ANALYSIS

California Association of Bioanalysts — **The Voice of the Bioanalyst, Jun. 1995**

President's Message:

It appears that AAB and CAB may be burying the hatchet. Bob Footlik and I met with the AAB Board during the week of the AAB National Convention in an attempt to heal old wounds. Our hope was that we would come to an understanding, so that our two organizations could become mutually supportive. We can assist them with national laboratory concerns which affect CAB as well, and they, in turn, can mobilize their resources when we have State problems with which they agree philosophically. In this day and age when laboratories and laboratory organizations are fighting for their lives, it makes sense to start working together with others who have similar goals.

In order to begin getting reacquainted, we are hoping to organize a jointly held educational meeting. The AAB Board agreed that they would help us arrange for national level speakers and assist us financially if we would co-sponsor such a meeting in San Diego at the beginning of February. If this works out, we may have some strong new friends.

I wish to thank all those who helped to make the 1995 convention successful. It is only with hard work from many individuals that we are able to offer twelve units of continuing education each year. Dan Leighton, our Vice President, provided our beautiful programs and helped tremendously with the educational sessions. Lew Soibelman picked out great menus, took care of all the hotel arrangements, and helped behind the scenes.

Thank you, one and all!

CAB TESTIFIES BEFORE STATE SENATE COMMITTEE

During our annual convention in Santa Barbara, we listened attentively as Karen Nickel, Ph.D., Chief, Laboratory Field Services, presented SB 113 (Maddy) from the perspective of the Department of Health Services (DHS) as sponsors of the bill, and how this bill would incorporate various aspects of the Clinical Laboratory Improvement Amendments of 1988 (CLIA) into California law. If SB 113 becomes law, it would enable California to apply to the federal Health Care Financing Administration (HCFA) for exemption from CLIA and its associated regulations. Presently, the only state that has been granted full exemption under CLIA is the State of Washington. Additionally, during the CAB business meeting, more specific features of SB 113 were discussed as part of the Legislative Committee report, and a recommendation to maintain a position of "oppose unless amended" was supported by the membership.

Approximately one week following our convention, the author of SB 113, the Honorable Ken Maddy (R-14), Senate

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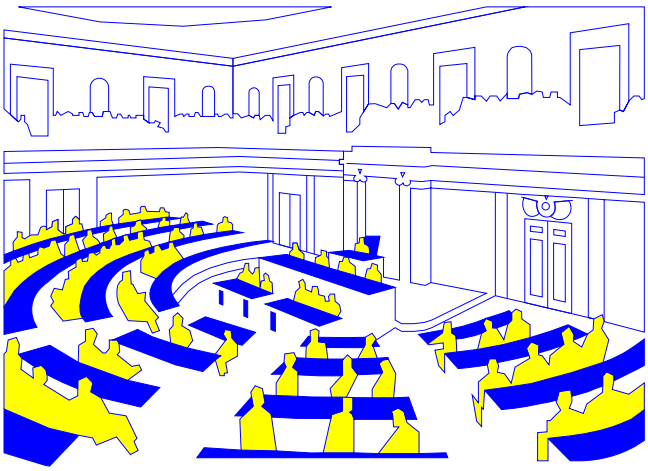
Minority Leader, made another 6 amendments to the bill. These were in addition to the 56 amendments made about 10 days prior to, and referenced during, our convention. Thus, before being heard by any senate committee, Senator Maddy already had made a total of 62 amendments to SB 113.

Although a couple of the 6 additional amendments purely were technical in nature, there were some changes of significance. In addition to licensed laboratory personnel and RNs, two amendments further limited those authorized to perform moderate complexity testing from anyone else providing direct patient care to psychiatric technician, LVN, midwife, nurse assistant, or home health aide. Another two amendments placed more responsibility on the laboratory director by requiring the director to comply with any regulations adopted by DHS that specify the minimum qualifications for, and the type of procedures that may be performed by personnel, in addition to any CLIA requirements relative to the education or training of personnel.



However, DHS still had not reached consensus on SB 113 with clinical laboratory interests who remained in opposition to the bill, including CAB. The reasons for this continued opposition will become clear in the remainder of this article. As reported at the CAB annual meeting, SB 113 had been rescheduled for hearing before the Senate Business and Professions Committee on Monday, April 24, 1995. On Sunday, April 23, I traveled to Sacramento for an evening meeting with members of the CCCLP (California Coalition of Clinical Laboratory Professions), which was coordinated by the California Association for Medical Laboratory Technology (CAMLT) and its lobbying firm, Rees & Associates. This meeting was used to coordinate testimony to be presented to the Senate Business and Professions Committee on Monday by those representing the laboratory professional associations.

Although Senator Maddy, DHS, and supporters of the bill (CMA, CAHHS, Kaiser Permanente, etc.) gave testimony first, the coordinated efforts of clinical laboratory professional associations that followed appeared to be quite successful. However, I have both good news and bad news to report.

First, the GOOD news:

As a result of our testimony, the committee requested Senator Maddy's acceptance of 3 major amendments to SB 113. In summary, these are:

1) To add the words, "when the person meets minimum personnel and training standards set forth in regulations adopted by DHS," to the end of the section authorizing psychiatric technician, LVN, midwife, nurse assistant, or home health aide to perform moderate complexity tests;

2) Regarding automatic adoption by California of any future CLIA regulations published as a final rule by HCFA, the Business and Professions Committee was very clear in stipulating that any future CLIA rule that lowers existing standards will NOT be adopted in California! Then, for any future CLIA rule that would make CLIA more stringent than California law, notice of changes must be given by DHS, and a public hearing would result, in accordance with the Administrative Procedures Act.

3) Regarding the placing of more responsibility on the laboratory director by requiring the director to comply with any regulations adopted by DHS that specify the minimum qualifications for, and the type of procedures that may be performed by, personnel, in addition to any CLIA requirements relative to the education or training of personnel, the committee stipulated that DHS MUST write regulations setting minimum standards giving guidance to the laboratory director to evaluate the new personnel who will be authorized to perform testing. Clearly, without this significant change, DHS would not have had to write any regulations. Without standards set by DHS for all to follow, such personnel requirements would vary from lab to lab, depending on the laboratory director and/or the laboratory OWNER's mandates to the

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laboratory director.

Although the Board of Registered Nursing (BRN) appeared ready to give up on the idea of the nurse practitioner, midwife, and nurse anesthetist performing high complexity testing as long as all RNs could perform moderate complexity testing, this compromise was lost in a confusion of dialogue between CAMLT, their lobbyist, Committee Chair Senator Daniel Boatwright, and the BRN representative. Thus, members of the CCCLP remain opposed to SB 113. Ideally, laboratory interests would like to see a compromise where the nurse practitioner, midwife, and nurse anesthetist are restricted to moderate complexity testing at MOST, with all other nurses restricted to using point-of-care testing devices or waived testing only.

Lest I have given the impression that the preceding paragraph was the bad news, now for the **BAD news:**

1. About an hour after the Senate Business and Professions Committee concluded their meeting on the day SB 113 was heard, I learned that Senator Maddy was summoned back to the committee because of a procedural error. Apparently, no formal motion had been made relative to amendment #2, above, regarding the automatic adoption issue. Chairman Boatwright, however, strongly recommended to Senator Maddy that he make the changes agreed upon during the hearing. Unfortunately, Senator Maddy's automatic adoption amendment turned out to have little, if any, relationship to the changes described in amendment #2, above. In other words, the senator really changed nothing about that issue!

2. Since each amendment was taken by Senator Maddy as an author's amendment, it was Senator Maddy and/or DHS who made the modifications. In spite of the fact that the Business and Professions Committee had ordered specific wording changes in strategic places, that did not occur where Mr. Maddy and DHS did not wish them to occur. As a result, amendment #3, above, applies ONLY to moderate complexity testing performed by a psychiatric technician, LVN, midwife, nurse assistant, or home health aide. Clearly, those of us present at the hearing understood the agreed upon amendment to apply to all new classifications of personnel who will be authorized to perform laboratory testing at all levels of complexity!

Therefore, CAB's position on SB 113 remains **"oppose unless amended."** Moreover, CAB has signed an agreement with the lobbying firm of Clarke and Associates to represent the association in Sacramento on an "as needed" basis. Accordingly, I have authorized Alan Clarke to work with the legislative advocates of key CCCLP members, CAMLT, the California Clinical Laboratory Association (CCLA), and the Engineers and Scientists of California in a unified effort to resolve these BAD news issues.

Robert I. Footlik, Chairman
Legislative Committee

EDITOR'S NOTE:
There have been further changes and we will keep you updated in the next edition of the Analysis.
Many Thanks to Bob Footlik for his fine efforts as Legislative Committee Chairman, and for keeping us so well informed.

CLIA '95 INTRODUCED IN HOUSE OF REPRESENTATIVES

On April 4, 1995, Congressman Bill Archer (R-TX), Chair, Ways and Means Committee, introduced HR 1386 in the U.S. House of Representatives. This Act has been cited as the Clinical Laboratory Improvement Act Amendments of 1995 (CLIA '95).

CLIA '95 is a one-page bill which, if signed into law, would COMPLETELY EXEMPT FROM CLIA a clinical laboratory in a physician's office (including an office of a group of physicians) which is directed by a physician and in which examinations and procedures are either performed by a physician or by individuals supervised by a physician solely as an adjunct to other services provided by the physician's office.

However, a physician office laboratory (POL) would NOT be exempt from CLIA when it performs a Pap smear analysis.

As speculated would happen at our annual convention in Santa Barbara, this bill comes as no surprise. While it has been proven that, in general, the poorest quality laboratory testing is performed in POLs, the Texas Medical Association and probably the AMA, as well, have seen fit to sponsor a bill which basically tells the American public that they are not entitled to the same quality of care from a POL as they are from any other clinical laboratory!

Please contact your local Congressional Representative to express your opposition to this bill!

Robert I. Footlik, Chairman
Legislative Committee

LFS MOVES TO OAKLAND

After decades of being located within the confines of the California Department of Health Services building at 2151 Berkeley Way in Berkeley, the main office of Laboratory Field Services (LFS) officially moved into the CalTrans facility at 111 Grand Avenue in Oakland on April 24, 1995.

With the expansion of responsibilities under the federal CLIA Program, additional space really became a necessity for LFS, and we wish the chief, Dr. Nickel, and her staff well in their new "home."

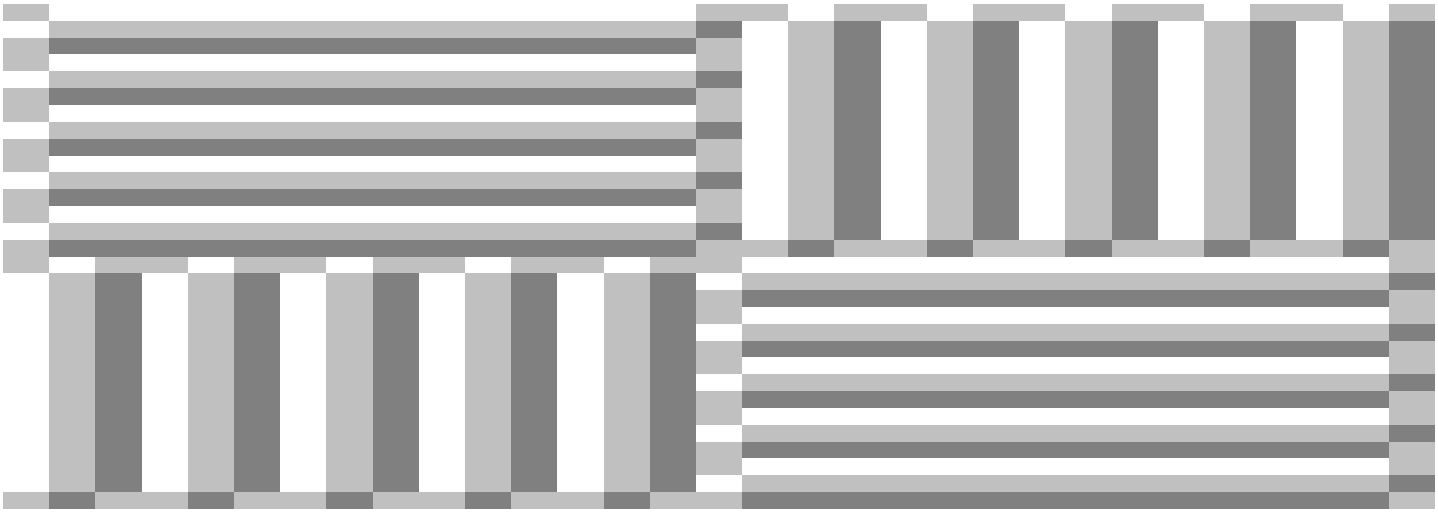
For general information, the new telephone number for the LFS main office is: (510) 873-6327 .....

However, DO NOT SEND MAIL TO THE OAKLAND ADDRESS! For the time being, please continue to send all payments and correspondence to the Berkeley address as follows:

Laboratory Field Services Branch
California Department of Health Services
2151 Berkeley Way
Berkeley, California 94704-1011

Although these changes do not affect the Los Angeles office of LFS, they, too, are in need of more space. Thus, we probably can anticipate a similar move for Elias Miguel, Examiner III, and his staff sometime in the near future.

Robert I. Footlik, Chairman
Legislative Committee



NEW CLIA '88 REGULATIONS

Keeping in mind that more stringent law still prevails in the State of California, the first changes to CLIA regulations in more than two years were published in the Federal Register on April 24, 1995.

Not to be confused with CLIA '95, introduced as HR 1386 in the House of Representatives on April 4, 1995, which if passed into law, would exempt physician office laboratories totally from CLIA (except where Pap smears are analyzed), the revised CLIA '88 regulations: 1) allow dentists and midlevel practitioners to perform tests in the "physician-performed" microscopy (PPM) subcategory of moderate complexity procedures and have renamed the PPM subcategory "provider-performed" microscopy; 2) have modified the personnel rules for high complexity testing personnel; and 3) have modified the personnel rules for general supervisors of high complexity testing.

To begin with, a midlevel practitioner has been defined as "a nurse midwife, nurse practitioner, or physician assistant licensed by the state within which the individual practices, if such licensing is required by the state in which the laboratory is located."

On the other hand, registered nurses who are not midlevel practitioners, licensed practical nurses, medical assistants, and emergency personnel were determined to have insufficient training to properly perform and interpret the microscopic examinations currently included in the PPM category. While the current PPM category consists of KOH preps, pinworm preps, urine sediment exams, wet mounts (vaginal, cervical, or skin specimens), post-coital qualitative exams of vaginal or cervical mucous, and Fern tests, three additional tests have been added to the "new" PPM category. These tests are: nasal smear examinations for granulocytes, fecal leukocyte examinations, and qualitative semen analysis (limited to the presence or absence of sperm and detection of motility).

Secondly, individuals who have the equivalent of an associate degree, or who, on or before April 24, 1995, completed a 50-week U.S. military medical laboratory training program, or graduated from an accredited (nondegree) clinical laboratory training program are now permanently qualified as high complexity testing personnel.

High school graduates who lack the above and who were performing high complexity testing on or before April 24, 1995, are also qualified as high complexity testing personnel, provided that those individuals must have either onsite supervision or a 24-hour review of their work by a qualified general supervisor (the onsite supervision requirement applies only to high school graduates, or the equivalent, who began performing high complexity testing after January 19, 1993).

Accordingly, the equivalent of an associate degree has been defined as: 60 semester hours, which must include either 24 semester hours of medical laboratory technology courses or 24 semester hours of science courses that include six semester hours of chemistry, six semester hours of biology, and twelve semester hours of courses in chemistry, biology or medical laboratory technology, in any combination. In addition, individuals must have completed either an accredited clinical laboratory or medical laboratory training program (which may be included in the 60 semester hours specified above) or three months of documented training in each specialty in which the individual performs high complexity testing.

Third, the general supervisor qualifications also have been modified to include:

1. Individuals who do not have a degree or who have a bachelor's degree that is not in a science if they meet the equivalency requirements of an associate degree and have at least two additional years of laboratory training or experience in high complexity testing.
2. Individuals who, on or before September 1, 1992, served as a general supervisor of high complexity testing and who, on or before April 24, 1995, completed a 50-week U.S. military

medical laboratory training program or an accredited (nondegree) clinical laboratory training program plus a minimum or two years of laboratory training or experience in high complexity testing. The laboratory training/ experience may be acquired before or after completing the accredited or U.S. military medical laboratory training program.

3. High school graduates, or equivalent, who, on or before September 1, 1992, were serving as general supervisors and who have at least ten years of laboratory training or experience in high complexity testing, including at least 6 years of supervisory experience in high complexity testing between September 1, 1982, and September 1, 1992.

Apparently, individuals who qualified as general supervisors by passing the former HHS Proficiency Examination and obtaining six years of training or experience prior to September 1, 1992, will continue to qualify without having to earn an associate degree.

Although these new CLIA '88 regulations became effective on April 24, 1995, comments to HCFA may be submitted until June 23, 1995 (final rule with comment period). Please mail any written comments (one original and three copies) to:

Health Care Financing Administration
Department of Health and Human Services
Attention: HSQ-216-FC
P.O. Box 26676
Baltimore, Maryland 21207

Robert I. Footlik, Chairman
Legislative Committee

FROM THE WHITE HOUSE

Greetings to all who are observing National Medical Laboratory Week, 1995, sponsored by the American Society of Clinical Pathologists and thousands of laboratories across the country.

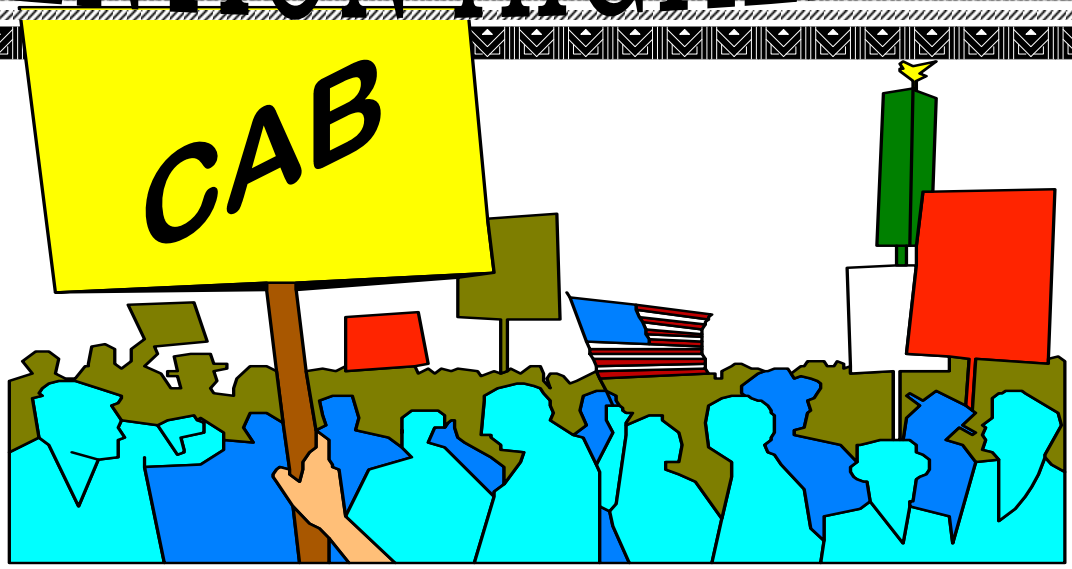
Most Americans rarely see the hardworking teams of lab personnel who make up such a vital part of our nation's health care system. Yet these dedicated professionals are owed a dept of gratitude for their commitment to scientific investigation, and their devotion to helping others. Every day, medical laboratory professionals make new inroads in our struggle to prevent illness, detect diseases, and develop innovative and cost-effective remedies. Their work helps to alleviate suffering and improve the quality of life for people across our nation and around the world. This week, I join my fellow Americans in expressing thanks to the laboratory professionals who are helping to make a safer, healthier society for all of us.

Best wishes for a most successful week.

Bill Clinton

For those of you who didn't personnaly receive the President's 'Best Wishes'...

CONVENTION HIGHLIGHTS



Santa Barbara wore it's finest weather for our Spring Convention at the Miramar Resort, until, on the last day, it literaly blew us out of town. Like many of us, the Miramar is aging quite gracefully.

As we were able to obtain all twelve required C. E. units during the convention, the days work began early. Friday's lectures began with Dr. Jack Bookout from SmithKline Beecham Laboratories discussing Polymerase Chain Reaction. He kept the subject limited to infectious diseases, never once mentioning the O.J. Simpson Trial. Bernie Lehman, also from SmithKline spoke about Safety in the Workplace. Barbara Dickman from Bayer, which was Miles, presented data on their new automated strip reader. The microscopic part wasn't mentioned. Wonder why? Completing the morning session, Janet Hindler, Senior Microbiologist from UCLA gave a run-down on Contempory Issues in Antimicrobial Susceptibility Testing.

The afternoon began with Dr. Munoz of SBCL reviewing current trends in Calcium Metabolism. While discussing Paget's Disease, he insisted on calling it "Pagay". Unfortunately, James Paget was English.

Saturday's session began with Alan Clarke giving a brief run down of current legislation. Dr. Karen Nickel discussed ramifications of the California bill to become exempt from CLIA. This bill, S.B.118 (Maddy) has caused consternation throughout the laboratory community and justly so. Many amendments and changes have been made, but we continue to oppose it in its present form and language. If it, or another legislative action is not enacted, however, we will be under all the rules of CLIA as well as California's. Ron Peterson, a CAB member as well as a Board member of CAMLT, spoke about laboratory regulation also. Dr. Geoffry Moyer, a Pathologist with SBCL presented a talk about TQM and CQI. Most of these presenters showed that they could read and thought that we could not. President Peggy Tessier presented information about violence in the workplace. The last scheduled talk, by Kristi Jenkins on the Impact of Managed Care rapidly became a discussion among all those present, and turned into one of the best sessions

The General Meeting of the Association was serene. All committee reports were received and filed. I miss the heated discussions we had in the past. Seems not many opinions are present in the room anymore. Of course, not many members were present either; some opting to leave immediately after getting their twelve credits.

At the evening banquet, Bob Footlik was presented with a plaque in thanks for his supreme efforts on behalf of the association. After a short Board meeting, all left for home. I wonder how much of that salad they really have...

James Dawson

OBITUARY
SYLVIA (LAZARONI) KAMIN
(November 6, 1918 - April 20, 1995)

Sylvia passed away on Thursday April 20. She had had chronic lymphatic leukemia for many years which became acute during the past year.

She was a pioneer Bioanalyst and one of the few women to own and direct her own laboratory in those early years before World War II. Sylvia was active in the American Association of Bioanalysts (AAB) and the California Association of Bioanalysts (CAB) until her retirement. As a member of CAB, she was a past president of CAB and served as editor of their newsletter, The Analysis, for many years.

Sylvia and her husband, Herman Safier, owned and directed their first laboratory in the Mission District in San Francisco after the war. Later she met and married Joe Lazaroni and the owned and directed Lazaroni Laboratories located in San Francisco and later relocated to Daly City. Joe died of lung cancer in the early 1980's. In spite of these tragic losses, Sylvia never faltered. She was a warm and loving person to be around; her enthusiasm was contagious. She established the Joseph Lazaroni Memorial Fund for students in the laboratory sciences at San Francisco State University. She again married, this time to a long time friend of both her and Joe's, Dr. Isadore Kamin. They were together for thirteen years until her death.

She is survived by three sons, Orin Safier of San Carlos, California; Phillip Safier of Albuquerque, New Mexico; and David Safier of Portland, Oregon; her husband, Dr. Isadore Kamin; and 4 grandchildren.

She will be remembered lovingly by those who knew her.

Don Amsbaugh

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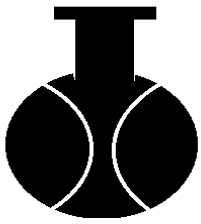

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