps that the CAP needs to take to address issues identified as areas of concern regarding our accreditation program.

Ultimately, the most important outcome for patients is consistently accurate laboratory results. As noted by GAO, the only comparative data available at this time to evaluate the quality of laboratory results in a systematic way is proficiency testing data.

Beginning in 2004, following the events at Maryland General Hospital, the CAP initiated its own evaluation of its LAP. The testimony we presented to this subcommittee on May 18 and July 7 of 2004 included information on those changes we had implemented by those dates. Since those hearings, the CAP announced that it has implemented and planned additional initiatives that are designed to

- Strengthen our inspection process
- Ensure consistency through enhanced, required training for inspectors
- Improve monitoring to ensure sustained compliance
- Reaffirm public confidence in objectivity of the accreditation process

In its report, the GAO acknowledges many of our new initiatives, including the following:

Moving to unannounced inspections
The CAP's move to unannounced inspections directly addresses the GAO's concern related to the accreditation system's ability to emphasize continuous regulatory compliance and adds credibility to the accreditation survey's conclusions as to the laboratory's ability to provide quality patient care. We began phasing in unannounced inspections this spring. By July 3, nearly 100 percent of all CAP inspections will be unannounced, with the exception of some federal facilities that cannot accept unannounced inspections due to security measures.

Enhanced and required training for all CAP inspectors
The CAP'S new mandatory inspector training addresses the GAO's concerns about using active and current laboratory professionals to conduct CAP surveys. This training will supplement their years of professional experience with specific guidance on inspection techniques. The CAP will require both team leaders and team members to successfully complete training within two years prior to inspections. This combination of professional experience in the laboratory and training in advanced inspection techniques makes CAP inspectors uniquely qualified to ensure compliance with CLIA standards.

Mandatory signage to facilitate reporting of quality complaints
The CAP's "anonymous complaint" poster, which was noted in the GAO report, was required by October 2004 to be displayed in all CAP-accredited laboratories. The CAP poster promotes the CAP toll-free reporting phone line that provides prompt and confidential routing of complaints and quality concerns. The CAP poster policy also includes "whistleblower" protections that shield the reporting laboratory worker from employer retaliation.

Strengthened conflict of interest policies
It is important to note that the CAP has always had policies and procedures to protect against conflicts of interest interfering with the objectivity of the inspection process. As a result of the GAO findings we have recently strengthened those policies by making the policies more comprehensive and explicit. Conflicts of interest is something that requires continued vigilance, so the CAP will continue to closely monitor this issue to determine if further actions are necessary.

Development of integrated data system to assess laboratory quality
The CAP is investing $9 million dollars over the next two years in new information systems and processes to strengthen our ability to monitor a laboratory for sustained compliance throughout its two-year accreditation cycle. The system will integrate quality factors, such as proficiency testing results and trend analysis, inspection findings and complaints, that contribute to a knowledge management system which will be utilized to support more effective accreditation decision-making that relies upon a comprehensive, multidimensional assessment of laboratory performance.

The GAO report provides valuable insights and new information for the CAP to consider as it strives to continuously improve its program. There are also portions of the report where we have a different perspective.

The CAP believes that the GAO underestimates the value of utilizing laboratory professionals in the inspection process. Our teams are multidisciplinary teams of laboratory professionals who have current expertise working in the laboratory, and who are quite familiar with the CLIA requirements. The

available evidence suggests that the CAP system is comparable to other models. For example, the CAP believes that the proficiency testing data cited in the report, for the most part, demonstrates that laboratories accredited by the CAP perform better on proficiency testing than those that are not. We believe that is a relevant measure of the quality of testing performed by laboratories accredited by the CAP.

We also have to keep in mind that CAP-accredited laboratories voluntarily choose CAP accreditation, which includes requirements that are more stringent than CLIA. We believe that this dedication to enhanced quality by laboratory professionals demonstrates a commitment to undertake more than is required by the federal government to assure quality laboratory testing.

With respect to the educational function of CLIA, as the GAO correctly noted, CLIA neither requires nor precludes an educational role for surveyors. The CAP believes that these dual objectives are not mutually exclusive and that education is an inherent and important outcome to the inspection process of identifying and correcting deficiencies. The CAP believes that the dual objectives should be complimentary, however, we recognize that the primary purpose of the CLIA statute is to ensure minimum standards.

The GAO also was charged with examining the quality of laboratory testing and was unable to make a determination about this issue. The CAP believes there are inherent challenges to measuring the quality of laboratory testing due to the complexity of the issue, which is why we are working to develop better systems for detecting laboratories with quality issues that potentially impact patient care.

Much of the report is devoted to examining federal oversight of CLIA. In general, we believe that CLIA provides for adequate federal oversight for ensuring accurate laboratory testing and promoting ongoing quality improvement. Over the years, the CAP has worked constructively with CMS and other accrediting entities. However, we're particularly pleased with the CMS Partners Initiative, which provides a forum for the sharing of information among all accrediting entities and provides a forum for the discussion of best practices in laboratory inspection and accreditation. We believe this enhanced CMS initiative is a strong indication of the commitment of the agency and all of the accrediting and oversight entities to improve our communication and strengthen the collaboration necessary to ensure laboratory quality.

Conclusion

The CAP accreditation program is dedicated to a single mission: raising the quality of laboratory testing to improve patient care. As with the laboratories we accredit, we are committed to the continuous improvement of our program and therefore take seriously the analysis provided in this report. We believe our actions demonstrate this commitment.

The CAP thanks the subcommittee for its interest in ensuring the highest quality laboratory testing and is firmly committed to working with Congress, CMS and other oversight entities and accrediting organizations on ways to ensure laboratory quality.

Mr. SOUDER. Thank you. We finish with—is it Beigel, correct?

Mr. BEIGEL. Yes, sir.

Mr. SOUDER. Mr. Doug Beigel, the chief executive officer of COLA.

STATEMENT OF DOUG BEIGEL

Mr. BEIGEL. Mr. Chairman, members of the committee, I am Douglas Beigel, chief executive officer of a nonprofit organization whose purpose is to promote excellence in laboratory medicine and patient care through a program of voluntary education, consultation and accreditation. COLA appreciates the opportunity to speak to you today about the findings and recommendations contained in the GAO report.

The COLA accreditation standards and methodologies were developed by internists, family physicians and pathologists to be practical and meaningful to the laboratory. The requirements have a positive and immediate impact on patient care. We are in the quality improvement business, and we expect our clients and ourselves to commit to continuous quality improvement. However, we must be vigilant to ensure that we do not disrupt patient care and that we maintain access to critical laboratory services that are convenient and important.

During the course of this study we responded to numerous written and verbal inquiries from the GAO and performed several in-depth data analyses. I'm pleased to share with you that we agree with the number of the GAO findings and recommendations, and I look forward to discussing those with you now. I will also touch on a few areas of the report that we found troubling.

We wholeheartedly agree that education to improve lab quality should not preclude identification and reporting of deficiencies that affect lab testing quality. We also believe that phase-in requirements are absolutely appropriate. Education is a critical component to the reasonable and appropriate implementation and enforcement of laboratory performance requirements. COLA takes its enforcement responsibilities very seriously, and we are proud of our consistent track record and the appropriate enforcement of CLIA.

We agree that laboratories should provide lab workers with instructions on how to follow anonymous complaints. And as an approved survey organization, we expect laboratories to act accordingly. We take complaints very seriously, and actively investigate all complaints. We require laboratories to post instructions to lab workers on how to file anonymous complaints. We agree that unannounced inspections in a smaller laboratory are destructive and unworkable.

The GAO is correct in concluding that unannounced inspections for the smaller laboratory will not be appropriate because these laboratories are so small, and because the medical and laboratory directors are often wearing many hats, and arriving unannounced causes disruption to the laboratory work, which, in turn, reduces the quality of patient care. We agree that CMS should be appropriately resourced and organized so that they can review and approve survey organization programs in a timely manner.

We have long appreciated the dedication and commitment with the CMS staff with whom we have worked so closely over the

years. We agree that where possible, CMS should make whatever structural change is necessary to ensure that survey organization programs and requirements are approved expeditiously and prior to the expiration date of the current approval.

And most importantly, we agree with the assertion that survey organizations, including CMS, should employ trained surveyors and assessors who perform consistent surveys. The report specifically mentions surveyor training and consistency assessments as key factors to a strengthened laboratory oversight system.

COLA is proud of its significant and extensive surveyor training program and our high level of consistency between surveyors. This means that COLA effects the same survey, whether the lab is located in Alaska, Maryland or Indiana. We utilize results of validation surveys to see if citations given by our survey match those of another. We look for patterns of validations that may indicate weaknesses in a particular area. We are proud that the GAO recognized these items already implemented by COLA as best practices for the industry.

We disagree, however, with the GAO's assertion that laboratory quality may not have been improved. COLA now accredits more laboratories than it has in the past 10 years. Data that COLA provided to GAO but was not used in the draft report shows that, in general, condition level deficiencies declined in laboratories that have been surveyed over multiple years.

Also, the percentage of COLA laboratories that fail proficiency testing has decreased. COLA is proud of the fact that our program is having a positive impact on laboratories and patient care.

We disagree with the GAO's assertion that education and enforcement are mutually exclusive. While COLA laboratory inspections are highly educational, we enforce 100 percent of our CMS approved accreditation requirements.

We disagree with the GAO's assertion that allowing a laboratory to prepare for a survey masks the discovery of laboratory problems. We know of no research that would support such a conclusion.

While much of the laboratory's evidence of compliance is documented, there is little of this evidence that can be fabricated in a short period of time. More importantly, however, the vast majority of laboratory professionals are dedicated to providing the highest quality of patient care possible, and therefore generally would not falsify records.

A qualitative interactive assessment of a laboratory, coupled with the ongoing participation in proficiency testing provides COLA with a more accurate picture of the overall quality of a laboratory. We have seen improvement and are proud of the strides we have made, but that doesn't mean we don't look ahead and raise the bar. Our paramount concern is provision or excellent patient care through meaningful standards and quality improvements. Thank you for inviting me to share my insights with you today.

[The prepared statement of Mr. Beigel follows:]



Written Statement

OF

Douglas A. Beigel,

COLA

ON THE

"CLINICAL LAB QUALITY:

OVERSIGHT WEAKNESSES UNDERMINE FEDERAL

STANDARDS"

SUBCOMMITTEE ON CRIMINAL JUSTICE,

DRUG POLICY AND HUMAN RESOURCES

COMMITTEE ON GOVERNMENT REFORM

UNITED STATES HOUSE OF REPRESENTATIVES

JUNE 27, 2006

Written Statement

OF

Douglas A. Beigel,

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ON THE

"CLINICAL LAB QUALITY:

OVERSIGHT WEAKNESSES UNDERMINE FEDERAL STANDARDS"

SUBCOMMITTEE ON CRIMINAL JUSTICE,

DRUG POLICY AND HUMAN RESOURCES

COMMITTEE ON GOVERNMENT REFORM

Mr. Chairman and Members of the Committee:

I am Douglas Beigel, Chief Executive Officer of COLA, a non-profit organization whose purpose is to promote excellence in laboratory medicine and patient care through a program of voluntary education, consultation, and accreditation.

COLA appreciates the opportunity to speak to you today about the findings and recommendations contained in the upcoming GAO report titled "CLINICAL LAB QUALITY: CMS and Survey Organization Oversight Should be Strengthened (GAO-06-

416)". This hearing and the GAO report on which we are commenting are significant and timely examinations of this important public service.

COLA was conceived by a number of very prominent medical associations including the American Academy of Family Physicians, the American Society of Internal Medicine (now the American College of Physicians), and the American Medical Association in 1985 and was incorporated in May of 1988. COLA's original constituency was quite unique. We served a laboratory community that was largely unregulated, but served an important clinical purpose. The physician office laboratory community produces laboratory results to support their own clinical decision-making.

The COLA accreditation standards and methodology were developed by internists, family physicians and pathologists to be practical and meaningful to the laboratory. The requirements have a positive and immediate impact on patient care.

The standards require that the laboratory director select the proper space, facilities, instrumentation, and personnel to provide prompt and accurate reports of results. There must be a quality assurance program in place that contains a quality control program; participation in Proficiency Testing; an instrument maintenance program; continuing education for staff; and documentation of laboratory activities.

Laboratories are evaluated against these standards using a detailed self-inspection checklist; an extensive personnel report form that describes personnel responsibilities

and training; successful participation in proficiency testing; and comprehensive, system-oriented on-site inspection of laboratory facilities.

I would like to emphasize that every laboratory participating in the COLA program has its Proficiency Testing results reviewed by COLA staff after every event. COLA continually monitors laboratory PT performance and, when performance is failing, we counsel laboratories on fixing the problems—and as appropriate, we do require laboratories to cease testing problem analytes or specialties.

In 1991, COLA accredited some 1336 laboratories. In four short years, laboratory enrollment had grown over 400%-- mostly in response to the newly promulgated CLIA regulations which required regular oversight of all laboratories. Many of our client laboratories were reluctant. Our challenge was to make these laboratories first understand what was important, and second to understand how to do it.

We currently accredit 7200 laboratories in 50 states as well as some international labs. We field 16 surveyors who survey an average of 200 laboratories per year, per surveyor. It is important to note that all COLA surveyors are employees of COLA. COLA does not run a Proficiency Testing program and does not operate a consulting service.

Again, I thank you for inviting me here today and I want to tell you that this is a real opportunity for COLA and others to more closely study the issues. Clearly, patient safety is a driving force as amplified by some highly publicized breakdowns. A number of improvement mechanisms have been suggested, including those by Representative Cummings. We have heard you and we are studying the issues. We are in the quality improvement business and we expect our clients and ourselves to commit to continuous quality improvement. We are improving everyday. We are looking at ways to instill continual readiness in all our laboratories. However, we must be vigilant to ensure that we do not disrupt patient care and that we maintain convenient access to critical laboratory services.

During the course of this study, we responded to numerous written and verbal inquiries from the GAO and performed several in-depth data analyses. As COLA assisted the GAO in this effort, we welcomed the critical, but focused examination of CLIA oversight, and we used the process to discover opportunities to improve our accreditation program. We believe that the GAO did an admirable job in performing this complex assignment. We think that GAO staff will acknowledge this difficulty in assessing such a unique public/private partnership. I am pleased to share with you that we agree with a number of the GAO's finding and recommendations and I look forward to discussing those with you now. I will also touch on a few areas of the report that we found troubling. This report reinforces and validates for COLA many of the guiding principles

that were used to design the most widely used laboratory accreditation program in the United States.

Agreement

As I noted, we agree with a number of the GAO's findings and recommendations. It was not difficult to find agreement, as COLA has employed these recommendations for years.

We wholeheartedly agree that education to improve lab quality should not preclude the identification and reporting of deficiencies that affect lab testing quality. We also believe that phase-in requirements are absolutely appropriate.

Education is a critical component to the reasonable and appropriate implementation and enforcement of laboratory performance requirements. COLA believes that such an educational approach is essential to the desired outcome of real improvement in laboratory performance and to prevent the continuation of deficiencies across inspection cycles. Education is essential to the improvement process as it empowers laboratories to meet or exceed the minimum expectations. COLA takes its enforcement responsibilities very seriously, and we are proud of our consistent track record in the appropriate enforcement of CLIA. The GAO is absolutely correct that COLA begins educating laboratories upon enrollment in our accreditation program. This approach

yields meaningful improvement-based interactions with our accredited laboratories over the course of their two-year accreditation period. The onsite inspection is but one aspect of the program. As we described to the GAO during the course of its examination, we continually monitor laboratory performance on Proficiency Testing, and we regularly communicate with and educate laboratories—before and after an onsite survey.

COLA's comprehensive surveyor training program, in conjunction with individual surveyor exposure to hundreds of laboratories yearly, provides the COLA surveyors with a unique opportunity to share their knowledge and experience during a laboratory's onsite survey. It has always been the goal of COLA's Accreditation program to bring laboratories, particularly the smaller Physician Office Laboratory with its less experienced staff, into compliance with the law by a combination of approaches that identifies the deficiencies present and shares with the lab the correct way to assure quality patient testing. COLA then follows up on the identified deficiencies and requires an evidence-based response from the laboratory before their accreditation is approved or continued. COLA cites ALL problems in the lab.

COLA exists to help improve laboratory medicine and patient care- the primary tenets of which are lasting improvement mechanisms and quality systems generated by committed, informed, and prepared laboratory directors and staff. CLIA's intent is to improve the quality of laboratory testing. As new technologies emerge and laboratory

testing evolves, it is more important than ever that the industry understands the principles of quality laboratory testing and apply them correctly.

We agree that laboratories should provide lab workers with instructions on how to file anonymous complaints—and that as an approved survey organization, we expect laboratories to act accordingly.

COLA takes complaints very seriously and actively investigates all complaints. We require laboratories to post instructions to lab workers on how to file an anonymous complaint. However, we do not think that simply knowing how to file an anonymous complaint is THE single solution for bringing laboratory problems to light. We require laboratories to have their own protocols for handling problem issues and we encourage laboratory leadership to solicit input from personnel.

We agree that unannounced inspections in the smaller lab are disruptive and unworkable.

The GAO is correct in concluding that unannounced inspections for the smaller lab would not be appropriate. Because these labs are so small and because the medical and laboratory directors often wear many hats, arriving unanounced causes disruption of the laboratory work which in turn reduces the quality of patient care. Also, because

personnel vital to an inspection process may not be present when inspectors arrive, many inspections would have to be postponed and rescheduled. This would undoubtedly contribute to increased costs for accreditation services to labs.

We agree that CMS should be adequately resourced and organized so that it can review and approve survey organization programs in a timely manner.

We have long appreciated the dedication and commitment of CMS staff with whom we have worked so closely over the years. Since 1992, we have spent nearly ten years (off and on) in approval or re-approval discussions. Because we do not implement new requirements prior to CMS approval, these delays can have a significant negative impact on survey organization flexibility. We agree that where possible, CMS should make whatever structural changes necessary to ensure that survey organization programs and requirements are approved expeditiously and always prior to the expiration date of current approval. We look forward to working with CMS to improve this process.

And most importantly, we agree with the assertion that survey organizations (including CMS) should employ trained surveyors and assessors who perform consistent surveys.

The report specifically mentions surveyor training and consistency of assessments as key factors to a strengthened laboratory oversight system. COLA is proud of its significant and extensive surveyor training program and our high level of inter-rater reliability.

When CLIA was enacted, there were many problems that have since been rectified. COLA, as the first CLIA-approved accrediting organization, was designed to promote quality improvement and excellent patient care through an interactive approach, effective enforcement, oversight and education. When the CLIA regulations were promulgated, many laboratories were unfamiliar with the concepts of "quality assurance," "quality control," and "proficiency testing." We committed ourselves to a program of comprehensive surveyor training, coupled with consistent, efficient survey methodologies to instill a culture of quality in our accredited laboratories. COLA's surveyors, all of whom are employed by COLA, are cross trained in multiple laboratory disciplines, quality systems, and more importantly, communications, conflict management, investigation, and root cause analysis techniques.

We utilize results of validation surveys to see how the citations given by our surveyor match those given by another. We look for patterns in these validations that may indicate weakness in a particular area.

Again, we agree with these finding and recommendations and are proud that the GAO recognized these items (already implemented by COLA) as best practices for the industry.

Disagreement

However, as we noted in our comments on the GAO report itself, while the GAO argues that data on laboratory improvement are misleading, we are confident that laboratory quality has improved since the promulgation of CLIA regulations in 1992. Also we disagree with any suggestion that education and enforcement are mutually exclusive. We feel that enforcement can successfully be coupled with education so that laboratories can learn what tools they need for compliance. Furthermore, the GAO's findings draw conclusions regarding notice for onsite inspections and overall laboratory preparedness that run contrary to a quality improvement philosophy. For this reason, COLA has expressed to the GAO and others serious reservations over the use of unannounced laboratory inspections—especially in the smaller laboratory environment.

Laboratory Quality has Indeed Improved

We disagree with the GAO's assertion that laboratory quality may not have improved. COLA now accredits more laboratories than it has in the past 10 years. We are

delighted to see our roles of accredited laboratories filled by conscientious, quality-minded laboratories.

Data that COLA provided the GAO (but not used in the draft report) show that, in general, condition-level deficiencies declined in laboratories that have been surveyed over multiple years. We view this as evidence that the quality of laboratories subject to continual and regular oversight has improved.

We were disappointed that the GAO seemingly discounted the improved Proficiency Testing performance by COLA-accredited laboratories and further intimated that overall laboratory quality has not improved. The percentage of COLA laboratories that fail PT has decreased. COLA is vigilant in the continual monitoring of Proficiency Testing performance by our laboratories. We educate laboratories on how to remedy Proficiency Testing problems and ultimately on how to ensure that all tests are performed in a controlled and analytically sound fashion. COLA is proud of the fact that our program is having a positive impact on laboratories and on patient care.

Education should not be confused with lack of accountability

We disagree with the GAO's assertion that education and enforcement are mutually exclusive. While COLA laboratory inspections are highly educational, we enforce 100% of our [CMS-approved] accreditation requirements]. Many federal requirements in many

regulated industries are "phased-in" in order to allow regulated entities the time to understand and effectively implement the requirements. There is little benefit to the laboratory and no benefit to public health and safety for the establishment of expectations that laboratories cannot meet.

Laboratory Preparation

We disagree with the GAO's assertion that allowing a laboratory to prepare for a survey masks the discovery of laboratory problems. We know of no research that would support such a conclusion.

While much of a laboratory's evidence of compliance is documentary, there is little of this evidence that can be fabricated in a short period of time. More importantly, I believe the vast majority of laboratory professionals are dedicated to providing the highest quality patient care possible and therefore would not falsify records. Personnel qualifications, root cause analyses of "out of limit" Quality Control (QC), failed Proficiency Testing, the release of patient results when QC is out of limits, incorrect frequency of Quality Control, the use of expired reagents, proper specimen identification, proper report elements - are all virtually impossible to create retrospectively after a survey is scheduled.

Clearly, laboratories that "fix" or complete records immediately prior to an announced onsite inspection (an example used in the GAO report) have critical management and

laboratory operations issues. Our surveyors are trained to spot these problems as well as others that may arise when a laboratory attempts to "fix" documents or data just before an onsite survey.

Documentation is only one part of the onsite assessment. The qualitative, interactive assessment of the laboratory, coupled with the ongoing participation in proficiency testing, provides COLA with a more accurate picture of the overall quality of the laboratory.

Conclusions

To conclude, as we noted in our comments to the GAO, we are very pleased with the many accomplishments of the CLIA program and COLA's accreditation program in particular in improving laboratory quality over the years. Generally, quality of laboratory testing can be measured in two ways: 1) by evaluating quality of laboratories and providing resources to assist them to correct deficient practices; and 2) by preventing laboratories that do not meet quality standards from continuing to provide clinical laboratory testing. We are appropriately achieving these outcomes.

In the past few years we have:

- Invested in an industry-leading Enterprise Information Technology platform that we are confident will further improve laboratory oversight operations as well as individual laboratory efficiency.

- Worked to establish new accreditation requirements that raise the bar.
- Challenged laboratory directors to be more involved.
- Enhanced our industry-leading surveyor training program. COLA's employee surveyors participate in three weeks of continuing education on technical issues, survey and investigative techniques, and communication skills each year.

We have seen improvement and are proud of the strides we have made, but that doesn't mean that we don't look ahead and raise the bar. Our paramount concern is the provision of excellent patient care through meaningful standards and quality improvements.

Thank you for inviting me to share my insights today. I look forward to your questions.

Mr. SOUDER. Dr. O'Leary, in his statement, said that one thing he believed that GAO overlooked was the pressures on kind of the increasing sophistication of what is needed in lab technicians and the supply of well-trained people. Do you—Dr. Soderman and Mr. Beigel, do you agree with that?

Dr. SODERMAN. There is a shortage of medical technologists, and there has been a decreasing number of training programs in medical technology for a number of years that, in fact, is resulting in a decreasing pool.

I would certainly agree with Dr. O'Leary in terms of the complexity of laboratory testing is certainly increasing and requires additional skills; however, built into the CLIA laws are very extensive competency testing requirements that through the accreditation program, we assure that those laboratories are completing that competency testing on individuals. And we think that supports the fact that the work force out there is a good work force, they know what they're doing, and they are getting the proper oversight to assure that they are performing appropriately.

Mr. SOUDER. Mr. Beigel.

Mr. BEIGEL. Yes. I agree with Dr. Soderman. Essentially, 80 percent of the laboratories, maybe a little bit more than 80 percent of our laboratories that we accredit are smaller laboratories, more in the physician office laboratory environment, one or two, three physician offices service that office. They are allowed, under CLIA, to have individuals that may not be medical technologists, depending upon the complexity of the testing conducted. So far, we have not seen a direct impact on the quality of laboratory testing, but this is a significant shortage. And we are projecting that shortage will have a significant impact in the years to come.

Mr. SOUDER. Is part of the shortage—I assume you haven't seen increases in Medicaid and Medicare reimbursement. Could you discuss what kind of—in these labs, what percentage of this is paid for by the government, and how does the tightness of and the pressures from private sector and insurance companies as well as the Federal Government on the cost pressures intersect with what you just described as the potential shortage or declining number of people at the entry level to the testing system?

Dr. O'Leary.

Dr. O'LEARY. Well, this is primarily a pipeline problem. You know, you have seen large numbers of 4-year med tech schools close. And so you have an aging work force of people, and now that gap is filled with 2-year tech trainees. And the CLIA requirements are not very stringent. In fact, if you want to perform waived testing, you just need to be a high school graduate or less. And I think that is where we have pipeline problems on the one hand, and now the inability to get the people, the temptation is going to be to get anybody who you can. And I think all of us, the fact is we are dealing with more complex testing generally in a wider array of tests. And if you match that against people of, you know, lesser training and, you know, competency, I think that is probably a disaster waiting to happen.

I'll just comment that when I went to the IQLM meeting about, I guess, 2 years ago, I raised a concern because we, for the first time, were seeing laboratories conditionally accredited or losing

their accreditation or bringing their hospitals down, I had never seen that before. And in the past 2 years, we have had nine hospitals go down because their laboratories lost their accreditation. And we have this 42 laboratories and hospitals conditionally accredited, we have never seen that before.

When I raised that question, all the people I talked to traced that to the quality of personnel issue. There wasn't even anything in second place. I think we've got a problem.

Mr. SOUDER. I don't want to jump to a conclusion, but probably not a lot of these were suburban hospitals?

Dr. O'LEARY. They were all kinds.

Mr. SOUDER. So this pressure wouldn't be just urban or rural, it is everywhere?

Dr. O'LEARY. It is everywhere.

Mr. SOUDER. Because one of the things that keeps many hospitals floating are private pay patients where they can be charged more. And to the degree you have HMOs, to the degree you have insurance plans and to the degree you have Medicaid and Medicare, I am trying to sort out how much of this is a reimbursement question.

Dr. O'LEARY. I don't think it is.

Mr. SOUDER. Why would the pipeline then be declining if there was adequate pay incentive for people to enter into the field? Has there been some kind of a shift?

Dr. O'LEARY. I don't know why this has become a less attractive profession. There are a lot of other dynamics going on in our society that people that didn't used to go into healthcare that go on to other walks of life today, and I think that is very real. So I cannot explain why we have seen this shrinkage in the medical technology field, but we do observe that it exists.

Mr. SOUDER. Because almost every medical group that comes into my office will tell me that they are looking at a decline in their field because of——

Dr. O'LEARY. Right, I understand that.

Mr. SOUDER [continuing]. Because the declining rate of income is what the general argument is.

Now, the nursing profession is slightly different because there is also shifting of opportunities for women, for example, historically that haven't been there in addition to the cost pressures and the other types of pressures on the system, and I was trying to sort out where the technicians are here.

Part of this whole decision here—I always think of the—Bill Cosby did a routine years ago—in fact, it was on an LP, which shows you how long ago it was that I heard this—about that he is in an operation and the doctor goes woops. And he goes, wait a minute; I know what it means when I say woops, what does it mean when the doctor says woops? And this is ultimately so critical in your area. We can't have really woops in a diagnosis of whether you have HIV, whether you have cancer, whether you have any one of any number of diseases, whether you are diabetic, oh, nope, you're not. Oh yeah, you are, that we can't have this kind of—this is the fundamental entry point of really everything else in medicine.

Dr. O'LEARY. I totally agree.

Mr. SOUDER. And the question is, if a fundamental problem here is the quality of service and trying to measure the quality of service, then in looking at the quality of service, we have kind of egregious errors and kind of second tier errors. And as I used the example earlier of restaurants, it's one thing if you don't have the ketchup bottle top on and it's another if you have meat that's been exposed and you get poisoning from it.

In the pipeline that you're talking about, if there is a shortage of people and you start bringing in people, which type of errors are you getting? Both. Is there a way for us to—and this gets to the education question, because if you are accelerating people coming into the system and you don't have a sufficient supply, the education component almost becomes on the oversight function, which isn't necessarily where you want it to be. And at the very least, we would hope that the oversight function would be kind of the ketchup-bottle type questions, not on whether you have turned the labeled around or whether you have mishandled the labels or got kind of fundamental errors in diagnosis or exposure of what was a lab test.

And in trying to sort through, that's kind of what was behind my question of starting out with the supply question, because how we deal at the end of the day with the bigger questions here of how much is education, how much is enforcement, how common can you have the standards, how do we determine what's egregious is really an underlying assumption of your work force.

Dr. O'LEARY. Let me just comment. First of all, I would be surprised if this is strictly a salary issue. I will tell you, in the nursing arena, if you don't fix that working environment, you are not going to have any nurses. And that has been studied——

Mr. SOUDER. Mandatory overtime.

Dr. O'LEARY. Right, mandatory overtime is a great case in point. So I think we need to get underneath this problem and figure out exactly what is going on. In the data base that we maintain, there are clear correlations between numbers of staff and competency of staff and the frequency of adverse events. There's no question about that. We don't have a lot of laboratory events in our data base, but just across the general hospital, if you don't have enough people and they are not properly trained, you get bad accidents.

Dr. SODERMAN. The problem that exists, Mr. Chairman, is the problem between regulatory and individuals to do the testing. If we tighten the regulations very high, we drive individuals out of the process. If we implement very strict licensing requirements within the States and control of how those individuals are used, we reduce the manpower that's the work. We have to utilize the tools that we have.

Yes, we need more medical technology schools, we need a greater investment by the Federal Government in those schools to allow that to develop to give us the personnel. In that interim, filling that pipeline is going to take years because it's taken years to close it, it's going to take years to open it. We have to find tools that we can use the individuals that are already in our laboratories to successfully do the testing and assure the competency that they have. I am not sure that can be—needs to be regulated more than it is regulated under the CLIA rules already.

Mr. SOUDER. Mr. Beigel, do you have any comments?

Mr. BEIGEL. I will speak maybe to the smaller laboratory environment.

I think that it's a real different situation that's being posed in the small laboratories. And it may affect patient care in some degree. Certainly, laboratory manufacturers have recognized the fact that labor shortages are going to come down the pike. I think the issue that they have done, then, is created a lot more instrumentation that will go under the waive category, so the laboratory test that you may see now at your point of care sight at your doctor's office, you may need to go to a reference lab to get your test done. So I think it will eventually have that kind of effect. We are seeing that now. Certainly in the CLIA data, you will see that a percentage of waived testing has significantly increased over the last 10 years, and I believe that is going to—that trend is going to continue, primarily driven by the fact there won't be qualified personnel in the physician office to be able to conduct the test appropriately.

Mr. SOUDER. Mr. Cummings.

Mr. CUMMINGS. Dr. Soderman, initially I think CAP expressed some concerns about the unannounced visits. And apparently it sounds like there may have been a change of heart here. Can you explain to me, and I may be inaccurate, but what is your—how did you come to the conclusion that unannounced visits might not be a bad idea?

Dr. SODERMAN. Our reservations were mostly how we were going to implement the process. It is not easy to take the number of labs that we accredit and assign teams to do that and turn it into an unannounced process. And I think our initial concerns were, how are we going to do this? Over this last year, we have worked at developing the policies in our accreditation program that will allow us to do that. With the implementation—final implementation in July, almost 100 percent of the laboratories will be unannounced.

Now, if you think about what it takes, it means that an accreditation team has to be put together, they have to be moved to that community. So you have to have hotels, motels, you have to let that team know what the expectations are at that site, and you have to assure that nobody on that team makes any contact whatsoever with the site that they are being inspected.

Our unannounced process does not allow a 2-week notice, it does not allow a 1-hour notice, we walk in unannounced. And it is the orchestration of that process that has taken us this last year to try to get implemented. We believe we have it in place now. We've been doing some pilot unannounced accreditation inspections over this last year to test this out, and we are ready to march ahead.

Mr. CUMMINGS. The whole issue of whistleblowers, Mr. O'Leary, do you think whistleblowers are very important in your industry?

Dr. O'LEARY. They sure are. We actually have a whistleblower protection provision in our requirements.

Mr. CUMMINGS. And how does that work?

Dr. O'LEARY. Well, if there is any evidence of—this is what we call a condition of participating in the accreditation process. So it's as bad as falsifying information. So if somebody blows the whistle

and there is evidence of retaliation, they can lose their accreditation just flat out on that basis.

Mr. CUMMINGS. And what about you, Dr. Soderman?

Dr. SODERMAN. The college has the same policy, in fact. If there is any retaliation against a whistleblower, their accreditation is immediately pulled.

We do believe in the whistleblower. We have developed posters, we have developed a route in which only two individuals at the college know the individual that calls in to assure that there is confidentiality maintained on this process.

Mr. CUMMINGS. So since you established—what about you, Mr. Beigel?

Mr. BEIGEL. We take whistleblowers very seriously, always have. We consider it a complaint against the laboratory. Some of the complaints come in anonymously, and obviously we don't know who that individual is, it could be a patient, it could be an employee of the laboratory, it could be a current employee, it could be a past employee, don't know. If the complainant does give us their name, it's held in strict confidence, it's not shared with anyone at the lab, it's not shared when we report the complaint to CMS who the complainant is. We consider it exceptionally serious.

Mr. CUMMINGS. Dr. Soderman, you found that there's been an increase in complaints; is that right, since you did this signage thing?

Dr. SODERMAN. Yes. Our complaint rate has doubled. And I suspect it's going to even go up and above that as we've made available to the laboratory technologists and technicians and pathologists and to the inspection teams themselves the ability to call in and express their concern about the accreditation process or a process that's taking place within the laboratory.

Mr. CUMMINGS. Because we are running out of time, I'm just going to ask one other thing.

You know, CMS makes a big deal of this standardized—some kind of standard—I'm sorry, GAO—by which they can—all the labs are being held to—I know we've got the CLIA standard, but apparently they feel clearly that there is more needed to be done. How do you all feel about that, how do you see accomplishing that? Dr. O'Leary.

Dr. O'LEARY. Well, as I said in my testimony, we don't think it is practically accomplishable the way the GAO has framed it. We need a common terminology and understanding as to what a serious deficiency is, and that is the development of a taxonomy. Mr. Hamilton spoke to that, we are very supportive of that. We think it is doable, we think it answers the need.

Mr. CUMMINGS. You, Dr. Soderman?

Dr. SODERMAN. I would agree with Dr. O'Leary. If we can get down the same terminology. As he expressed in his discussions early on, there are differences between how we approach inspection of laboratories, and it's important that differences be allowed. At least the base standards have to be similar. So we ought to be able to communicate when those base standards are failed.

Mr. CUMMINGS. Let me just—Mr. Beigel.

Mr. BEIGEL. I absolutely agree.

Mr. CUMMINGS. One of the things that was very interesting in the Maryland General case is there was an issue as to machinery

not working properly, and that the—and the allegations were that key people knew the machinery wasn't working properly and were not disclosing the information, not correcting the machine. And it seems to me that is the kind of thing that no matter how you look at it should send all kinds of red lights flashing, no matter how you all do what you do. Is that accurate? Would that be an accurate statement? In other words, if you knew that there was a machine not properly doing what it is supposed to do, knowing that—not knowing, but strong allegations that it probably was giving false readings, and that people who knew this were holding back information, I mean, would that kind of thing cause you all to say wait a minute, this is—if this is true, you've got a major problem?

Dr. O'LEARY. Maryland General's situation is a horrible situation. There were so many things wrong with that picture and so many lessons to be learned out of it. I mean, we have an unusual situation in this situation because we accredited the hospital in which the laboratory existed. So in that case, for us it was a failure in—it was a failure in communication. Now, we can blame people for not communicating with us, but we had an obligation to create the mechanisms to assure that communication happened. And we now have that in place, and we would not have had that in place without Maryland General.

So I hope that we will harvest some important lessons out of the Maryland General situation because it was—you know, the communication problems were really horrible, probably the worst—I think the worst part of that whole situation.

Dr. SODERMAN. One of the interesting aspects of the college program is that we send in, as part of the team, medical technologists and pathologists that are actively working in the laboratory. Our hope is that these individuals will interact and appeal to peer relationship and hopefully uncover problems like this. The real key in the inspection process is to get the inspector in front of and at the work bench, and not have their nose constantly in paperwork that may reflect past experiences or results of the test, but an active dialog with the individuals in that laboratory. Because there is a greater chance of in that dialog, they will share information that is critical to give us some idea of what the real performance is within that lab.

So one of the keys that we have learned from Maryland General is you not only have to go in there and inspect the paperwork, but we recognize that there are hundreds of thousands of pieces of paper at any time you inspect a lab, we can't inspect every one. It is that personal one-to-one relationship that is the real key in successfully inspecting.

Mr. CUMMINGS. I have some followup questions. Thank you, Mr. Chairman. I will send them to you in writing.

Mr. SOUDER. Thank you. And one of the challenges, just like we went through this machine question and the company then said the whole succession of employees didn't know how to operate the machine, given what you said about what is likely to be happening in the workplace, the bottom line is if you have a whole group of employees who say they can't work the machine, it's real irrelevant whether it's the machine or the employees because we are headed into that type of determination.

Thank you for your testimony today. We look forward to continuing to work with you. And please stay in touch with us as any legislation may evolve and the regulations may evolve. With that, the subcommittee stands adjourned.

[Whereupon, at 4:26 p.m., the subcommittee was adjourned.]