

A Brief 60-Year History of the American Association of Bioanalysts (1956-2016)

This summer marks the 60th anniversary of the founding of the American Association of Bioanalysts (AAB). AAB was formed in 1956 when the eastern-based National Association of Clinical Laboratories (NACL) merged with the western-based Council of American Bioanalysts (CAB) to provide a unified voice for bioanalysts determined to maintain their right to direct clinical laboratories in the face of organized medicine's attempts to classify the provision of clinical laboratory services as the practice of medicine.

At the time of the merger, Marion F. Dooley was CAB President, and Isadore Asen was President of NACL. Others active in the merger included: Dr. Michael Horti, Meyer Samson (owner of one of the first independent laboratories), Frederick Truelove, William Reich, Dr. Nell Hollinger, Dr. Albert Dickman, Dr. Robert Thornberg, Theodore Levatter, Thomas Hosty, Louis Nielson, and Donald Abel, who became the first AAB President.

The guiding force in the merger was Lucien D. Hertert, who was executive secretary for CAB and then for AAB, until 1962. He coined the term "Bioanalyst," which is widely used and accepted. For example, the State of California denotes a license to direct a clinical laboratory as a "Bioanalyst License."

The charter members of AAB were men and women who had been trained in the bioanalytical sciences. They owned and/or directed an estimated 1500 laboratories throughout the United States.

Early in its existence, AAB instituted an annual lecture honoring Dr. Margaret Beattie, a professor at the University of California. Many bioanalysts had been her students. Among the Beattie lecture speakers were Dr. Maxwell Wintrobe, developer of the Wintrobe sedimentation rate, Dr. Edward Teller, noted nuclear physicist, and Dr. Linus Pauling, two-time recipient of the Nobel Prize.

For almost a decade prior to AAB's establishment, organized medicine tried to eliminate the non-physician directed laboratory by claiming that laboratory services were the practice of medicine. This issue continued to be the central focus of AAB's legislative and regulatory activities in the 1950s, 1960s, and early 1970s, and it is still an important issue today.

Complexity was added to the issue in the mid-1960s with the passage of the Clinical Laboratories Improvement Act of 1967 (CLIA '67) and the establishment of the Medicare program in 1968.

The initial Medicare regulations and legislation posed an enormous challenge and threat for AAB and all Bioanalysts. In the initial Medicare proposals, services of independent laboratories were excluded. AAB's Government and Professional Relations Committee, headed by Bernard I. Diamond, BLD, launched a campaign on Capitol Hill to include independent laboratories in federal programs. In 1967, over 200 Bioanalysts marched on Washington to tell their story. The result, of course, is well known: regulations were promulgated that included Medicare reimbursement for independent laboratories.

In addition, the original Medicare rules excluded non-doctoral degreed directors and non-baccalaureate degreed medical technologists. AAB's efforts, led by John Boffa, HCLD(ABB), Alvin Salton, HCLD(ABB), Bernard Diamond, HCLD(ABB), and David Birenbaum [and ISCLT leaders Keith Knudson, RMT(ISCLT), and Stanley Reitman, MD] succeeded in persuading the federal government to include alternate qualifying routes in the Medicare/CLIA '67 regulations. For non-doctoral degreed directors this took the form of a Public Health Service Examination administered three times between 1967 and 1970. For non-baccalaureate degreed

medical technologists this became the HEW (then HHS) Proficiency Examination, which was administered seven times between 1975 and 1987 to over 65,000 individuals, with approximately 31,000 passing.

On the issue of whether clinical laboratory testing constituted the practice of medicine, AAB scored important victories when legislation in California and New Jersey won independent laboratories the right to perform laboratory services through licensing, even though restrictions and limitations were written into the bills at the urging of organized medicine. This issue finally came to a head in the mid-1970s when AAB member James Prier, Ph.D., HCLD (ABB), then director of Pennsylvania's Bureau of Laboratories, promulgated state clinical laboratory regulations that applied to all laboratories, including physician-directed laboratories. The Pennsylvania Medical Society filed suit, claiming that the regulations improperly encroached on the state's Medical Practice Act. The Pennsylvania Medical Society won a trial court decision that struck down the regulations, but on appeal the Pennsylvania Supreme Court reversed the lower court's decision, ruling in a landmark and precedent-setting decision that the provision of clinical laboratory testing does **not** constitute the practice of medicine.

An interesting side note to the legal battle in Pennsylvania was that the rules put forth by Dr. Prier contained eight "simple" tests frequently performed by physicians that were exempt from regulation. According to Dr. Prier, his intent was to end the exemption after one year, which he felt was long enough for physicians to become accustomed to Pennsylvania's regulations. These eight simple tests turned out to be the forerunners of the original "waived" tests in the CLIA '88 statute, much to the chagrin of Dr. Prier.

In 1968 AAB helped found an independent certifying board for clinical laboratory directors, the American Board of Bioanalysis (ABB). ABB became one of only four certifying boards for clinical laboratory directors recognized in the original Medicare/CLIA '67 regulations, and ABB continues to be recognized under the CLIA '88, and most state, laboratory personnel regulations. Under the chairmanship of Everett S. Beneke, Ph.D. [from 1968-2004], John Boffa, HCLD(ABB) [from 2004-2012], and Brooks Keel, Ph.D., HCLD(ABB) [from 2013-present]. ABB branched out to certify supervisors and consultants, in addition to five levels of directors (BCLD, HCLD, PHLD, ELD and ALD).

At the suggestion of Brooks W. Keel, Ph.D., HCLD(ABB), Jeffrey Boldt, Ph.D., HCLD(ABB), and Al Anouna, HCLD(ABB), ABB decided to certify andrology and embryology laboratory directors and supervisors, beginning in 1994. Today, ABB is the major certifying board for laboratorians in assisted reproductive technology (ART) laboratories. A certification in Molecular Diagnostics was added in 2003, and a certification in Public Health Microbiology was established in 2009.

A major concern of AAB throughout its history has been to improve the quality of clinical laboratory services. In 1949, Dr. Nell Hollinger founded one of the world's first proficiency testing programs for clinical laboratories. Dr. Hollinger's program eventually became AAB's Proficiency Testing Service (PTS). In the early years, only a few dozen to a few hundred laboratories participated. Keith Selvey directed the program through 1968, and then Nicholas T. Serafy took over as AAB's PTS Director after Mr. Selvey's unexpected resignation that year.

Under Mr. Serafy's leadership, AAB's Proficiency Testing Service flourished, with enrollment growing from a few hundred laboratories to over 6,500 laboratories in the 1990s, settling to over 4,000 laboratories in 2016. Nicholas T. Serafy Jr. helped his father manage the growth of AAB's Proficiency Testing Service through the 1980s and the 1990s, and then took over as AAB's PTS Director following his father's death in September 2004. Along the way, Charles P. Truby, Ph.D., Dennis Jay, Ph.D., and Eric W. Vanderslice, Ph.D. [currently the Technical Director of AAB's PTS], assisted Mr. Serafy in managing AAB's PTS program.

Another long-time objective of AAB has been to facilitate cooperation and communication between laboratory professional associations. In the late 1950s AAB was active in establishing a Congress of Allied Health Sciences. It was hoped that the Congress, the first of its kind, would be the mechanism for establishing meaningful communication between clinical laboratory scientists and pathologists. But this effort failed.

Subsequently, AAB was involved in the formation of the Intersociety Committee of Laboratory Services Related to Health, which eventually became the National Council on Health Laboratory Services (NCHLS). In the 1970s and 1980s, the NCHLS was the major forum at which laboratory organizations discussed important issues of the day. Several AAB representatives, including David Birenbaum and Richard C. Paul, BLD(ABB), chaired NCHLS.

Following the disbanding of NCHLS in the 1980s, a period ensued with little formal interaction among laboratory associations until the mid-1990s, when AAB proposed the formation of the Clinical Laboratory Coalition (CLC). AAB offered to host the CLC meetings, and under the expert leadership of AAB's Washington, D.C., representative, Robert Waters, the CLC became an effective laboratory coalition for dealing with Medicare and other important legislative and regulatory issues. In 2003, AAB's Executive Officers Section, led by Pat Lanza, and the Clinical Laboratory Coalition (CLC) orchestrated a massive grassroots campaign that succeeded in derailing a Congressional proposal to reinstitute a 20% co-payment for Medicare Part B laboratory reimbursement. AAB's Grassroots Campaign was so successful that it prompted the then CEO of LabCorp, Tom MacMahon, to comment that while LabCorp had aggressively lobbied against the 20% lab co-payment, smaller independent laboratories were even more vociferous. "I've never seen such an outcry," said McMahan. "I think it's the small labs that will cause it [the lab co-pay proposal] to fail."

But AAB's successful opposition to the 20% co-payment proposal had an unintended consequence. Although the 20% co-payment was dropped from the Medicare Reform Act (P.L. 108-173) signed into law on December 8, 2003, Congress instead froze the Part B Clinical Laboratory Fee Schedule (CLFS) for five years **and** mandated that a competitive bidding demonstration project for Part B clinical laboratory services be conducted by 2010.

The Centers for Medicare and Medicaid Services (CMS) decided to begin the first competitive bidding demonstration project in Southern California in 2007. Once again, AAB's Executive Officers Section, reconfigured as the National Independent Laboratory Association (NILA), led the laboratory industry's opposition to CMS's competitive bidding demonstration project.

In addition to a Grassroots Campaign opposing competitive bidding, AAB and NILA joined in a lawsuit challenging the methodology of the competitive bidding demonstration project. A few days before winning bidders were to be announced, a federal judge on April 8, 2008, awarded an injunction to three San Diego laboratories (one of which was a NILA member) to temporarily halt the demonstration project.

Although the injunction was not permanent, it allowed enough time for Congress, on July 15, 2008, to pass legislation (HR 6331) containing a provision repealing CMS's authority to conduct the clinical laboratory competitive bidding demonstration project. To pass that legislation, Congress had to take the unusual step of overriding a veto by President Bush. Thus ended CMS's Competitive Bidding Demonstration Project for clinical laboratories.

In the 1980s, AAB challenged New York inspection and permit fees that charged community clinical laboratories nearly as much as the largest publicly traded laboratories. [For example, the most a laboratory could be charged was \$8,000; most small to medium-sized laboratories were being billed \$6,000 to \$7,000.]

Led by AAB's general counsel, Jeffrey J. Sherrin, AAB won a legal settlement that changed the method New York's Health Department used to calculate the fees, significantly reducing the fees for community clinical laboratories.

But in the mid-1990s, New York's inspection and reference fees nearly tripled without explanation. When AAB's efforts to discover the causes behind the increase in fees were rebuffed by the New York State Department of Health (NYSDOH), AAB filed a lawsuit in 1999 challenging the legitimacy of the fees. AAB scored a major victory in New York State when, on September 24, 2008, retired Supreme Court Justice Edward R. Sheriden struck down what amounted to millions of dollars of fees charged each year from 1999-2006 to New York's licensed clinical laboratories. Judge Sheriden's ruling culminated the lawsuit brought by AAB in 1999 claiming that the New York State Department of Health (NYSDOH) had been illegally inflating clinical laboratory inspection and reference fees to pay for unrelated expenses.

The legal victory allowed several dozen AAB member laboratories to receive over \$5 million in refunds from the NYSDOH.

AAB followed up with a lawsuit covering the years 2007-2011 that resulted in a March 2013 settlement agreement in which over 200 New York licensed laboratories collected \$18 million in refunds from the NYSDOH's inflated inspection and reference fees.

Over the past few years, NILA and AAB led the Clinical Laboratory Coalition (CLC) in successful campaigns opposing an attempt in 2009 to reinstitute a 20% co-payment and an attempt by CMS in 2011 to require a physician signature on all laboratory requisitions.

Unfortunately, community clinical laboratories suffered a major setback in late 2009 when Congress passed the Affordable Care Act (aka "ObamaCare") that contained five consecutive cuts of 1.75% annually, from 2011-2015, to Medicare's Part B Clinical Laboratory Fee Schedule.

NILA and AAB, alone among the laboratory professional organizations, pointed out in 2009 that these cuts would fall disproportionately on community clinical laboratories, whose revenues consist of 25-60% Part B CLFS payments, compared to 10-12% for the two largest publicly traded laboratories. But NILA and AAB were unable to persuade other laboratory organizations that these cuts were unfair and unwise.

The Part B CLFS cuts in the original ObamaCare legislation were only the beginning. Since then, the Part B CLFS has been reduced by an additional 2% in 2012 to pay for a Physician "Pay Fix" and another 2% in 2013 for "Sequestration." And on April 1, 2014, President Obama signed the "Protecting Access to Medicare Act of 2014" (PAMA), which includes a complete overhaul of Medicare Part B's Clinical Laboratory Fee Schedule (CLFS) that threatens to drive many community and regional clinical laboratories out of business. NILA and AAB vociferously opposed PAMA, which was supported by the two largest publicly traded clinical laboratories.

Implementation of the PAMA-required modifications to the Part B CLFS, which was supposed to begin on January 1, 2016, are significantly behind schedule, and NILA continues to lead opposition to the proposed PAMA regulations published on October 1, 2015.

The increasing use of molecular diagnostics has created a heated controversy over which federal agency [the Food and Drug Administration (FDA) or CMS's CLIA program] should regulate these test procedures. That battle will be played out in 2016 and beyond.

AAB has also been very active in the area of continuing education. Under the dedicated leadership of

Shirley Cresswell, HCLD(ABB), AAB and ISCLT (now the AAB Associate Member Section) developed, on very short notice, a comprehensive two-day review program to help individuals prepare for the HEW Proficiency Examination for medical technologists that was administered seven times between 1975 and 1987.

The “Proficiency Examination Reviews,” or “PERs,” as they came to be known, were a huge success, attended by over 16,000 individuals between 1975 and 1987. The lecture notes used during the reviews were compiled into a reference manual that became the *PER Handbook*.

The *PER Handbook*, entering its 10th edition in 2016, is still used by many individuals to prepare for state licensing and private certifying examinations and as a handy day-to-day reference manual for “bench” technologists/technicians in the disciplines of clinical chemistry, hematology, immunology, immunohematology, and microbiology.

AAB’s educational activities also include the development of a comprehensive two-day review program for andrologists and embryologists, and an accompanying *Andrology and Embryology Review Course Manual*, which has now been translated into Spanish and Portuguese.

In 2005, Tammie Schalue, Ph.D., HCLD(ABB), in just a few short months, put together a comprehensive compliance manual on CD-ROM to make it easier for Assisted Reproductive Technology (ART) laboratories to comply with the U.S. Food and Drug Administration’s Human Cell & Tissue Products (HCT/P) rules. Over half the ART clinics in the United States obtained Dr. Schalue’s manual to help develop their laboratory’s FDA Compliance Program.

In 1997, AAB’s first special interest group, the College of Reproductive Biology (CRB), was established. Since its founding, the CRB has become one of the largest organizations of andrology and embryology laboratorians in the world. Shortly after the formation of the CRB, two other special interest sections were created, the Environmental Biology and Public Health Section (EBPH) and the Executive Officers Section (EO), which became the National Independent Laboratory Association (NILA).

Fifty years ago, AAB was incorporated as a trade association whose primary purpose was to protect the interests of bioanalytical laboratories. In 1975, AAB’s primary purpose was modified from protecting the interests of laboratories to protecting the interests of laboratory directors and supervisors, thereby transitioning AAB’s main focus from a trade association to a professional association.

Then, in what may be viewed as a return to AAB’s roots, the AAB Executive Officers Section transformed itself in 2006 to become the National Independent Laboratory Association (NILA), a trade association for independent laboratories. NILA has already become the voice of the community clinical laboratory and has participated in a number of important legislative and regulatory battles, including opposition to competitive bidding (2007-2008); reinstatement of a 20% co-payment for Part B CLFS payments (2009); opposing a requirement for physician signatures on all laboratory requisitions (2011); opposing President Obama’s 2014 Budget proposal to implement eight more cuts of 1.75% to Medicare’s Part B CLFS (2013); and continuing to lead the opposition to the 2015 proposed PAMA regulations.

After Lucien Hertert retired as AAB Executive Director in 1962, William Reich became AAB’s second Executive Director. Although Mr. Reich was a die-hard AAB member and supporter throughout his life, AAB’s fortunes headed downhill during his three years as executive director. By 1965, AAB was in debt and current year’s dues were being used to pay the previous year’s expenses.

The AAB President in 1965, Nicholas T. Serafy (Senior), had heard about a fellow named David

Birenbaum in St. Louis who in 1962 had been instrumental in starting up a new association for medical technologists called the International Society for Clinical Laboratory Technology (ISCLT). Mr. Birenbaum, an electrical engineer by training, worked for the firm of Ahner & Associates in St. Louis.

Mr. Serafy contacted Mr. Birenbaum and invited him and Mr. Ahner to a meeting of the AAB Board of Directors in Miami on May 6, 1965. There, after a rigorous interview process, the AAB Board of Directors decided, by an overwhelming vote of 9 to 8, to retain the firm of Ahner & Associates to manage AAB's affairs, with Mr. Birenbaum designated as AAB's administrator. [Mr. Birenbaum, who liked to embellish the story, claimed the vote was 9 to 8. However the official records indicate the vote was 11 to 6.]

One of the first matters addressed by Mr. Birenbaum was a \$12,000 invoice from a Mr. Turiel for printing AAB's scientific journal *Abstracts of Bioanalytical Technology* (ABT). Mr. Birenbaum discovered a \$3,000 error in the invoice and requested documentation of the other charges submitted by Mr. Turiel. When the documentation was not produced, Mr. Birenbaum offered \$3,000 to settle the outstanding debt, which Mr. Turiel accepted. This episode became known to AAB insiders as the "Saga of Turiel," and its resolution allowed AAB to regain its financial footing.

For the next 30 years, until his death in March 1994, Mr. Birenbaum led AAB through many challenging times, managing dramatic growth in AAB and its activities. Along the way, he collected hundreds of really bad jokes, which he relished telling to AAB members (or anyone unfortunate enough to have to listen), and which his son, who joined the firm of David Birenbaum & Associates in 1978, preserved for present and future AAB members, to their eternal dismay.

After Mr. Birenbaum passed away in 1994, Mark Birenbaum, Ph.D., a molecular biologist by training, became AAB's administrator.

Over the years, AAB attended many meetings in Washington, D.C., and organized a number of "Marches on Washington" or "Capitol Hill Days," as they are now called.

Some years ago AAB representatives were in Washington, D.C. when a small aircraft crashed on the White House lawn. Another time a man drove a truck he claimed was loaded with explosives up to the Washington Monument.

But nothing compares to AAB's Capitol Hill Day that was in full swing on the morning of September 11, 2001. AAB members participating included Annette Iacono, Al Salton, Phil Amuso, and Mel Bishop, along with Robert Waters, AAB's Washington representative, and his staffers Ilisa Halpern, Tiffany Galluzzo, and Stacy Harbison.

Normal assumptions turned out to be wrong that day. Knowing that the World Trade Center had been hit, Representative Jim Davis (R-FL) told the laboratory group visiting his Capitol Hill office that "We might as well just stay here. It's probably the safest place for us to be because it's so well protected."

"Then you could hear a boom," said Phil Amuso, Ph.D., HCLD(ABB). "It was close enough to almost feel it. That was probably the plane hitting the Pentagon. The next thing you know, things weren't normal at all. Guards began running through the building saying, 'Evacuate the building; we're under attack.' "

A number of AAB andrologists and embryologists were attending a meeting in Manhattan that day, just blocks away from the World Trade Center. Rita Basuray, Ph.D., HCLD(ABB), recalls that the meeting was abruptly cancelled at 9:15 a.m. because a plane had slammed into the World Trade Center.

For the next three days she helped distribute clothing and blankets at a distribution center set up by St. Luke's Roosevelt Hospital. "We distributed information on hospitals, blood donation sites and emergency contacts. The hardest was when we had to talk to people searching for missing loved ones and had to tell them that we didn't have anyone who wasn't accounted for. I said that I'll be factual, but the pain in their eyes still haunts me."

Despite the notable achievements of AAB over the past 60 years, many problems still confront the privately owned community and regional clinical laboratories, including domination by publicly traded corporate laboratories, declining third-party reimbursement rates, "sole-source" managed care contracts, the proliferation of "waived" testing, personnel shortages, and constantly changing technology.

Although challenging and stressful, these problems are a force that drives AAB and its Special Interest Groups (CRB, EBPH and NILA) to not only seek solutions, but to discover opportunities.

Those of you who were instrumental in the beginnings of this group effort for constant professional and personal enrichment can congratulate yourselves on your achievements.

And those of you who joined AAB after its start-up and who participated in many of AAB's important achievements and activities should also be proud of the role you played in making AAB a success.

And those of you who are new to AAB, we're excited to have you along as we address together the challenges of the coming years. AAB needs your energy, expertise, and enthusiasm. Most importantly, AAB needs your commitment. The future is in your hands!

- Revised and updated May 2, 2016, by Mark S. Birenbaum, Ph.D., incorporating the original 25-year history written by Louise O. Simonson, publisher of *Lab World*, in May 1981 and the 50-year history by Mark S. Birenbaum, Ph.D., written in May 2006.