The Heritage Foundation Backgrounder

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CUTTING RED TAPE ON CLINICAL LABS: WHY CONGRESS SHOULD DEREGULATE DOCTORS

INTRODUCTION

While Members of Congress try to reform Medicare and reduce the paperwork burden on doctors and patients, they also should realize that doctors' medical laboratories are caught in a web of government red tape that adds billions of dollars to America's health care costs. This misguided regulatory intervention is based on faulty data; has caused the loss of private, physician-based laboratory testing by thousands of doctors throughout the United States; and has compromised patient access to timely, high quality care for millions of Americans. To eliminate unnecessary regulation of the health care sector of the economy and improve both the productivity and efficiency of patient care, Congress should eliminate the burdens imposed on doctors by the Clinical Laboratory Improvement Amendments of 1988. This can be done easily within the broader context of Medicare reform.

The Clinical Laboratory Improvement Amendments of 1988 (CLIA) constitute the nation's most sweeping regulation of physician-based laboratories. Under CLIA, doctors must submit to regulatory requirements for the simplest and most common tests used in the routine treatment of patients, including tests for pregnancy and strep infections. According to the Health Care Financing Administration (HCFA), the U.S. Department of Health and Human Services (HHS) agency that administers Medicare, Medicaid, and CLIA, implementation of CLIA adds between $1.2 billion and $2.1 billion annually to the cost of performing clinical laboratory tests in doctors' offices.[1] To the extent that they are aware of them at all, most taxpayers probably think laboratory regulations affect research centers, hospitals, or other facilities staffed by white-coated researchers in ster-

1 "Archer Bill To Reduce Doctor Paperwork, Patient Costs," *News from Congressman Bill Archer*, April 4, 1995.

ile rooms filled with exotic equipment. CLIA applies to these entities, but it also reaches into the two-room doctor's office in New York's central Harlem and the private practice of an internist in Ames, Iowa. As Representative Bill Archer (R-TX), Chairman of the House Ways and Means Committee, has noted:

> The CLIA restrictions have caused thousands of physicians to discontinue all or some portion of essential clinical laboratory testing in their offices. This creates a barrier to patient compliance with diagnostic treatment protocols and causes patient inconvenience. For example, for many tests a patient must be referred to an outside laboratory to have a specimen taken and tested. This poses a substantial hardship for many patients, most notably the elderly, the disabled and families who live in underserved areas. Often times, these patients cannot travel or find someone to take them to these facilities. The result is that they do not obtain the necessary testing.[2]

Doctors and hospitals must struggle with mountains of government-generated paperwork to comply with thousands of pages of rules, regulations, and guidelines promulgated by the Health Care Financing Administration.[3] As Congress debates Medicare's future, particularly how to ensure its financial solvency and stability, it also must address the impact of these rules and regulations on doctors, hospitals, and private medical practice. Though responsible for only a part of this paperwork burden, CLIA's impact on private medical practice has been significant. Not only is it costly; it has lowered the quality of patient care by causing unnecessary changes in office practice: inconvenience for doctors and patients alike, decreased patient access, and diagnostic delays.

In recent years, Members of Congress have begun to rethink CLIA. For example, Representative Archer and Senator Kay Bailey Hutchison (R-TX) have introduced legislation to correct CLIA's excesses. Representative Archer's Clinical Laboratory Improvement Act Amendments of 1995 (H.R. 1386) would exempt physicians' office laboratories from CLIA rules. Senator Hutchison has introduced similar legislation (S. 877). To reform the American health care system, especially the bureaucracy that runs federal health programs, Congress should lift this unnecessary burden on the expeditious delivery of high-quality health care.

THE ROOTS OF LAB REGULATION

CLIA is rooted in congressional deliberations almost thirty years ago. When Wilbur Cohen, Secretary of the U.S. Department of Health, Education and Welfare (HEW), and Dr. D. J. Sencer, Director of the U.S. Public Health Service's Communicable Disease Center, appeared before the House Committee on Interstate and Foreign Commerce on May 2, 1967, they testified that the error rate in laboratory testing was as high as 25 percent. Secretary Cohen's testimony also included a sensational case of a woman who lost her breast because of a lab error that occurred in 1936.

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2 *Ibid.*

3 For an account of the bureaucratic and regulatory burdens of the Medicare program, see John C. Liu and Robert E. Moffit, "A Taxpayer's Guide to the Medicare Crisis," Heritage Foundation *Talking Points*, September 27, 1995, pp. 13-14.

Dr. F. William Sunderman, noted pathologist and father of the quality control methodology known as proficiency testing,[4] challenged Dr. Sencer's testimony. Along with other noted pathologists, Dr. Sunderman questioned the statement that "erroneous results are obtained in more than 25 percent of all tests analyzed." Dr. Sencer responded but included no timely supporting data, except for the results of analyses done by Dr. Sunderman himself 22 years earlier in 1945,[5] before the laboratory profession voluntarily began to conduct proficiency testing.

Based on the archaic data presented by HEW (predecessor of today's HHS) and fueled by the political intervention of Senator Jacob Javits (R-NY) and a front-page story in *The New York Times*, Congress passed the Clinical Laboratory Improvement Amendment of 1967. Members of the professional medical community protested. Twenty-two pathologists submitted refuting testimony, delineating numerous technical errors in previous HEW testimony, but to no avail.[6]

In 1980, Dr. Joseph Boutwell, Deputy Director of CDC's Bureau of Laboratories, charged that there was a 14 percent error rate in some of the most commonly performed medical tests. Dr. Boutwell eventually admitted his estimates were much too high,[7] but no anxious reporters were waiting to publish the CDC's retraction of the misleading data. The damage had been done. Boutwell's error laid the foundation for a governmental grip on laboratory and medical practice that became increasingly stifling as the 1980s came to a close.

Twenty years after CLIA '67, in 1987 and 1988, federal regulation of laboratories again surfaced with naive and sometimes sensational articles in the *Wall Street Journal*, *New York Times*, and *Ladies Home Journal*. A February 1987 *Wall Street Journal* article, "False Negative: Medical Labs, Trusted as Largely Error-Free, Are Far from Infallible," by Walter Bogdanich began, "It was 4:30 a.m. when cancer finally choked the last breath of life from Janice Johnson. She was 34 and the mother of two, and she died never knowing why her disease had been so unforgiving." Describing this and several other negative outcomes of laboratory error, the story railed against the lack of government regulation of laboratories, focusing on Pap Smears and shopping mall cholesterol screening. Members of Congress held a frenzy of media-oriented hearings. Senator Brock Adams (D-WA) called as a witness a woman who had cancer of the cervix, but an expert reviewer of a preceding malpractice suit indicated that no laboratory error was involved.[8] Unfortunately, no HCFA or CDC witness ever acknowledged that "not only did they already have jurisdiction over the so-called Pap mills, which they did under CLIA '67, but also that they could have closed any one of them at any time if they elected to do so."[9]

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4 Proficiency testing is a technical method for "testing" samples performed in the lab or physician's office and sending the results to a second lab, where they are compared to a standard.

5 F. William Sunderman, "The History of Proficiency Testing/Quality Control," *Clinical Chemistry*, Vol. 38, No. 7 (1992), pp. 1205-1209, esp. p. 1208.

6 *Ibid.*, p. 1208.

7 "CDC Official Admits Mistakes in Report on Lab Result Errors," *American Medical News*, May 5, 1980, p. 3.

8 "Clinical Chemistry Forum: Discussion Session I," statement by Dr. William Hamlin, College of American Pathologists, *Clinical Chemistry*, Vol. 38, No. 7 (1992), pp. 1218-1228, esp. p. 1223.

9 *Ibid.*

The federal regulatory locomotive steamed along with unrelenting speed, and Congress passed CLIA '88. Pamela Nash, Director of Governmental Affairs for the American Association of Clinical Chemists, called it "legislation by anecdote, not by overwhelming evidence, and not by an understanding of this very complex and technical field."[10]

The scope of CLIA '88 is daunting. It includes not only the 13,000 laboratories regulated by CLIA '67, but also an estimated 100,000 to 150,000 physician office labs. CLIA's real significance, however, lies not in its numerical reach, but in its jurisdictional impact. For the first time, Congress established federal authority to regulate the practice of medicine, and the regulatory regime expanded dramatically. Sponsored by Representative John Dingell (D-MI), the eight-page bill led to 1,600 pages of bureaucratic regulation after a three-and-a-half year gestation period.

Congress gave the Department of Health and Human Services the authority, under CLIA, to regulate laboratory testing tools and procedures employed in a physician's office. The agency responsible for drafting the regulations was HHS's Health Care Financing Administration. Despite the fact that many simple and accurate technologies would qualify for a certificate of waiver because so many of these tests "have an insignificant risk of an erroneous result" or "pose no reasonable risk of harm to the patient if performed incorrectly,"[11] only nine tests were exempt. Moreover, HCFA has not proven to be a model of flexibility in granting waivers. As a result, the same paperwork that is required of the megalabs is required of individual physicians.

Physician laboratories that perform only an occasional test for mononucleosis now must conduct two additional control specimens, tripling the cost of the test. Proficiency testing[12] is required for all tests regardless of where they are performed. The list of regulatory requirements is considerable and has prompted a cottage industry of physician office lab consultants. As Michael Jahn, senior editor of the *Medical Laboratory Observer*, has noted, "With or without extra schooling, CLIA is providing a sizable number of laboratorians with new career options. Nearly one-third of respondents (30%) report that they or a colleague in their laboratory have begun acting as a consultant to POL's (physician office labs) as a result of CLIA."[13] Few busy physicians could keep up with the reams of regulations and the frequent revisions and additions generated by regulators. In a letter to the White House shortly after the regulations were issued, an Iowa doctor poignantly described his dilemma: "I have taken what little time I have and consulted laboratory personnel, laboratory directors in larger hospitals, paid and sent for materials explaining the standards, and spent several thousand dollars in equipping and changing our laboratory to meet many of the regulations that are impacting our office at this time."[14]

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10 *Ibid.*, statement by Pamela Nash, p. 1223.

11 Public Law 100-578, October 31, 1988, p. 2905.

12 See note 4, *supra.*

13 Michael Jahn, "CLIA After Year 1: No Help to Patients and a Hindrance to Labs," *Medical Laboratory Observer*, May 1994, pp. 20-26, esp. p. 22.

14 Letter to White House from a physician in Red Oak, Iowa, September 9, 1992.

The final HHS regulations, drafted by HCFA officials, became effective at the end of 1992. In 1993, however, it appeared that even members of the Clinton Administration recognized that CLIA was an unnecessary burden. Initial drafts of Hillary Clinton's health care reform proposal, leaked in September 1993, would have provided substantial "CLIA relief." But as the health care reform debate intensified, concessions to powerful liberals in Congress led to the unraveling of any CLIA reform efforts on the part of the Administration.

In the meantime, thousands of physicians have closed their simple labs; numerous on-site testing kits and devices, once in the pipeline, have been scrapped; and countless patients have fallen victim to diagnostic delays or, in some areas, to complete lack of access to simple, on-site diagnostic technology. Ironically, though CLIA '88 mandated on-site proficiency testing for technicians interpreting Pap smears—the very problem that generated the legislation—this testing still has not been implemented.

A LAW IN SEARCH OF A PROBLEM

A Personal Observation. One day, after an extended weekend vacation, I returned to my office a little early, knowing that I would be facing a five-day pile of mail. While sifting through test results that had been returned, I came across a positive strep screen. The patient's throat had been only slightly infected, and I had performed a throat culture that was sent out to the reference lab. Had this been 1991, I would have performed a simple strep screen, realized treatment was needed, and sent her on her way, prescription in hand. She had gone untreated for five days, but had not developed rheumatic fever. She was lucky, and I was relieved. Months earlier, we had been advised by hospital laboratory consultants that it would be better to eliminate any test that the CLIA bureaucrats considered "moderately complex" because the cost of complying would be too high. Since we served the poor and the Medicaid population, we knew the projected threefold price increase for doing strep screens under CLIA would be prohibitive. I thought back to my experience in Africa several years earlier. My patients there had access to more on-site testing than patients in my inner-city clinic in 1995. Moreover, my practice was not unique. A January 1994 article in the *Journal of the American Medical Association* indicated that because of CLIA, almost a quarter of all pediatricians had stopped or had planned to stop office testing for strep infections.[15]

The 1988 legislation mandated that five studies relating to the relevance and impact of CLIA be conducted by 1990,[16] two years before the final regulations were issued. One mandate required HHS to examine the validity, reliability, and accuracy of proficiency testing, something physicians' office labs now must perform three times a year, and at considerable cost, for each non-waived test they conduct on-site. Today, proficiency testing is a multimillion-dollar business, with most of the testing performed by the College of American Pathologists. Another mandate required an examination of the "extent and

15 B. Schwartz *et al.*, "Pediatricians' Diagnostic Approach to Pharyngitis and Impact of CLIA 1988 on Office Diagnostic Tests," *Journal of the American Medical Association*, Vol. 271, No. 3 (January 19, 1994), pp. 234-238.

16 "Not later than May 1, 1990, the Secretary shall report to the Congress the results of the studies conducted under subsection (a)." Public Law 100-578, October 31, 1988.

nature of problems in the diagnosis and treatment of patients caused by inaccurate laboratory test results."[17] By the time the final regulations were published in 1992, not one of these studies had even been initiated; HHS officials complained no funds had been allocated. Federal bureaucrats were unwilling or unable to spend a few million dollars to conduct research that might have guided the regulatory pen. Nonetheless, HHS officials had no hesitancy about charging ahead with a final regulation that would cost consumers billions of dollars.

In 1992, after issuance of the final regulation, the *Archives of Pathology and Laboratory Medicine* conducted a literature search to determine the impact of laboratory errors. The "bottom line" question was whether testing errors that occurred in physicians' offices before CLIA '88 resulted in negative health outcomes for patients. The question could not be answered because the data did not exist. Only one hospital-based study even examined the impact of testing errors. Of the 328 patients involved in those incidents, not one was "harmed."[18] No true outcomes data existed for physicians' offices.

In other words, there are no data showing that patients are harmed as a result of testing in the physician's office as opposed to a reference lab. In fact, recent evidence collected by the Ambulatory Sentinel Practice Network (ASPN) suggests that sending specimens off-site for analysis may increase the likelihood of lab error.[19] Consistent with earlier research, the ASPN found that 83.4 percent of lab test-related problems occurred before or after actual performance of the test itself (pre- or post-analytical); 75 percent of all identified problems occurred in tests referred to an outside laboratory. Of the ten problems judged to have a significant impact on patient care, half occurred because specimens were delayed or lost—hazards related to transporting specimens to outside labs. The logical interpretation: Because fewer tests are performed on site, more negative outcomes are likely.

RISING COSTS

CLIA was not supposed to add to America's tax burden, but recent HHS budgets have seen millions of dollars allocated to various agencies for CLIA-related costs. Because physicians and laboratories must assume the many extra costs attached to CLIA, charges are likely to be passed on to working families, adding to the health care cost-shifting they already experience from Medicare and Medicaid. Of course, HCFA officials know this: "The final rule will significantly increase the operating expenses of the nation's laboratory industry—perhaps by as much as 6% per year. Most laboratories will successfully pass on these cost increases to patients and other consumers of their services."[20] Officials felt they could even predict how "willing" the public was to pay the extra costs: "We project that non-poor American households may be willing to pay anywhere from 5 percent to 25 percent more for laboratory services...."[21] At the same time, however,

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17 *Ibid.*, p. 2914.

18 D. Joe Boone, M.D., "Literature Review of Research Related to the Clinical Laboratory Improvement Amendments of 1988," *Archives of Pathology and Laboratory Medicine*, Vol. 116 (July 1992), pp. 681-693, esp. p. 688.

19 Unpublished data from the Ambulatory Sentinel Practice Network, January 1995.

20 *Federal Register*, February 28, 1992, p. 7107.

"many physician offices may see their laboratory costs increase by 10 percent or more—and the cost of an average test rise in excess of a dollar."[22] HCFA's glib analysis reflects government's failure to understand "real world America." With medical overhead costs already running over 60 percent and tens of millions of uninsured unable to pay for basic health care, CLIA has forced tens of thousands of physicians' office labs to curtail their operations or shut down altogether.

Though HCFA officials acknowledged that CLIA would add $1.2 billion to $2.1 billion to America's health care cost burden in 1994 alone, and even more in later years,[23] they failed to account for many other cost factors:

- ✘ **Abrupt changes in practice patterns** and the number of POLs that would cease operation;
- ✘ **The cost of return visits to have test results,** previously often available at the time of the initial visit, explained and a treatment regimen advanced or initiated;
- ✘ **Unnecessary hospitalizations and emergency room visits** when a physician cannot perform certain tests in the office because of excessive administrative and regulatory costs;
- ✘ **Increased morbidity and complication rates** from diagnostic delays and difficulties in notifying patients of serious problems because tests now are sent out and the results not returned until at least the next day; and
- ✘ **The dramatic market shift** that would make this new technology inaccessible.

Yet these officials did not hesitate to impose a multibillion-dollar regulatory burden even though "These cost increases may reduce the ability of certain already-financially burdened providers to deliver services, and of the poor, uninsured, and underinsured to obtain needed care."[24] And they showed no hesitation over imposing substantial administrative "hassles" even though "there exists no irrefutable evidence demonstrating that the clinical laboratories or public health status will improve tangibly under our regulation."[25] Even HCFA officials concede that CLIA rules are expensive. But, given the dramatic change in physician office labs and the testing device industry, it may be impossible to quantify their broad financial impact.

ADDITIONAL PAPERWORK FOR DOCTORS

An ancillary benefit of the national debate on the future of Medicare, the huge and financially troubled government insurance program that covers approximately 38 million elderly and disabled Americans, is that taxpayers finally are learning about the mountain of paperwork generated by this bureaucratic system. According to Nancy Dickey, M.D.,

21 *Ibid.*
22 *Ibid.*, p. 7106.
23 *Ibid.*
24 *Ibid.*, p. 7107.
25 *Ibid.*, p. 7121.

a practicing family physician and Vice Chair of the Board of Trustees of the American Medical Association (AMA), "It has been estimated that physicians now spend over 25 percent of their time processing paperwork and complying with the technical requirements of an unending blizzard of Medicare regulations. This is time that could be used more productively treating patients."[26] This burden has been growing without interruption for many years. In a survey conducted by Louis Harris and Associates on behalf of the Physician Payment Review Commission (PPRC), an independent panel that advises Congress on physician payment in the Medicare program, seven out of ten physicians expressed deep concern over administrative "hassles" and further expressed the view that "red tape" is worse in Medicare than in any other insurance plan, including managed care plans and Medicaid.[27]

CLIA's regulations are making matters even worse, yet there is no evidence additional lab regulations, paperwork requirements, costs, inspections, and proficiency testing improve the quality of medical care. The Texas Medical Association surveyed Texas physicians in 1994 to determine whether they felt CLIA improved quality. Sixty-eight percent said "no," and only 7 percent responded affirmatively. An American Association of Dermatology survey yielded even more striking results: 97 percent of respondents saying CLIA did not improve accuracy and 82 percent expressing the opinion that CLIA "reduced the overall quality of care." These sentiments are not confined to doctors. According to a 1994 survey published in *Medical Laboratory Observer*, "Roughly two out of three laboratorians feel CLIA has failed to improve the quality of patient care and has adversely affected the clinical laboratory profession."[28]

Some professional medical organizations have attempted to help physicians comply with CLIA rules by publishing "How To" manuals. These manuals, often inches thick, describe the tedious documentation required under CLIA. Keeping up can be a full-time job. HCFA's voluminous regulations constantly germinate and spawn revisions, retractions, and additions. The Texas Medical Association analyzed the labor and administrative overhead resulting from implementation of CLIA and discovered that added costs average $10,000 per year per physician office lab site, with one three-person practice running additional costs of $36,000.[29]

CLIA'S IMPACT ON MEDICAL PRACTICE

Taxpayers should realize that, in principle, CLIA '88 represents a profound change in federal policy. It is the first time the government has succeeded in planting its foot in the physician's office to regulate the everyday practice of medicine. This forerunner of government-run medicine should not be dismissed lightly.

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26 Nancy Dickey, M.D., "On the Solvency of the Medicare Program," statement of the American Medical Association to the Committee on Finance, U.S. Senate, May 17, 1995, p. 6.

27 Sharon McIlrath, "Red Tape Doctors' Top Complaint in Medicare Reform," *American Medical News*, October 12, 1992, p. 6.

28 Jahn, "CLIA After Year 1: No Help to Patients and a Hindrance to Labs," p. 20.

29 Texas Medical Association, Health Care Financing Department, Division of Medical Economics, 1995.

Physicians consider testing devices "tools of the trade" in much the same sense as a stethoscope, blood pressure cuff, or thermometer. They use laboratory tests to confirm what they already expect as a result of their clinical judgment. An ophthalmoscope is an instrument a physician uses to look at the back of a patient's eyeball. What the doctor sees there can reveal many things about the patient. In principle, a physician's use of a microscope to look at blood from that same patient should be regulated no more than his use of an ophthalmosscope or a stethoscope. All are tools that allow the physician to develop a more complete picture of the patient. The ironies are innumerable. A dermatologist may inspect a skin lesion with a magnifying glass or under a special fluorescent light (Wood's lamp), but scraping off a few flakes of skin to examine under a microscope is a federally regulated lab activity. But most patient laboratory testing errors are not caused by the testing device or procedure itself (7.3 percent); they are attributable to events occurring before (preanalytic, 45.5 percent) or after (postanalytic, 47.2 percent) the test itself was performed.[30]

Lab Closures. It is estimated that 50 percent of all laboratory testing occurs on an outpatient basis. Before CLIA '88, physician office laboratories were the most rapidly expanding segment of the laboratory industry, representing about half of all outpatient lab testing in 1986.[31] The projected annual growth rate for this sector was about 16 percent through 1990.[32] According to recent CDC data, of an annual total of 4.2 billion tests, physicians' offices now perform 294 million per year, or only 7 percent of the total.[33] Pre-CLIA projections were for 2.7 billion tests performed in physicians' offices.[34] By all estimates,[35] the 1994 CDC data represent a dramatic departure from predictions just a few years earlier and have stunning implications for the future of the market. The American Academy of Family Physicians noticed a particularly steep drop. When asked, "Do you perform *any* clinical laboratory tests in your office?" only 78.9 percent responded that they did. A few years earlier, the same question elicited a 93 percent affirmative response.[36]

The 1994 Texas Medical Association study found that CLIA's impact was greatest among the primary care specialties. Thirty percent of Texas family physicians and general practitioners, 19 percent of pediatricians, and 20 percent of OB/GYNs have closed their labs because of CLIA,[37] while 57 percent of OB/GYNs, family physicians, and GPs and 59 percent of pediatricians have stopped doing some tests because of CLIA. The American Academy of Dermatology found the same thing when it surveyed its members

30 J. W. Ross and D. J. Boone, assessing the effect of mistakes in the total testing process on the quality of care. Cited in Boone, "Literature Review of Research Related to the Clinical Laboratory Improvement Amendments of 1988," p. 689.

31 M. L. Kenney and D. P. Greenberg, "Final Report on the Assessment of Clinical Laboratory Regulations," submitted to HHS, 1986, pp. 11-17; cited in *Federal Register*, February 28, 1992.

32 P. M. Fischer, "Education and the Physician's Office Laboratory," *Journal of the American Medical Association*, Vol. 254, No. 20 (1986), pp. 2941-2945.

33 Data presented by CDC at meeting of the Clinical Laboratory Improvement Advisory Committee, Atlanta Georgia, May 6, 1995.

34 Findings of Boston Medical Consultants, 1990; cited in *Federal Register*, February 28, 1992.

35 Fischer, "Education and the Physician's Office Laboratory."

36 American Academy of Family Physician, Survey of Office Practice Characteristics, 1994.

37 Texas Medical Association, 1994 Survey of Texas Physicians, July 1994.

at a February 1995 conference: 75 percent of dermatologists had eliminated testing altogether or cut the number of tests they did in their offices, while 82 percent felt CLIA led to a reduction in the overall quality of care.[38]

Factors other than CLIA, such as the growth of managed care, are often cited as responsible for this shift in practice patterns. However, in a survey of family physicians, among those who felt their in-office testing capabilities were insufficient to meet the needs of their patients, "too much government red tape" was mentioned by over 90 percent as the main reason.[39]

Advances in lab technology were promising before CLIA '88. The development of highly accurate test kits and devices, as simple to use as home pregnancy testing devices and home blood sugar monitors, was skyrocketing. These testing devices were subject to rigorous FDA approval standards. But with imposition of CLIA '88, potential markets for the promising new technology quickly disappeared. Some large companies abruptly changed course. Some persevered, finding new markets for their on-site diagnostic tests in European and Third World countries.

Consider the computer industry. In the beginning, there were the big mainframes. Giant computer "brains" were needed to store masses of data that now can be stored in a small shoe box-size container that fits comfortably beneath a desk. Data entry was tedious and depended on keypunch operators and stacks of manila cards with various patterns of rectangular holes. Extracting and manipulating data was equally challenging, requiring a sophisticated understanding of computer language. Problems were common. Computers required a special expertise. Over the past two-and-a-half decades, however, computers have become efficient, "user friendly," and relatively problem free. Even children have become computer literate, fail-safe systems have eliminated data loss crises, and machines that once required moving vans can be tucked away in the side compartment of a carry-on bag.

But imagine that as the technology improved, as it became smaller and simpler to use, as it became available to the average person, the federal government required all purchasers and users of the new laptops to purchase and possess a license to use them, to keep log-in records, and to be inspected and tested on their ability to use correctly each item of software they loaded onto their hard drives. That, in effect, is what CLIA '88 has done to the clinical laboratory community. As the technology has become more accurate, user friendly, and available to the primary care physician, costly regulations and red tape have caused tens of thousands of physicians to lock up their labs.

Not all lab tests are subject to the rigors of CLIA. Nine are "waived." Three of these are available to the public for home use, three were invented before World War II, and the urine dipstick test has been available for well over three decades. CLIA's "Complexity Model" indicates that the new technology is what should worry Americans.[40]

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38 American Academy of Dermatology, 1995 Survey.

39 American Academy of Family Physicians, Survey of Office Practice Characteristics, 1994.

40 The CDC-generated Complexity Model is an arbitrary set of criteria by which tests were judged on their levels of difficulty or complexity. The model was never tested in the real world, and raters of these tests judged only their package inserts, never the tests themselves.

Strep throat screens, for example, have been labeled "moderately complex" even though they are as simple to perform as home pregnancy tests. A 1992 study published in the *Journal of the American Medical Association* found that sixth and seventh grade students in the Augusta, Georgia, public schools were able to perform this test with 95 to 100 percent accuracy on their first attempt after reading the directions.[41]

Because their performance was so successful on the first try, the study was unable to demonstrate a learning curve. CDC's "moderate complexity" ranking, for this test and for others using the same technique, has resulted in abandonment of on-site labs in thousands of physicians' offices across the United States.

Such results and incongruities call CDC's entire complexity model into question. This model depends on subjective ratings of testing devices against several arbitrary criteria. Despite its far-reaching impact, however, federal bureaucrats never tested its real-world validity and reliability before it was imposed on the testing device marketplace and physicians' offices.

The CLIA Police. The CLIA police were out in force this past year. Thousands of physicians' offices were cited for violations, the vast majority of which were procedural and paperwork irregularities irrelevant to patient care. Penalties for noncompliance can be as high as $10,000 a day. While the fines on doctors can be onerous, in many cases the inspectors themselves do not know the first thing about patient care. A New York dermatologist, for example, was surprised to find that he was being inspected by a former patient who had been an unemployed engineer.

Unquestionably, the federal regulatory police did find deficiencies in the labs. But the vast majority were classic bureaucratic transgressions related to neglected paperwork and documentation errors: a missing signature, for example, or the lack of procedure manuals (which no one consults anyway). Just as CLIA regulatory policy promotes the "dark ages" of testing techniques, it also represents a throwback to the dark ages of quality management. Modern quality management addresses outcomes. In not one instance can CDC officials say with certainty that adhering to any aspect of this strangulating body of regulation improves the outcome for the patient.

REGULATING WITHOUT SCIENTIFIC CONSENSUS

Within the scientific community, a great deal of discord exists regarding CLIA. In the multimillion-dollar proficiency testing business, for example, manufacturers of laboratory "instruments and reagent systems design and then manage and control the manufacturing process to ensure consistent results on fresh, human specimens." But there are a number of flaws in the proficiency testing program. One is that materials sent to physicians' offices to test the accuracy of their results frequently are taken from chickens or cows, often are frozen and thawed numerous times, and frequently have to be reconstituted when received.[42]

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41 D. G. Ferris and P. M. Fischer, "Elementary School Students' Performance With Two ELISA Test Systems," *Journal of the American Medical Association*, Vol. 268, No. 6 (August 12, 1992), pp. 766-770.

42 R. H. Laessig *et al.*, "Limitations of Proficiency Testing Under CLIA '67," *Clinical Chemistry*, Vol. 38, No. 7 (1992), pp.

Even the founder of proficiency testing, Dr. F. William Sunderman, opposes using it as a regulatory device.[43]

Proficiency testing was never intended to be a regulatory tool. No existing studies link better scores on proficiency testing to improved patient outcomes. Many scientists have raised questions about the very nature of proficiency testing specimens (analytes). Proficiency testing specimens that are accurate for one type of machine often are not appropriate for another. Often, these analytes are non-human materials. For example, measuring a physician's ability to perform accurate testing on chicken blood has become the important regulatory measure of excellence, but medical device manufacturers sought to develop on-site testing devices that would perform best on fresh human serum. Now promotion of their products depends more on passing proficiency tests on chicken sera than on accuracy in testing human blood.

Cutting Services. CLIA 1988 unquestionably has dampened and even deadened on-site laboratory testing and the promise it held. Because of the formidable regulatory costs and the realization that patients and the health care system cannot afford any additional financial burden, physicians have closed and cut back on many services they once offered their patients, in many cases for free or at "break even" rates. Testing devices are relegated to dark corners on storage shelves, and microscopes have been boxed. To escape CLIA's costly embrace, and to be classified as a "waivered" lab, doctors often have traded 1990s' technology for pre-World War II models like copper sulfate hemoglobin analyses and centrifuge-generated hematocrits.

But patients are the real losers. The ultimate financial burden generated by the additional costs of paying for cholesterols and strep cultures performed in outside laboratories rests with them. They must endure the unavoidable delays that result from sending specimens off site, or the preanalytic and postanalytic errors that make up the bulk of laboratory testing problems. They have to take more time off from work. They have to pay "Elderbus" fares for return visits that now have to be scheduled to discuss test results after they have come back from outside labs.

But no data show, and no scientific research confirms, that a major national problem ever existed. The inconsistencies in the federal "complexity models" and "quality standards" are apparent. A 20 percent failure rate is acceptable in screening for cervical cancer, but an elevated cholesterol level must be more accurate than most physicians feel is necessary to make treatment decisions. Even worse, the problem that initiated this federal fiasco—erroneously read Pap Smears—still has not been addressed. Despite the specific attention given to this problem in the original legislation, on-site proficiency testing for this cytology test has not even been started.

1237-1244, esp. p. 1240.

43 Sunderman, "The History of Proficiency Testing/Quality Control."

THE BUREAUCRACY'S EXCUSES

The office of the HHS Inspector General (IG) recently conducted a study to determine whether CLIA resulted in laboratory availability problems for Medicare patients. The conclusion: "The CLIA appears not to have affected physician ability to secure laboratory services for their patients."[44]

This report represents a stunning lack of understanding of the important issues surrounding CLIA. Instead of addressing the effects of CLIA, its conclusion deals with physicians' efforts, despite regulatory obstacles, to secure needed health services for their patients. But the lack of availability of tests was never the issue. No one said patients would not be able to obtain tests; Americans no longer depend on the pony express, and medical tests can be sent to, or performed at, reference laboratories. The issues that were not addressed are precisely the ones that should have been: issues that relate to increased inconvenience, increased costs, lack of immediate access to test results, consequent treatment delays and the need for follow-up visits, and—most important—the inevitably decreased quality of care and increased morbidity.

In other words, the IG's study failed to address the very issue—quality of care—that formed the impetus for the Clinical Laboratory Improvement Amendments. It also failed to analyze CLIA's impact on physician practice patterns after the final regulations took effect. Surveys by professional organizations indicate that CLIA's major impact on physician practice occurred after the final regulation took effect in late 1992.[45]

Hence, the data regarding the impact on physician office practice prior to that time are irrelevant.

The IG did find that "CLIA appears to have some effect on the volume and types of tests being billed by POLs. Shifts from moderate and high complexity to waived testing procedures are evident...."[46]

But that finding is, in effect, an admission that physicians have returned to pre-World War II technologies. Most of the highly accurate, new on-site tests are out of reach for the "waivered" site.

Consider what would happen if the HHS bureaucacy's reasoning were applied in any other sector of the national economy. Suppose, for example, that a large plant employing two thousand workers closes down because the owners cannot afford to comply with regulations requiring them to remove asbestos from sealed encasements and inside walls. No scientific study has shown that encased asbestos poses any harm to humans, but publicity related to deaths among asbestos-exposed shipyard workers spills over to cause a rash of regulations not supported by fact. Two thousand workers lose their jobs, but a government study determines that the regulation has had no significant impact because

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44 "CLIA's Impact on the Availability of Laboratory Services," Office of the Inspector General, U.S. Department of Health and Human Services, June 1995.

45 American Academy of Family Physicians, Survey of Office Practice Characteristics, 1994; Texas Medical Association, 1994 Survey of Texas Physicians; American Academy of Dermatology, 1995 Survey.

46 "CLIA's Impact on the Availability of Laboratory Services," p. 11.

95 percent of these displaced laborers find work within two years. The lesson is simple: Those who ask the wrong questions get irrelevant answers.

CONCLUSION

Congress can return to reason in regulating clinical labs. Already, new Members are rethinking how federal regulation has been implemented in the past. Cost-benefit analyses are being considered before any new layers of regulation are imposed. Existing regulations are being reexamined for reasonableness and scrutinized for need. The fact that hundreds of billions of dollars are taken from hard-working consumers because of regulatory costs added to the price of goods and services finally is being taken seriously.

Fortunately, CLIA's regulatory burdens on doctors and impact on patients have attracted attention in both the House and Senate. In the House, Bill Archer and dozens of his colleagues are leading the effort to reintroduce some sense and sanity to this issue. Representative Archer has introduced H.R. 1386, the Clinical Laboratory Improvement Act Amendments of 1995, and Kay Bailey Hutchison and colleagues are sponsoring a similar bill, S. 877, in the Senate. Congress can release the physician's office from a set of costly and unnecessarily restrictive rules that amount to regulation in search of a problem. By changing policy, Congress can change the environment in a way that benefits both doctor and patient.

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