

The SPEAKER pro tempore. Under a previous order of the House, the gentleman from New Jersey (Mr. PALLONE) is recognized for 5 minutes.

(Mr. PALLONE addressed the House. His remarks will appear hereafter in the Extensions of Remarks.)

#### CLINICAL LABORATORY COMPLIANCE IMPROVEMENT ACT OF 2005

The SPEAKER pro tempore. Under a previous order of the House, the gentleman from Maryland (Mr. CUMMINGS) is recognized for 5 minutes.

Mr. CUMMINGS. Mr. Speaker, today I am introducing the Clinical Laboratory Compliance Improvement Act of 2005, legislation to improve accuracy and reliability in medical testing and provide protection for employees who report laboratory problems to their superiors or regulatory entities.

Medical laboratory testing is a fundamental pillar of our Nation's health care system. Virtually every American undergoes testing in the course of receiving medical care and relies on the accuracy of laboratory tests to receive appropriate medical care and treatment. Incorrect test results in the worst case can contribute to a misdiagnosis that leads to inappropriate care and possible adverse health consequences for the patient. In the best case, incorrect or invalid results can lead to undue stress and inconvenience.

Inaccurate testing for communicable diseases can pose a serious threat to the public health. In May and July of 2004, the House Subcommittee on Criminal Justice, Drug Policy and Human Resources of the Committee on Government Reform held hearings to investigate lab deficiencies that led to the release of hundreds of invalid test results by the Maryland General Hospital located in my district in Baltimore City. I requested the hearings as the subcommittee's ranking minority member, and with the cooperation and support of the distinguished chairman, the gentleman from Indiana (Mr. SOUDER), the subcommittee conducted the hearings on a strictly bipartisan basis.

During the hearings, the subcommittee received testimony from Teresa Williams and Kristin Turner, two former laboratory employees who complained to superiors and State health officials about serious, long-standing deficiencies in the lab, including failure to implement quality controls on a diagnostic device used to read tests for HIV and hepatitis.

Officials from the Food and Drug Administration and the Centers for Medicare and Medicaid Services, responsible for implementing Federal regulations governing medical diagnostic devices and laboratory operations, respectively; the former chief executive of Adaltis US, Inc., manufacturer of the device used to run the invalid test; the College of American Pathologists, a private accrediting organization responsible for certifying the labora-

tory's compliance with Federal and State regulations on behalf of CMS and the State; and the Maryland Department of Health and Mental Hygiene all testified.

It was Ms. Turner's complaint in December 2003 that triggered investigations by the State CMS, the Joint Commissioner on Accreditation of Healthcare, JCAHO, and CAP, between January and March. The investigations confirmed Ms. Turner's allegation that during a 14-month period between June 2002 and August 2003, Maryland General Hospital issued more than 450 questionable HIV and hepatitis test results to hospital patients.

During this time period, the hospital laboratory was inspected and accredited for 2 years by CAP, receiving CAP's Accredited With Distinction Certificate. Despite an earlier anonymous complaint by Ms. Williams and several colleagues, the State also was unable to identify the problems, and serious deficiencies in two key departments of the lab went undetected by CAP and the State until January of 2004.

In Spring of 2004, inspectors from the States' EMS and JCAHO concluded that the laboratory staff had falsified federally required instrument quality control results and reported patient results even though quality control checks had failed. Learning of the problems by way of news reports, CAP conducted a complaint inspection in April, found similar deficiencies, and suspended accreditation of the lab's chemistry and point-of-care departments for 30 days.

To its credit, Maryland General Hospital conducted its own internal review and vigorously undertook efforts both to retest the affected patients and to revamp the lab's leadership and operations.

Fortunately, retesting verified the accuracy of the overwhelming majority of tests, and Maryland General has made enormous strides in improving its lab operations so that patients receive results that are accurate and reliable.

Nevertheless, Mr. Speaker, this is a situation that caused great distress to the community that the Maryland General serves.

I should note that I live in that community, and I have received care at Maryland General Hospital. This is a situation that could have put lives in jeopardy and one that simply should never have occurred, given the regulatory safeguards that exist to ensure quality testing.

Congress recognized the importance of ensuring that all Americans receive accurate diagnostic test results when in enacted Federal Standards for Medical Laboratories under the Clinical Laboratories Improvement Amendments of 1998, now known as CLIA. Under the CLIA, the Centers for Medicare and Medicaid Services were charged with developing and implementing regulations to ensure that all labs conform to strict Federal guidelines.

CMS directly inspects some labs to ensure CLIA compliance and State health agencies are responsible for inspecting and certifying the compliance of others. In addition, pursuant to CLIA regulations and agreements between CMS and the States, clinical laboratories that choose to be accredited by CAP or one of five other private accrediting organizations, are deemed to be in compliance with State and Federal regulatory requirements and can bill for services provided for Medicare beneficiaries.

Mr. Speaker, there is no doubting the fact that CLIA has made medical testing more accurate and more reliable, and surely the overwhelming majority of labs do their best to conform to these high standards. Unfortunately, the Maryland General case clearly demonstrates that not all laboratories will play fair and that the current system does not guarantee that serious instances of noncompliance will be detected or corrected.

Testimony before the subcommittee indicated that in the Maryland General case, laboratory supervisors failed to implement quality control measures and deliberately masked lab deficiencies from inspectors from CAP and the State. Employees who complained were subject to retaliation and intimidation.

#### NO CRISIS IN SOCIAL SECURITY

The SPEAKER pro tempore. Under a previous order of the House, the gentleman from Texas (Mr. GENE GREEN) is recognized for 5 minutes.

Mr. GENE GREEN of Texas. Mr. Speaker, I rise to help dispel the ridiculous myth that Social Security is in a state of crisis.

If you listened to the President at the State of the Union or out on the stump, you have heard the President use words like "broke," "bust" or "bankrupt." Mr. Speaker, Social Security is neither broke nor bankrupt. The program is certainly not in crisis. A crisis is an imminent problem. Yet, while the President cries "crisis," Social Security continues to bring in more than it pays out in benefits.

According to the Social Security trustees, the program will continue to do so for the next 13 years, until 2018, when the trust fund will be tapped to help pay for benefits. Even then the cries of "crisis" would be melodramatic because the money accumulated in the trust fund would be able to provide full benefits for the next quarter of a century.

As a recent Washington Post article put it, calling 2018 a crisis point is "like saying that Bill Gates will be strapped if he works only part-time." Just as Bill Gates has his personal trust fund to draw down, the Social Security trust fund will have more than \$3.7 trillion in it in 2018. If our government is going to pay back the debts we owe to someone in a foreign country that invests in Treasury notes, why