

MEMORANDUM

To: Shirley Sagawa
From: Chris Jennings
Lynn Margherio
Date: July 29, 1993
RE: Response to Senator Cohen concerning CLIA

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Per your request, we have drafted a response to Senator Cohen from Mrs. Clinton. We have been in contact with the Senator's staff to arrange a meeting to discuss CLIA. The meeting will likely occur in mid-August.

THE WHITE HOUSE

WASHINGTON

July 29, 1993

Senator William S. Cohen
United States Senate
Washington, D.C. 20510

Dear Senator Cohen:

Thank you for advising me of your concerns regarding ongoing Administration discussions about reforming some aspects of CLIA. I am well aware of your past involvement in this legislation and your opinion is highly valued in this matter.

As you know, a number of concerns have been raised in the health care provider community about regulatory and administrative burdens related to CLIA. Having said this, there is no question that we must do all we can to ensure that tests are safely performed in clinical labs. This most certainly was the intent behind the CLIA legislation.

It is our hope and expectation that working with Congress we can modify and strengthen the legislation. It is for this reason that we have advised your staff that we would like to hold a briefing to discuss policy options. I believe a meeting held in the next few weeks would be advantageous for everyone.

Thank you again for writing. I appreciate having the benefit of your views and look forward to working with you and your staff on this and other important issues relating to health reform.

Sincerely,

Hillary Rodham Clinton

HRC:ms

cc: Shirley Melanice

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United States Senate

WASHINGTON, DC 20510

Senator Cohen
Appreciate concerning
the to discuss w/
your staff
* CLIA *
* HHS *

As my staff has indicated
I thank you for advising
me of your concerns on CLIA
In context of H care reform
I'm well aware of your past
involve in this & value your
Currently the administration
tapping into policy experts in WH, HHS
& outside are reviewing alternative
policy options for policy reform

* Send Memo to HRC *

Mrs. Hillary Rodham Clinton
The First Lady
The White House
Washington, D.C. 20500

Dear Mrs. Clinton:

I am writing to express my concern regarding recent reports indicating that the Administration will recommend significant relaxation of regulations implementing the Clinical Laboratory Improvement Act of 1988 ("CLIA '88") in an effort to gain the support of physicians for the Administration's comprehensive health care reform proposal.

As you know, I strongly support efforts to reduce the administrative and paperwork burdens that are contributing to the skyrocketing costs of health care. I am very concerned, however, that such efforts not jeopardize the quality of thousands of clinical laboratory tests that are performed on patients each year in physician office laboratories.

CLIA '88 was passed by the Congress following extensive investigations of faulty lab testing practices, particularly in the reading of Pap smears. As you may recall, these investigations revealed major gaps in the regulation and enforcement of quality standards governing clinical laboratory testing.

CLIA '88 for the first time extended federal quality standards to the over 85,000 physician office laboratories, which conduct an increasing share of the lab tests performed nationwide. The rationale behind this extension was that patients should be able to depend on the accuracy of all medical tests, regardless of the location of the laboratory performing the test. To eliminate or substantially roll back the provisions of CLIA '88 regarding physician office labs would severely jeopardize the quality of lab tests performed in these sites, resulting in significant risks to patients.

As you know there have been a number of concerns about statutory requirements for CLIA... H care provides commentary about regulations & minimum standards related to CLIA... There is no question that the intention behind the legislation is to improve patient safety & strengthen the regulation... and we have no intention to repeal CLIA... working w/ Congress we can modify & strengthen the legislation... CLIA '88 was passed by the Congress following extensive investigations of faulty lab testing practices... To eliminate or substantially roll back the provisions of CLIA '88 regarding physician office labs would severely jeopardize the quality of lab tests performed in these sites, resulting in significant risks to patients.

We have advised your staff that we want to hold a briefing to discuss deliberations on this. We think it can be held few weeks & I thank you for - Please contact me w/ any concerns

Mrs. Clinton
June 15, 1993
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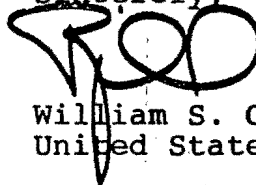
As a principal author of CLIA '88, I admit that I have been extremely disappointed and frustrated by the Department of Health and Human Services' implementation of the law since its passage, including extended delays and many missed deadlines in promulgating regulations.

Despite this dissatisfaction with HHS's handling of CLIA regulations, it is critically important that we do not allow our zest for simplification of regulatory requirements to undermine the original intent of CLIA '88, which is to ensure the quality of all medical lab tests, regardless of where the test is performed. I would be greatly disturbed if any effort to gain support for comprehensive health care reform sacrifices this important goal.

I look forward to working with you as we seek solutions to our nation's pressing health care problems and look forward to reviewing any recommendations you may have to revise CLIA regulations to ensure that they are consistent with the underlying purpose of the statute.

With best wishes, I am

Sincerely,

A handwritten signature in black ink, appearing to read 'W. Cohen', with a stylized flourish at the end.

William S. Cohen
United States Senator

cc: The Honorable Donna Shalala

MEMORANDUM

TO: Chris Jennings
FROM: Lois Quam
DATE: June 3, 1993
RE: Meeting with Senator William Cohen

I spoke at a Maine forum today with Senator Cohen. The forum went well with an audience of about 600 people.

Cohen was guarded in his support of the reform but supportive of the President and the First Lady personally. He made the following points:

- There would be no filibuster; there would be cooperation on the plan; and that he wanted to see the President succeed.
- The proposal should be delayed to the fall to avoid clash with the budget and give time for working out difficult parts of the plan.
- He has great confidence in the First Lady and her abilities to provide leadership.
- He was concerned that the decision about the benefit package not be politicized. In addition, he was concerned about how the National Health Board would be cushioned from political pressure.

cc: Steve Edelstein