

*In Pursuit of Excellence:  
The College of American Pathologists,  
1946–1996*



*Celebrating Fifty Years of Excellence*

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*In Pursuit of Excellence:*  
*The College of American Pathologists,*  
1946–1996

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# *Dedication*

*To Francis C. (Frank) Coleman, MD, 1915–1988*

*CAP President, 1960–1961*

*CAP Archivist-Historian, 1977–1988*

*who, of all people, would have been most pleased to see this work completed*



# Table of Contents

Introduction.....	v
Acknowledgments .....	vii
Chapter 1 <b><i>The Beginning</i></b> .....	1
Loyd R. Wagner, MD	
Chapter 2 <b><i>Building the Structure</i></b> .....	9
Loyd R. Wagner, MD; James G. Carson, PhD	
Chapter 3 <b><i>Membership and Its Benefits</i></b> .....	23
Loyd R. Wagner, MD; James G. Carson, PhD	
Chapter 4 <b><i>Laboratory Standards</i></b> .....	41
Loyd R. Wagner, MD	
Chapter 5 <b><i>The Surveys Program</i></b> .....	51
Loyd R. Wagner, MD	
Chapter 6 <b><i>Laboratory Accreditation</i></b> .....	61
William B. Hamlin, MD; John K. Duckworth, MD	
Chapter 7 <b><i>Quality Assurance Service (QAS)</i></b> .....	75
Noel S. Lawson, MD; Peter J. Howanitz, MD	
Chapter 8 <b><i>Anatomic and Consultative Pathology Practice</i></b> .....	95
Herbert Derman, MD; Loyd R. Wagner, MD	
Chapter 9 <b><i>Ethics and Professional Relations</i></b> .....	111
Loyd R. Wagner, MD	
Chapter 10 <b><i>Legislation and Regulation</i></b> .....	121
Jerald R. Schenken, MD; James G. Carson, PhD	
Chapter 11 <b><i>Inter-Organizational Relationships</i></b> .....	135
Loyd R. Wagner, MD	

Appendices

CAP History Timeline .....	145
Statistical Summary of CAP Growth .....	155
CAP Presidents .....	157
Officers, Governors, Speakers, Vice-Speakers, and Residents' Forum Chairs .....	161
Honorary Fellows .....	165
Chief Executive Officers .....	165
CAP Awards and their Recipients .....	167
CAP Offices .....	171
Index .....	175
Index of Authors Cited .....	187

# Introduction

A golden anniversary is an appropriate time to honor past accomplishments and to document the circumstances and events that have molded an individual or an organization. As the 50th anniversary of the College of American Pathologists (CAP) approached, the College's Board of Governors recognized that its history had never been systematically recorded, despite previous attempts to compile such a record. Thus the Board, in September 1990, instructed Executive Vice-President Lee VanBremen, PhD, and John C. Neff, MD, the chair of the Council on Education and Membership Services, to develop a plan for a written history of the College. In February 1991, the Board appointed the CAP History Editorial Board and charged it to produce a history by June 30, 1996. The result is now before you in this volume.

The Board had recognized the importance of recording the organization's history as early as 1958, when the College's first Historical Committee was appointed. However, no sustained activity occurred until 1977 when past President Frank C. Coleman, MD, was appointed by the Board of Governors to the newly created position of historian. One of Dr. Coleman's principal goals was the establishment of an archival collection of pathology materials in conjunction with a major medical school. This goal was achieved with the establishment in 1983 of the Special Pathology Collection at the Owen Wangensteen Library of the University of Minnesota College of Medicine. The Collection acquired the papers of a number of pathologists who have made significant contributions to pathology and to the College, including some 3,000,000 microfilm frames and 72,000 other documents, which formerly constituted the ASCP/CAP library housed in the offices of the American Society of Clinical Pathologists.

The Collection remained at the Wangensteen Library until 1991, when it was returned to the College headquarters and placed under the care of a professional archivist. Among the materials in the CAP Archives are minutes of the meetings of the Board of Governors and of various committees, commissions, and councils; legal records; College publications; and a series of oral history interviews with present and past leaders of the CAP, which provide many interesting anecdotes, as well as personal perspectives on pivotal events in the College's history. All these materials have proven invaluable in assembling this volume.

It has been said that "Those who are ignorant of history are doomed to repeat it." Certainly the records of the College are replete with instances that prove this axiom. It has also been said that "The more things change, the more they stay the same." Indeed, one is struck by how many organizational features of the College have stayed the same. For example, its extensive proficiency testing and laboratory accreditation programs, as well as the concepts of resource committees and practice guidelines, all can be traced to the very earliest years of the College's existence, even if not all were successfully implemented at that time. Reflection on this fact can only cause one to marvel at the foresight of the College's founders and early leaders.

On the other hand, it goes without saying that change—positive and negative, from within and without—has been even more of a constant during the College's first half-century. And the most impressive legacy of its founders is to be seen, not in any organizational structures—however durable and useful these may have

proven—but in the College’s objectives, essentially unchanged since its founding, which have helped it chart a steady course through developments in the profession and in the world at large that the founders could never have imagined. It is hoped that, if this account does not prevent the repetition of history, at least it will provide an understanding of why the College was formed, and an appreciation of its contributions to excellence in the practice of pathology and laboratory medicine and to the welfare of both practitioners and patients.

# Acknowledgments

Many persons have contributed to the preparation of this history by providing or verifying factual information, and by reviewing and critiquing drafts of the various chapters. With apologies to any who may have been inadvertently omitted, the editors wish to express their gratitude to Margaret Barnett (Mrs. Roy N.); Jack R. Bierig, JD, CAP general counsel; William H. Hartmann, MD, FCAP, executive vice president, American Board of Pathology; Jane Kenamore, archivist, American Medical Association; George W. Stephenson, MD, FACS, archivist, American College of Surgeons; and John F. Zwicky, PhD, archivist, American Society of Clinical Pathologists. Valuable assistance has also been furnished by CAP Fellows including Herbert Derman, MD; Dennis B. Dorsey, MD; Thomas L. Gavan, MD; and John C. Neff, MD. Further thanks are owed to the CAP 50th Anniversary Ad Hoc Committee, chaired by the late Pierre W. Keitges, MD, for its financial, administrative, and moral support of the CAP history project.

We are also indebted to a number of current and former CAP staff members including Beverly Albert, Barbara J. Barrett, Mary Ann Bartlett, Janice Carrier, Karole Cecich, Jayne Hart Chambers, Elizabeth A. Cramer, Pamela Cramer, Mischa Frederick, Gloria Hopewell, Judy Koch, Michael C. Palmer, Mary Paton, Sherrie A. Rice, Lee VanBremen, PhD, William E. Williamson Sr., and Ruth Young.

In addition to the individuals listed above, hearty thanks are owed to the reference staff of the Health Sciences Library of the University of Illinois at Chicago; and to the anonymous reviewers who critiqued the several chapters in preparation for their publication as a series of articles in *Archives of Pathology & Laboratory Medicine*, the official journal of the College of American Pathologists. Following is a list of bibliographic citations to these articles.

- Chapter 1 Wagner LR. The College of American Pathologists, 1946-1996: The beginning. *Arch Pathol Lab Med.* 1996;120:1151-1155.
- Chapter 2 Wagner LR, Carson JG. The College of American Pathologists, 1946-1996: Building the structure. *Arch Pathol Lab Med.* 1997;121:177-186.
- Chapter 3 Wagner LR, Carson JG. The College of American Pathologists, 1946-1996: Membership and its benefits. *Arch Pathol Lab Med.* 1997;121:427-437.
- Chapter 4 Wagner LR. The College of American Pathologists, 1946-1996: Laboratory standards. *Arch Pathol Lab Med.* 1997;121:536-541.
- Chapter 5 Wagner LR. The College of American Pathologists, 1946-1996: The surveys program. *Arch Pathol Lab Med.* 1997;121:646-651.
- Chapter 6 Hamlin WB, Duckworth JK. The College of American Pathologists, 1946-1996: Laboratory accreditation. *Arch Pathol Lab Med.* 1997;121:745-753.

- Chapter 7 Lawson NS, Howanitz PJ. The College of American Pathologists, 1946-1996: Quality Assurance Service (QAS). *Arch Pathol Lab Med.* 1997;121:1000-1008.
- Chapter 8 Derman H, Wagner LR. The College of American Pathologists, 1946-1996: Anatomic and consultative pathology practice. *Arch Pathol Lab Med.* 1997;121:1214-1222.
- Chapter 9 Wagner LR. The College of American Pathologists, 1946-1996: Ethics and professional relations. *Arch Pathol Lab Med.* 1997;121:1009-1014.
- Chapter 10 Schenken JR, Carson JG. The College of American Pathologists, 1946-1996: Legislation and regulation. *Arch Pathol Lab Med.* 1997;121:1303-1310.
- Chapter 11 Wagner LR. The College of American Pathologists, 1946-1996: Inter-organizational relationships. *Arch Pathol Lab Med.* 1997;121:1296-1302.

# Chapter One

## The Beginning

Lloyd R. Wagner, MD

Any individual is the sum of his or her genetic make-up and the environmental factors which influence human development. Changes in that individual occur as adaptations are made to both internal and external forces. The same is true of an organization, and only with an awareness of the circumstances in which it originated, developed, and changed can there be an understanding of that organization's success or failure. Knowledge of the events preceding 1946 and coming into conjunction in that era is essential if one is to understand the formation of the College of American Pathologists and appreciate its contributions to the medical profession and to the specialty of pathology.

*The Background* Throughout the history of medicine, morbid anatomists, as exemplified by Karl Rokitansky (1804–1878), have made significant contributions to the description of morphologic changes caused by human diseases. In the 1840s and 1850s, Rudolph Virchow (1821–1902) used the microscope to study the cellular changes of disease and broaden understanding of the changes first described by the earlier practitioners of gross pathology. By the end of the 1800s, anatomic pathology had progressed to a fairly high degree of sophistication. Pathologists performed autopsies to define the anatomic manifestations and extent of disease, and they examined specimens from living patients and reported the diagnostic findings to the surgeon. The leaders of the profession—figures such as Virchow and Rokitansky, along with some outstanding American colleagues—also achieved considerable prestige and were revered both by their associates and students, and by the public at large. However, the typical “in-the-trenches” anatomic pathologists went largely unsung among their medical colleagues and unnoticed by the patient and the general public.

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In the first decades of the 20th century, the sophistication of clinical pathology lagged behind that of the anatomic branch. The few simple laboratory tests that existed were generally performed by individual physicians for their own hospital patients. Occasionally, a small room (to become known as the clinical laboratory) was set aside for this testing. By the early 1920s, however, advances such as Landsteiner's recognition of blood groups, the development of serological tests for syphilis and typhoid, and the growth of medical microbiology had increased the definition and complexity of clinical pathology to such a degree that a group

of physicians practicing in clinical laboratories felt the need for a society focused specifically on the needs of this emerging specialty, since the pathology societies of that time were focused almost entirely on anatomic pathology. As a result, the American Society of Clinical Pathologists (ASCP) was organized. Frank W. Konzelmann, MD, ASCP president from 1944 through 1946, wrote in a May 1947 editorial in the *American Journal of Clinical Pathology* that this event was “the first step in the establishment of clinical pathology as a specialty of medicine.”<sup>1</sup>

In many ways, it was the lowly professional status of the average hospital-based pathologist that led to the formation of the ASCP on May 22, 1922. That pathologists were not considered as “equal” in the practice of medicine by their colleagues is well expressed in this statement of Philip Hillkowitz, MD, at the first meeting of the ASCP: “We are assembled here today to take counsel together how best to strengthen the status of the clinical pathologist from the scientific as well as the economic viewpoint....We must elevate the status of the clinical pathologist to the same level as that of the internist or surgeon; namely, as a consultant who uses laboratory methods as aids to diagnosis.” These purposes of the ASCP were reiterated in somewhat more detail by Ward Burdick, MD, in the *Journal of Laboratory and Clinical Medicine* in September, 1924.<sup>2</sup>

The prestige of the clinical pathologist received a boost in 1926, when the American College of Surgeons revised its Minimal Standards for Hospitals to require that clinical laboratories be under the direction of MD physicians with special training in clinical pathology, and that “all tissue removed at operations shall be examined in the laboratory and reports rendered thereon.”<sup>3</sup> The professional status and recognition of pathologists were further enhanced by the formation of the American Board of Pathology (ABP) in 1936 through the efforts of the ASCP and the Section on Pathology and Physiology of the American Medical Association (AMA).<sup>4</sup>



**Fig 1-1.** Alfred S. “Jerry” Giordano, MD (1893–1958), long-time secretary-treasurer of the American Society of Clinical Pathologists, carried on a one-person crusade to improve the socio-economic status of pathologists, which provided much of the impetus for the founding of the College. (Photo courtesy of ASCP Archives.)

Despite this development, however, pathology as a profession remained considerably fragmented, and largely relegated to the basements of most hospitals, throughout the 1930s. Pathology was not even considered to be the practice of medicine by hospital administrators, the public, or many fellow physicians as late as World War II. In many, if not most states, medical licensure was not required to practice pathology. Not until 1943 was pathology recognized as the practice of medicine by the House of Delegates of the AMA, largely as a result of an effort spearheaded by Alfred S. Giordano, MD, then secretary-treasurer of the ASCP (Fig 1-1). According to John R. Schenken, MD, CAP Pathologist of the Year in 1962, Dr. Giordano “carried on a one-man socio-economic operation for the benefit of pathologists throughout the United States, especially in their relations to hospitals and with each other.”<sup>5</sup>

In the years preceding and during World War II, third-party payment of medical expenses was emerging on the scene. Blue Shield (physicians’ services) and Blue Cross (hospital services) policies were being issued, which paid for laboratory and pathology services to hospitalized patients under Blue Cross contracts. With payment being made to the hospitals, pathologists were having increasing problems in their relationships with hospital administrations.

The end of World War II gave rise to new problems for pathologists. They were still often unrecognized as medical practitioners by either their colleagues or state licensing boards. Changes in hospital management were leading to lay control of laboratories. State health department laboratories were beginning to provide direct patient diagnostic services. Unknown to the public they served, the economic and professional outlook for pathologists was not favorable.

*The College Is Conceived* Just as the lowly status of clinical pathology in 1922 led to the formation of the ASCP, forces were now coalescing which would lead to the formation of the College of American Pathologists, an organization that had been considered at least nine years before its actual founding. Unfortunately, surviving archival documents do not provide as clear a picture as might be desired of the exact circumstances that led to the founding of the College. As early as 1956, ASCP Secretary-Treasurer Clyde Culbertson, MD, responded to a request for information regarding the College's founding by stating that "...in fact the whole thing is rather sketchy."<sup>6</sup>

What is clear is that pathologists were requesting assistance in resolving their problems with hospital administrations from the various existing pathology organizations. There was general dissatisfaction with the help received, as illustrated by reports to the 25th annual meeting of the ASCP in June 1946. Dr. Giordano, then secretary of the ASCP, states: "During the past two years, our office has been particularly impressed with correspondence from members desiring guidance in improving economic relationships with hospitals. There has been a very strong feeling that the Society should take a more positive action in protecting the economic welfare of the members. This feeling is shared by the Secretary, who has done everything possible to answer the numerous inquiries." The report of the Committee on Hospital and Public Relations adds, "Several Fellows of the Society have indicated their displeasure with the apparent reluctance of the Society, or its inability, to engage more actively in the solution of local problems. The officers of the Society have continued the policy of informing hospital administrators of the position taken by the AMA and ASCP relative to hospital-pathologist relations (condemning exploitation) and have urged the county, state, or regional societies of pathologists to handle their own problems on a local level. The Executive Committee realizes that this policy has not been effective in many instances." Dr. Schenken in 1977 characterized the mind-set of other pathology organizations at the time as "anything economic or political was dirty."<sup>7</sup>

While these national associations were perceived by pathologists as ineffectual in addressing the socio-economic needs of the members, some individual state organizations of pathologists were active and successful. Concerned about the widespread performance of urinalysis by druggists, pathologists in Washington, DC, spearheaded a successful 1926 effort to amend the District's Medical Practice Act to define certain laboratory tests as the practice of medicine. In the early 1940s, pathologists in Indiana were successful in changing Blue Cross policy to designate laboratory services as a medical service for reimbursement purposes, even though payment was still made to hospitals. In 1943 or 1944, Michigan had been successful in establishing payment by Blue Cross and the Michigan Hospital Association to Blue Shield for laboratory services, although payment was made jointly to both the pathologist and the hospital administration.

Foremost in the Michigan effort was Frank W. Hartman, MD, of Detroit, a medical educator, founder and past president of the ASCP, and founder and long-time secretary of the American Board of Pathology (Fig 1-2). He was chair of a committee charged with enhancing the professional status of the members of the Michigan Pathology Society, primarily by dealing with hospital management and Blue Cross payment issues. On the basis of his success in this endeavor, the president of the ASCP, in late 1944 or early 1945, named him chair of the ASCP Committee on Hospital and Public Relations to address similar issues on a national basis.



**Fig 1-2.** Frank W. Hartman, MD (1890–1979), as chair of the ASCP Hospital and Public Relations Committee, devoted countless hours to organizing the College and was rewarded by his election as the CAP's first president (1947–1949).

One of the suggestions of this “Hartman Committee” was to form a separate society—an Academy of Pathology—to deal specifically with issues of economics and practice. This suggestion met with a mixed reception. In the September 30, 1945, minutes of the ASCP Executive Committee, the following appears: “The question of the movement to organize an Academy of Pathology was discussed and it was decided that the Society would favor such an organization, but would not take an active part in promoting it.”

Why the ASCP took this supportive but non-involved stance is unclear. Other forces were gathering, however, which were to lead to the founding of the College. David A. Wood, MD, in his report as president to the membership of the College in 1955, recalled that a group had discussed the formation of such a society at a meeting of the American Association of Pathologists and Bacteriologists in Chicago in February 1946.

At the 25th Annual Meeting of the ASCP in June 1946 in San Francisco, a resolution from the Michigan Pathology Society was adopted that called on the Society to “adopt a policy to uphold the dignity of its members as physicians and lend its assistance to accomplish this aim,” and provided that the “Committee on Hospital and Public Relations of this Society be instructed to undertake a study of ways and means for the attainment of the objective of indicating to hospital administrators that Clinical Pathology is the practice of medicine and as such the services of physician-pathologists and of the laboratories which they direct should be included in the prepaid medical care and hospitalization contracts as the services of physicians and be distinctly so considered.” The Executive Committee was then “empowered to assist in the study and formation, if it is deemed advisable, of an organization such as that suggested in the report of the Committee on Hospital and Public Relations.” There is no record that any official action was taken at the meeting to carry out this directive of the membership.

However, F. William Sunderman, MD, the only surviving member of the first Board of Governors of the College, recalled, in a personal communication with the author in October 1993, that the president of the ASCP announced a “rump session” for anyone interested in forming such an organization. There was no agenda, no chair, and no minutes were kept of that meeting. At that San Francisco meeting, however, Dr. Hartman “proposed a constitutional convention with the view to establishing a group with more uniform [professional] qualifications, namely [that membership be restricted to] those certified by the ABP.” This proposal was endorsed by those present at the meeting with only a single dissenting vote, although there were several abstentions.<sup>8</sup>

During the six months following the June 1946 San Francisco meeting, Dr. Hartman continued the activities which culminated in the formation of the College, mobilizing pathologists from the other pathology societies interested in forming such an organization. His personal commitment to the venture is illustrated in a letter to Dr. Schenken on April 7, 1961, in which he recalled: “I was informed by the secretary of ASCP that they would not support any further activity in this direction, but so much ground work had already been done and so much interest was shown by the certified men that I continued alone with my own money sending out the announcement of the convention to all certified pathologists. I was still secretary of the ABP at the time....CAP eventually repaid the money I spent for postage.”<sup>9</sup>

Other pathologists were also promoting the formation of the proposed new organization. In another personal communication in October 1995, providing information from his diary, Dr. Sunderman notes that pathologists present at the San Francisco meeting had been encouraged to stimulate enthusiasm for founding the CAP among board-certified pathologists not in attendance at that meeting. Dinner meetings were held around the country, including one organized by Dr. Sunderman in Philadelphia with more than 200 present. Support for the creation of a new society was almost unanimous.

***The College Is Born*** On December 12 and 13, 1946, 140 pathologists certified by the American Board of Pathology met in Chicago to discuss and move forward with the formation of an organization to deal more directly with the socio-economic and practice issues facing pathology. The first day was devoted to a discussion of the problems facing the profession—lack of recognition of pathology as the practice of medicine; payment issues, especially under Blue Cross/Blue Shield contracts; the movement of state health department laboratories into direct patient service functions; and the public non-image of pathologists.

Discussions also outlined the successful efforts by some state societies to address pathologists' problems, as well as cooperative efforts with other hospital-based specialties such as anesthesiology and radiology. Max Cahal, executive director and legal counsel of the recently formed American College of Radiology, recounted the steps taken to organize that society and outlined a proposed organizational structure including commissions, councils, and committees. That structure eventually was adopted by the CAP, and exists today.

The second day of the meeting was devoted to the actual organization of the CAP. A long debate resolved the issue of naming the new organization. The name "American College of Pathology" was rejected because of concern about confusion arising from the use of initials, i.e. that ACP might be confused with the American College of Physicians. One group wanted "clinical" added to the name; another wanted "laboratory medicine" included. Some feared an eventual split between anatomic and clinical pathologists. However, the members adopted the view that "pathology" was all-encompassing and the name "College of American Pathologists" was ratified.

A constitution and initial bylaws had been prepared in anticipation of the College's founding, and both were adopted (Fig 1-3). Dr. Hartman was elected the first president and Granville Bennett, MD, the first vice-president, both for three-year terms. Nine governors—Frederick H. Lamb, MD; Josiah J. Moore, MD; Thomas B. Magath, MD; Tracy B. Mallory, MD; Oscar B. Hunter Sr., MD; F. William Sunderman, MD; James B. McNaught, MD; Ward H. Cook, MD; and Everett L. Bishop, MD—were elected by the general membership. Three other positions were to be filled by representatives of each of the three existing major pathology societies—American Society of Clinical Pathologists, American Association of Pathologists and Bacteriologists, and American Society of Experimental Pathologists. The Board of Governors was to select a secretary-treasurer for a one-year term.

The original constitution and bylaws provided for the formation of geographically-based Regional Committees, whose primary function was to present scientific educational programs. A committee was to be appointed to set standards for the adequacy of hospital laboratories and issue certificates of compliance. A pledge of membership was adopted, supporting the College and pledging adherence to its Code of Ethics. (In 1969, the CAP dispensed with its own Code of Ethics, opting instead for a formal declaration that CAP members were bound by the AMA *Principles of Medical Ethics*.)

The Finance Committee recommended an initial annual budget of \$25,000. Dues of \$50 a year were suggested, an amount thought by member Otto Saphir, MD, to be "quite a bit of money for most pathologists."<sup>10</sup> An initiation fee was rejected because it could be perceived as a way of "buying membership."

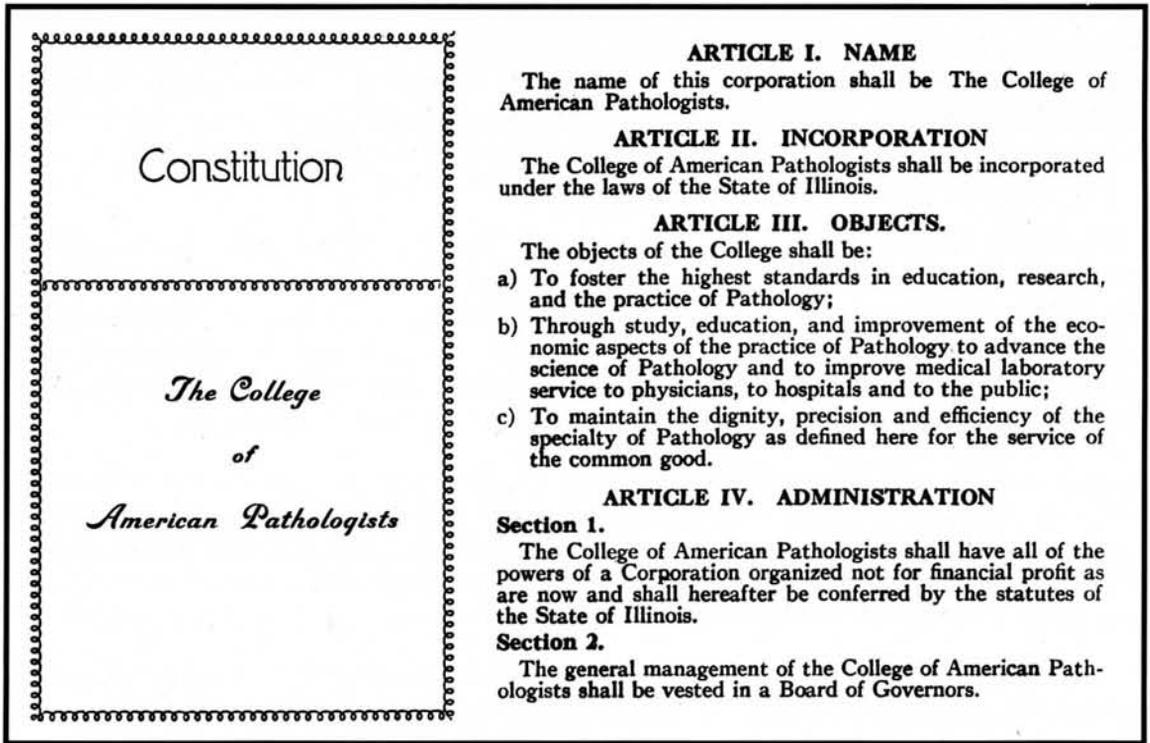


Fig 1-3. Excerpt from the CAP's first constitution, adopted December 13, 1946.

The organizational meeting of the Board of Governors was held in Chicago on January 4–5, 1947. The College was incorporated under the laws of Illinois on May 14, 1947 and application was made for tax-free status under the Internal Revenue code—an application that was later found to have been “lost in the voluminous files” of the IRS.<sup>11</sup> Several committees were appointed, notably those on Ethics, Standards, and Evaluation of Hospital Laboratories.

At the same meeting, membership requirements and dues were set. Residents could apply as Junior Members in the third year of residency and were to pay \$5 annual dues. Initially, it was contemplated that most practitioners joining the College would hold the status of “Member,” paying dues of \$25 a year. The status of “Fellow,” the norm in today's College, was conceived at first as a relatively rare distinction. During the first two years of the organization's existence, any board-certified pathologist could apply for Fellowship with dues of \$50 per year; but beginning in 1949, a pathologist could be elected to Fellowship only by the Board of Governors in recognition of superior service to pathology, medicine, or the community. Listing as a Founding Fellow required a dues payment of \$100 for the first year only. Fellows earning less than \$5,000 per year and Members earning less than \$3,000, could receive a refund of 50 percent of their dues upon request.

By May 1947, an executive office had been established at 203 North Wabash Avenue in Chicago, and Melbourne G. Westmoreland, MD, a bacteriologist and former staff member of the American Medical Association, had been employed as the first executive secretary of the College. By June, 525 applications for membership had been received; and before the end of that year, a Code of Ethics had been adopted and a Placement Bureau established.

Thus by the end of its first year of existence, firm foundations had been laid for the College of American Pathologists. During the ensuing half-century, a host of dedicated pathologists working within the framework of the College—in cooperation with bioscientists, academic pathologists, and allied scientific and professional societies—have pursued excellence through myriad avenues. They have set and monitored adherence to standards that assure the highest quality of pathology and laboratory medicine for patients not only in the United States, but worldwide. They have instituted pioneering programs to inspect and accredit laboratories, and to monitor laboratory performance through regular comparative surveys. They have been active in promoting the highest ethical standards for the specialty, and in bringing the best professional expertise to bear on the formulation of legislation and government regulations. They have written and edited publications of the highest quality, and sponsored professional education programs, which play an increasingly crucial role in equipping practitioners with the most current scientific knowledge and techniques.

The College's accomplishments in these and other areas will be described in detail in the remaining chapters of this volume. But it seems safe to say at the outset that, as a result of these efforts, the professional and socio-economic status of pathologists has improved, and wider recognition has been accorded to the contributions of the profession of pathology to quality medical practice. Without question, these developments amply justify the vision and perseverance of the College's founders.

## Notes

1. Konzelmann FW. The development of clinical pathology as a specialty of medicine. *Am J Clin Pathol.* 1947;17:393.
2. Burdick W. The American Society of Clinical Pathologists. *J Lab Clin Med.* 1924;9:873-874.
3. MacEachern MT. Report on hospital standardization for the year 1926. *Bull Am Coll Surg.* January 1927;11:48.
4. Abell MR, Kirby NM. The American Board of Pathology: 50 years of service. *Arch Pathol Lab Med.* 1986;110:1097-1110.
5. Schenken JR. Unpublished manuscript on CAP history, 1977 Nov. CAP Archives, Historical Writings Collection.
6. Culbertson C. Letter to John R. Schenken, MD, 1956 Aug 8. CAP Archives, Alfred S. Giordano Papers.
7. Schenken JR. Unpublished manuscript.
8. Andujar JJ. Personal communication, 1996 Feb 14.
9. CAP Archives, Frank W. Hartman Papers.
10. CAP Organizational Meeting Minutes, 1946 Dec 13:177. CAP Archives.
11. CAP *Secretary's Newsletter*, 1948 Jun:6.

## Chapter Two

# Building the Structure

Loyd R. Wagner, MD  
James G. Carson, PhD

The foundation of the College of American Pathologists was laid at the organizational meeting on December 12–13, 1946, in Chicago, Illinois, when the original constitution and bylaws were adopted. It fell to the officers and governors elected then to carry out the duties spelled out in these documents. The success of their first meeting on January 4–5, 1947, was due in large measure to careful planning and preparation by President Frank W. Hartman, MD, truly the father of the CAP.

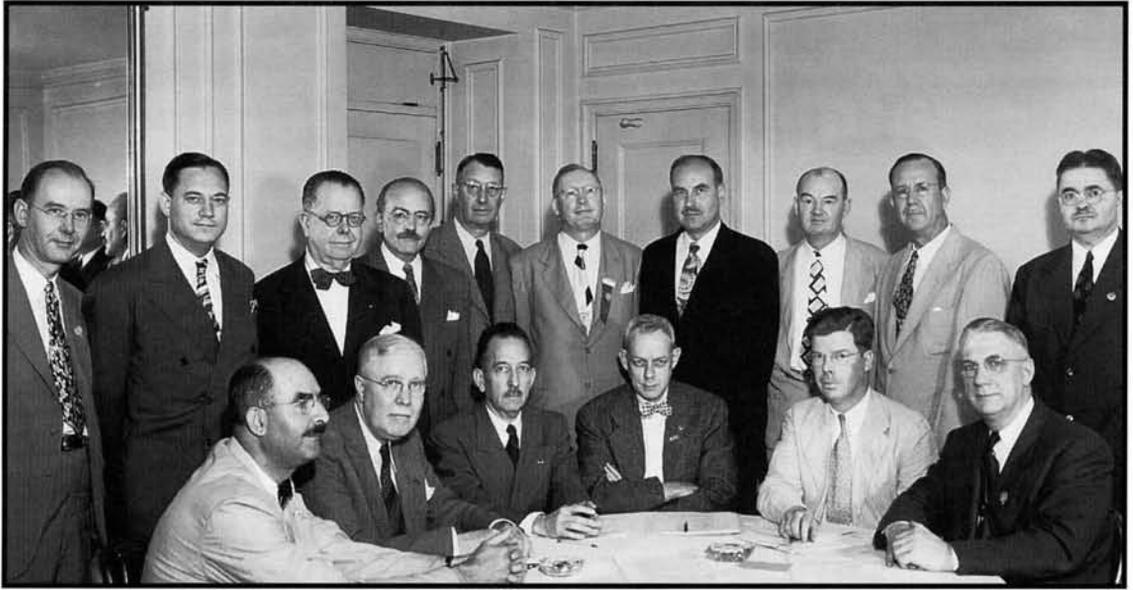
Each action of the first Board of Governors, and all of its successor Boards, has been taken to further the objectives of the College as stated in the original constitution:

- To foster the highest standards in education, research, and the practice of Pathology
- Through study, education, and improvement of the economic aspects of the practice of Pathology to advance the science of Pathology and to improve medical laboratory service to physicians, to hospitals, and to the public
- To maintain the dignity, precision, and efficiency of the specialty of Pathology as defined here for the service of the common good.

Incorporated under the not-for-profit corporate statutes of the state of Illinois on May 14, 1947, the College has been throughout its history a tax-exempt 501(C)(6) corporation as defined by the United States Internal Revenue Service. Under this status, any excess revenues over expenses are not taxed if used for the purposes for which the corporation was founded. This status also allows the College to lobby in the legislative and regulatory arenas; but it cannot receive tax-deductible contributions from members or others. The College's income-tax exemption was first approved in the summer of 1948 under section 101.7 of the then-current Internal Revenue code (now section 501(C)(6)). At the time, the Board of Governors gave some consideration to filing an appeal for re-classification under section 101.6, equivalent to the present section 501(C)(3), which would have allowed tax-deductible contributions to the College, but would have forbidden lobbying and other political activity. However, the Board apparently felt that the privilege of lobbying more than offset the loss of deductibility for contributions to the College; no appeal was filed, and the College's 501(C)(6) classification has continued to the present.<sup>1</sup>

*The success of the  
first meeting was due  
in large measure to  
careful planning  
and preparation by President  
Frank W. Hartman, MD,  
truly the father of  
the CAP.*





*Fig 2-1. The earliest known group photograph of the CAP Board of Governors, October 1948. Standing, left to right: Melbourne G. Westmoreland, MD, executive secretary; Frank B. Queen, MD; Oscar B. Hunter Sr., MD; Ward H. Cook, MD; Everett L. Bishop, MD; Josiah J. Moore, MD; F. William Sunderman, MD; James B. McNaught, MD; John L. Goforth, MD; Harry P. Smith, MD, representing the American Society of Experimental Pathologists. Seated, left to right: Theodore J. Curphey, MD, representing the American Society of Clinical Pathologists; Frederick H. Lamb, MD; Thomas B. Magath, MD; Tracy B. Mallory, MD, secretary-treasurer; Granville A. Bennett, MD, vice-president; Frank W. Hartman, MD, president.*

**Board of Governors** Under applicable Illinois law, responsibility for the general management and operation of the College is vested in the Board of Governors. In addition to the duties defined in statute, other duties of the Board are delineated in the bylaws of the College. These functions include appointing members of committees; establishing rules for the election of officers and governors; and appointing administrative personnel to oversee the daily operation of the organization.

The original bylaws provided for a Board of Governors to consist of between nine and 12 members (Fig 2-1). Nine members were to be elected by the membership of the College at the annual meeting, from a slate submitted by a nominating committee, with three governors elected each year to serve a three-year term. At the first annual meeting, three members each were elected for terms of one, two, and three years, in order to establish a pattern of staggered terms. To encourage geographic diversity on the Board, the bylaws provided that nominations were to be accepted from recognized state and regional pathology societies, as well as from the current Board and from the floor of the annual meeting.

In addition to the nine governors chosen from the College's own membership, one additional member was to be chosen from each of the three major pathology organizations in existence at the time, namely the American Society of Clinical Pathologists, the American Association of Pathologists and Bacteriologists, and the American Society of Experimental Pathologists. These three organizations were each to nominate two candidates to the Board of Governors, which would then select the individual to represent that society.

Elections were held at the annual meeting of the College, usually in the fall. At first, however, newly-elected governors and officers did not take office until January 1 of the following year, resulting in a "lame duck" interim which frequently caused a hiatus in College activities.

The first significant revision of the College's nomination and election procedures came in 1955, when the bylaws were amended to require that names of nominees be posted 24 hours in advance of the annual meeting. Another 1955 amendment provided that nominations could be made by petition, signed by a minimum of 25 Fellows, as well as by the current Board or from the floor. Also in 1955, the composition of the Board of Governors was changed to provide that all 12 governors be elected by the general membership, thus ending representation from the other pathology societies as established in 1946.

The "lame duck" hiatus was remedied in 1961 when the bylaws were amended to install officers and governors in office immediately following election. In 1969, elections were removed from the agenda of the annual meeting, and a new procedure was instituted, which allowed voting during a designated span of time by all Fellows attending the fall meeting. Balloting was formalized with printed ballots, followed in due course by voting machines, poll watchers, and election committees. Campaigns by candidates for office became commonplace; most candidates, then as now, had compiled substantial records of service on College committees or in leadership positions in the House of Delegates.

Another round of revisions in the bylaws in 1972 required that a majority of the Nominating Committee membership consist of current members of the House of Delegates, and dictated that the committee give "due consideration" to geographic diversity in recommending candidates for the Board of Governors. The Nominating Committee was expanded in 1984, increasing representation from the House of Delegates; at this time, the required number of Fellows for a nominating petition was also increased to 100 from the previous 25. Also in 1984, a mail ballot was initiated, replacing the elections at the fall meeting. At first a Fellow desiring to vote was required to request a ballot, but since 1986 ballots have been mailed to all Fellows eligible to vote. Under current procedures, secret ballots are returned to the College and then tabulated by independent auditors.

**Officers** The president of the College serves as the principal executive officer of the society; is an ex-officio member of all committees except the Nominating Committee; chairs the Board of Governors, with voting privileges; and presides at all official meetings of the association. While committee appointments are the prerogative of the Board of Governors, the president also recommends members for all committees.

Initially, the term of the president was established as three years, with the vice-president to serve concurrently. In 1949, Frederick H. Lamb, MD, then vice-president, suggested that the term be shortened from three years to one in order to allow more members to have the honor of the presidency. Other Board members objected that the office "is not bestowed upon an individual as an honor but should be considered as a serious call..."<sup>2</sup> Apparently feeling that yearly turnover in the presidency would result in an unacceptable loss of continuity, the Board tabled Dr. Lamb's suggestion indefinitely. The presidential term was not changed until 1955, when the present two-year term was instituted on the recommendation of then-President David A. Wood, MD. At the same time, the immediate past president was made an ex-officio member of the Board of Governors during the year following completion of his/her term of office.

Also in 1955, the office of president-elect was created, with a term of one year, coinciding with the second year of the president's term. Despite the implications of the name, election as president-elect did not at first ensure automatic assumption of the presidency, a second election being required for that position. Although the office of president-elect was usually held by the sitting vice-president, on occasion the two offices were

held by different individuals. In 1991, the position of vice-president was eliminated. The president-elect now serves for two years, concurrent with the president's term; performs the duties of a vice-president; and succeeds automatically to the presidency.

The offices of secretary and treasurer have always been combined. Originally the Board of Governors selected a secretary-treasurer from among its members for a one-year term, and the funds of the College were deposited in a bank chosen by the secretary-treasurer in that individual's city of residence. In 1972, the bylaws were revised to do away with the custom of electing the secretary-treasurer from among the Board of Governors; since that time, the secretary-treasurer has been elected by the general membership. The term of office has also been lengthened to three years, with a maximum of two terms served by any one individual.

**Regional Committees** The founders of the College of American Pathologists were strongly convinced that all areas of the United States should be represented on the governing body and in the anticipated activities of the new organization. To this end, in addition to providing for geographic diversity on the Board of Governors, the constitution and bylaws also established Regional Committees. Members and chairs of these committees were to be appointed by the Board of Governors after consultation with local pathologists—though the latter provision was adhered to sporadically at best. Throughout the 1940s and 1950s, the assignment of states to regions was changed periodically to bring about more equal distribution of members and to facilitate access to the scientific programs presented by the Regional Committees. It appears, however, that such geographic machinations rarely made anyone happy!

The primary responsibility of the Regional Committees was scientific post-graduate medical education; in fact, the very earliest membership listings of these committees give them the title "Postgraduate Education," with or without the parenthetical qualifier "Regional." Funds were allocated for their programming, but frequently went unspent. The programs' success varied with the dedication of the individual pathologists assigned responsibility for their planning. A number of regions held no programs, while others requested additional funding for their programming efforts, most of which were focused on new and emerging technology. Early editions of the *CAP Secretary's Newsletter* listed a number of successful regional programs on topics such as usage of radionuclides in the clinical laboratory and on varied anatomic pathology subjects; a successful cytology program in Memphis, for example, attracted 28 participants early in 1957. Generally, regional scientific programs were presented as a membership service without charge, since many pathologists reportedly voiced strong opposition to charging fees for these programs, and the Board of Governors went on record as opposing the concept in 1954.

The Regional Committees were also intended to serve as a grassroots network to provide input about local concerns to the governing body of the College, and to inform College members about ways to address issues confronting pathologists in their practice. Most of these issues had to do with the ethics of billing and financial compensation for pathologists, and/or matters related to contracts between pathologists and the hospitals in which they worked. At first this liaison function was duplicated by the ASCP Councilors, who were also chosen on a geographical basis, and were used to exchange information between the Board of Governors and the membership, as well as to address some of the ethical situations which arose. Soon, however, objections to this arrangement were raised, since a number of the Councilors were not members of the College and could therefore be perceived as having conflicting interests in ethical matters. Eventually this use of the ASCP Councilors was done away with, as the CAP's own structure evolved to enhance grassroots representation. However, similar internal conflicts over functional "turf" would also arise between the Regional Committees, Sections, and the Assembly of the College, and would continue until the demise of the Regional Committees in the late 1960s.

*Assembly/House of Delegates* By the mid-1950s, the effectiveness of some Regional Committees, their structure, and the method of appointment of members, as well as the use of the ASCP Councilors to deal with CAP issues, were all called into question by the Board of Governors and others. As a search began for an alternative, more broadly representative “grassroots” body in the College, the concept of an Assembly was born. Based on the idea of “proportional representation,” the original proposal for an Assembly called for one delegate to be elected for every 50 CAP Fellows in a given state. The Assembly was to assume the duties previously assigned to the Regional Committees and the ASCP Councilors.

In February 1957, the Board of Governors approved the establishment of an Assembly in time for the fall meeting of the College in New Orleans, Louisiana. Its stated purposes were to improve communication between the Board and the membership; to identify members who could be potential Governors and/or committee members; to involve more members in activities of the College; and to strengthen the regional educational programs. It was proposed that the CAP president be the presiding officer of the Assembly “to maintain control of the activities of the Assembly...” Some Governors expressed fears that the Assembly could become autonomous, relegating the Board of Governors to the role of a merely judicial body.

The first meeting of the Assembly was held in New Orleans in fall 1957. Most of the members reportedly had neglected to read the materials provided in preparation for the meeting, resulting in confusion and prolongation of the proceedings. One thing became clear, however: The Assembly objected strenuously to being presided over by the president of the College.

There now existed two grassroots organizational structures within the College—the members and the Regional Committees. Given this scenario, conflict was inevitable and soon surfaced. The Regional Committees were represented in the Assembly, and at least one member of the Assembly was to be named to each Regional Committee. Furthermore, the older Regional Committees, which had formerly reported directly to the Board of Governors, were now being asked to report to the newer Assembly.

Conflict between the Board and the newly constituted Assembly was also soon apparent. Although the Board had set the rules for the first meeting of the Assembly, in June 1958 it agreed to allow the Regional Committee chairs to draw up a protocol for the future operation of the Assembly, so long as it did not contravene the constitution and bylaws of the College. At the same time, it informed the chair of the Assembly Steering Committee, Richard F. Birge, MD, that he could set the agenda for the second meeting. While one item of business on the agenda could be the election of a speaker and vice-speaker, a specific proviso was included that the officers of the College were also the officers of the Assembly. Even though elected by the Assembly, the speaker would be allowed to preside only at the discretion of the president of the College.

Unfortunately, the exact role of the Assembly had not been defined; as one Fellow commented at the time, “I nowhere see that the Assembly has any duties or responsibilities...”<sup>3</sup> Among the unanswered questions were these: Were committees to report to the Board of Governors or the Assembly? Could the Assembly set policy or was it purely advisory? Could the Assembly appoint its own reference committees? Fears were expressed that the Assembly might even want to elect the governors and officers! Had the Board given birth to an offspring that it could not control? After all, the Assembly had met twice by the end of 1958 but the Board had only authorized one meeting in 1957. Finally in 1960, the constitution and bylaws were amended to provide for an Assembly—the bastard child had been made legitimate!

Still, the role of the Assembly and its method of operation continued to command a good deal of Board discussion during the early 1960s. Fears that the Assembly could become autonomous persisted among the

officers and governors. As early as 1962 a resolution was introduced in the Assembly that called for it to be converted to a House of Delegates with explicit legislative powers, “similar to that of the American Medical Association in its duties and functions...” At that time the Assembly voted instead to form “an Ad Hoc Committee...to study and recommend methods and procedures to be followed in the relationship of the Assembly to the Board of Governors.” Apparently in response to this mandate, a written charter and bylaws for the Assembly were drafted, only to be almost totally rewritten when they were brought to the Board of Governors for approval early in 1963. Future CAP President William Reals, MD, then Speaker of the Assembly and a guest at the meeting, accused the Board on this occasion of operating “in the stratosphere” and talking “only to each other and...not...to the membership.”<sup>4</sup>

Eventually this crisis was weathered, and the operations of the Assembly slowly evolved over time. Terms of office were defined for the speaker, vice-speaker, secretary, and a Steering Committee. Election procedures for Assembly officers were codified. Reference Committees began to receive reports of the officers, Councils, and Commissions; hear testimony pro and con on the various issues; and make recommendations for consideration by the entire body.

In 1969, the Assembly was in fact converted to a House of Delegates. At this juncture, its policy-generating function was made explicit in a set of objectives reading, in part, “The House is identified as a body within the College which formulates policy so that the actions and policies of the College of American Pathologists may reflect the needs and wishes of its Fellows. The House of Delegates...shall act as a legislative body of the College, initiating business, considering the reports of the College’s Officers, Executive Director, Councils and Committees, and the Officers and Committees of the House, passing such actions on to the Board of Governors.” In order to facilitate communication between the House and the Board of Governors, the speaker and vice-speaker of the House began attending meetings of the Board as guests. By 1971, the House was requesting voting membership for the speaker on the Board. Ex-officio Board membership was granted to the speaker in 1972, but without voting privileges, which were added in 1984. While the House of Delegates has no independent authority to make policy, its resolutions and recommendations are transmitted to the Board of Governors, where they almost always have received favorable consideration and have been adopted as policy. Through this mechanism, the House serves as the true grassroots voice of pathology.

The stature of the House of Delegates has continued to grow with the inclusion of its speaker and vice-speaker on the Board of Governors. When the speaker was granted ex-officio membership on the Board with vote in 1984, the proviso was added that the vice-speaker serve as alternate in the absence of the speaker. In 1989, ex-officio membership on the Board of Governors was also granted to the vice-speaker. This arrangement provides direct and on-going communication between the House and the Board and ensures that the views of practicing pathologists are fully presented to the Board of Governors.

**Sections** In the early 1960s, the role and purposes for which the College was founded fueled a wide-ranging debate. Some members thought its functions should be focused solely in the socio-economic arena; others believed strongly in a scientific educational role as well; still other Fellows believed that the interests of certain groups of pathologists were not being adequately served by the College.

One of the latter group was Henry L. Wollenweber, MD, a former governor of the College (1951–1953). In 1959, he incorporated the Private Practitioners of Pathology Foundation, later to become the American Pathology Foundation. One of its stated purposes was “to advance the common interest of the trustees and members...in the private practice of pathology...through the improvement of business conditions of the private practice of medicine and pathology...” Fearing that the formation of this new organization would lead

to fragmentation of the profession, the CAP Plans and Scope Committee suggested the formation of Sections within the College to represent the interests of members practicing in different professional settings.

Several governors objected strongly to the concept of Sections. Their argument was made most forcefully by Frank Coleman, MD, then vice-president and later president (1960–1961) of the College. Dr. Coleman stressed the recent formation of the Assembly, and argued that it should be given an opportunity to mature before other representative structures were added to the College's organization. However, his proved to be a minority opinion, and the Board appointed an Ad Hoc Committee on Sections in November 1959.

The Ad Hoc Committee reported its endorsement of the Section concept to the Board of Governors in April 1960, and its report was subsequently approved. Each Section was to elect its own officers and have representation either on the Board or in the Assembly; each Fellow was to annually select a Section. Each Section could decide if additional dues were to be collected for the operation of that Section. Four Sections were originally established: Practice of Pathology in Institutions; Practice of Pathology in a Private Laboratory; Practice of Pathology in a Governmental Setting; and Practice of Pathology in an Academic Setting.

There now existed *three* separate, supposedly representative, membership bodies within the College—the Assembly, Regional Committees, and Sections. More than ever, overlapping functions and conflicts were inevitable. In 1972, concerns were raised with the Board about the effectiveness of the Section structure. The performance of the Sections in carrying out their purposes was described as “spotty” at best. While each Section was expected to meet and present programs targeted to the needs of its members, the success of these programs depended entirely upon the enthusiasm and dedication of the officers of the Section.

The assignment of pathologists to Sections was also problematic. Members of the Section on Private Practice did not want their deliberations “diluted” with problems relating to practice in institutions. The College, however, continued to oppose the inclusion of “full-time service” clauses in pathologist-hospital contracts. Thus, many hospital-based pathologists were also establishing independent laboratories, and found that the forced choice between private-practice and institutional Sections was at odds with the realities of their practices—a situation that threatened to fragment the College into opposing and antagonistic camps.

In response to these concerns the Board appointed a task force in April 1972 to address the future of Sections, at the same time referring the matter to the House of Delegates. As it turned out, the House was basically opposed to Sections, while the Board Task Force recommended retention and strengthening of the Section structure. In the face of this ambiguous outcome, the status quo prevailed, and Sections continued to exist until their abolition in 1977.

**Other Committees** In addition to the Regional Committees, a number of other committees were also formed during the initial organization of the College, either mandated by the constitution and bylaws or established by the Board of Governors. Among them were a Committee on Finance, an Ethics Committee, a Committee on Clinical Laboratory Standards, and a Committee on Evaluation of Hospital Laboratories. These committees usually held their meetings in conjunction with the national meeting of CAP, and reported directly to the entire membership at the annual business meeting, as well as to the Board between annual meetings. By 1953, some 20 committees had come into existence; in that year, they were for the first time grouped under three Councils on “Practice of Pathology,” “Education and Research,” and “Organizational Matters.” For reasons which are not recorded, the Council structure was abandoned the following year, not to reappear until the early 1970s.

The Committee on Clinical Laboratory Standards was the most active early committee of the College, and from it came many of the later committees designed to oversee the proliferation of laboratory improvement

programs. The volume and complexity of the Surveys programs prompted the formation of numerous subcommittees, later to become independent as the “Resource Committees.” Composed of experts in specialized fields of pathology, these committees were given responsibility for the design and operation of the multiple interlaboratory programs, or Surveys, which came into existence.

As committees became more independent and more numerous, a need became apparent to group those with similar duties and/or interests in order to coordinate their functions, and to reduce the burden of committee reports submitted to the Board and the membership. These concerns led to a study of structural reorganization, undertaken early in 1972 and chaired by Tyra T. Hutchens, MD, a future president of the College (1977–1979). The outcome of this study was a loose grouping of committees with related responsibilities, resulting in a Council/Commission/Committee structure that was further developed in 1974 under the leadership of Dennis Dorsey, MD, CAP president in 1975–1977. This plan provided for the formation of four councils—Quality Assurance; Government Relations and Liaison; Education and Information Services; and Laboratory Administration. A few committees, such as the Budget Planning and Review Committee and the Constitution, Bylaws and Resolutions Committee, continued to report directly to the Board of Governors, but most committees reported to one of the four councils, which in turn reported to the Board.

This basic council structure persists to the present, having undergone a number of refinements, name changes, and re-alignments of committees and commissions within the councils. Reporting mechanisms of the many committees have been more clearly defined, and the various councils have been given expanded authority to operate the programs under their jurisdiction.

***Residents Forum*** 1988 marked the formation of the Residents Forum. A residents section had first been suggested in 1973, but the concept remained dormant until 1987 when a residents section was again proposed. However, Sections had been abolished in the meantime; thus, the proposal did not fit the existing organizational pattern. Restructured as a “Forum” and again submitted to the Board, the concept was adopted. The Forum was established to interest pathologists in College activities at an earlier stage of their careers, and to identify younger individuals for leadership roles in the organization.

The Residents Forum operates in the same format as the House of Delegates. Meeting on the Saturday of the spring and fall meetings, it adopts resolutions, which are then submitted via the Forum’s elected delegate to the House of Delegates. The chair of the Forum attended meetings of the Board of Governors as a guest until 1996, at which time the chair was made a full voting member of the Board.

Also in 1989, residents were first included among the appointees to various committees of the College. This allows residents to associate with experts in the various subspecialties of pathology, thereby enhancing their careers, while they make their own distinctive contributions to the functions of the respective committees.

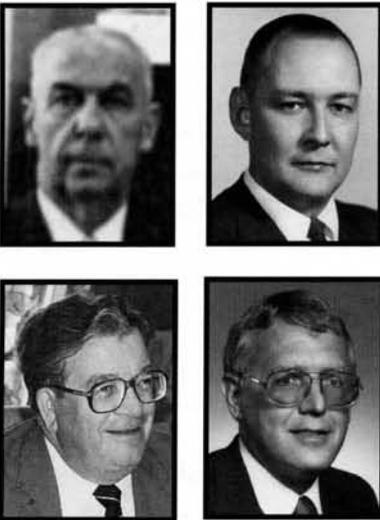
***Logo and Motto*** The origin of the first logo of the College is not recorded in the CAP Archives collection. However, by the end of 1948 the College’s publications and stationery began to carry a logo featuring the staff of Aesculapius on a dark round background, surrounded by the words “College of American Pathologists” in a white border (Fig 2-2).

In the 1960s, strenuous efforts were directed toward improving the public and professional image of pathologists and the CAP. A motto for the organization, “Join us in the Pursuit of Excellence,” was adopted in August 1967. Over the years this motto evolved, apparently without any official action, to simply “In Pursuit of Excellence.”



**Figs 2-2-2-4** At left, the College's first logo. The origins of this design are unknown, but it was in general use by the end of 1948. The logo at center was adopted in 1968. Elements of both designs were combined in the 50th anniversary logo shown at right.

In August 1968, a new College logo was adopted. The seal, still in use at this writing, depicts the stylized outline of an Erlenmeyer flask with a central dot (Fig 2-3). A description of the logo published in the *College Bulletin* at the time states that it was chosen for its "crispness and flexibility," and because it depicts "an organization that is in the business of solving problems." According to its designer, the educational, informational, and service aspects of the College were all inherent in the design.<sup>6</sup> It was intended that the central dot could be altered to identify various programs of the College; for example, the number "50" was added for the fiftieth anniversary celebration during 1997 (Fig 2-4). In the late 1980s, a policy was adopted which explicitly included the name of the College as part of the logo, and provided guidelines for consistency in type size and style, color, and layout.



**Figs 2-5-2-8** Chief Executive Officers of the CAP. [5] Arthur H. Dearing, MD (1953–1963); [6] Oliver J. Neibel, JD (1963–1972); [7] Howard E. Cartwright (1972–1989); [8] Lee VanBremen, PhD (1989–present).

**Executive Staff** One of the actions taken at the initial January 1947 meeting of the Board of Governors was the appointment of Melbourne G. Westmoreland, MD as executive secretary. A professor of bacteriology at a small medical school, Westmoreland had previously been active in the AMA Council on Education. Not being a pathologist, but having heard of the December 1946 meeting at which the College was founded, he attended the organizational meeting and applied for the position of executive secretary. Apparently without any explicit mandate from the Board, he initiated the *CAP Secretary's Newsletter* and wrote most of the material in the early editions. In a 1985 oral history interview, he takes credit for much of the rapid early growth in membership, establishment of the Placement Bureau, and stimulation of pathologists to rent space from hospitals for their laboratories, rather than continuing as salaried employees of the institutions.<sup>7</sup>

In 1953, Arthur H. Dearing, MD was named executive secretary, replacing Dr. Westmoreland (Fig 2-5). A graduate of the Harvard University School of Medicine, Dr. Dearing was trained as a surgeon and served in the Navy in various service and command positions. During his Naval career, he served on the Board of Directors of the Armed Forces Institute of Pathology, although not himself a pathologist. He had retired from the Navy with the rank of Rear Admiral. In November 1957, Dearing's title was changed from "executive secretary" to "executive director," a change which generated a good deal of rancorous discussion among Board members about the meaning of titles and the duties that titles implied.

Dr. Dearing served the College until the spring of 1963. At that time, the duties of the chief executive officer were assumed on an acting basis by the College's then-Secretary-Treasurer Ernest E. Simard, MD. In November 1963, Oliver J. Neibel was appointed as Dr. Dearing's successor (Fig 2-6). Neibel received a bachelor's degree in business administration from the University of Arizona and was graduated from the University of Virginia School of Law. After serving in the Attorney General's office of the state of Washington, primarily dealing with medical disciplinary concerns, he was employed in the legislative and legal department of the AMA for two years prior to joining the College.

In January 1972, partly in response to Board concerns about the financial health of the College, Neibel resigned and was subsequently replaced by Howard E. Cartwright, who had served as assistant executive director since 1967 (Fig 2-7). Coming from a position with the American Medical Association, Cartwright served as executive director during a time of explosive growth in College membership and programs. Assuming his position when the organization was nearly bankrupt, he oversaw its growth into a multimillion-dollar-a-year operation. The College staff increased from 28 to nearly 200 employees. Drawing upon his extensive communications and public relations background, Cartwright was instrumental in the establishment of *CAP TODAY*, which has become the leading publication in the laboratory community. Three major relocations of the College headquarters also occurred during his tenure, culminating in the construction of the present headquarters building in Northfield, Illinois, in 1989.

Following Cartwright's retirement as chief executive officer of the College in December 1989, Lee VanBremen, PhD, was named as the executive vice-president (Fig 2-8). A graduate of Pennsylvania State University, Yale University, and the University of Connecticut, Dr. VanBremen had previous executive-level association experience with the American Academy of Facial Plastic and Reconstructive Surgery and the National School Boards Association. Assuming his duties at a time of major changes brought about by a new headquarters building, consolidation of the computer functions into the College's main headquarters in Northfield, and massive growth in College programs responding to legislative mandates, it fell to Dr. VanBremen to guide the College through a time of difficult transition. Under his leadership, there was a significant increase in the number of staff personnel, and a major reorganization was accomplished to support the ever-growing complexity of the College's operations.

***Headquarters and Other College Locations*** The first College headquarters office was established early in 1947 in Room 200 of the 203 North Wabash Avenue Building in downtown Chicago. Soon after the opening of this office, the possibility was raised of sharing office space with the American Society of Clinical Pathologists (ASCP); but the ASCP's insistence that the office be located in South Bend, Indiana, brought the discussions to an impasse. The CAP office remained at 203 North Wabash until 1956, though increasing space needs prompted at least two moves within that building—to Room 1510 in 1948, then to Room 2200 in 1952.

Finally the accelerating growth of staff and programs forced the College to relocate from the Wabash Avenue facility entirely. In a move which perhaps enhanced its forward-looking image, the College became one of the original tenants of the new Prudential Plaza in Chicago, the first downtown skyscraper erected there since the Great Depression had brought a virtual halt to commercial construction in the early 1930s. The College's tenancy at 2115 Prudential Plaza extended from April 1956 through February 1965. During that time the growth of various College programs—notably the Surveys program in the 1950s, and the Inspection and Accreditation Program for laboratories in the 1960s—continued to demand more and more space. In March 1965, the offices were relocated again to the 11th floor of the Carbide and Carbon Building at 230 North Michigan Avenue in downtown Chicago. Once again, consideration was given to sharing space in the new ASCP building then under construction, but the Board decided to maintain physically separate offices.

In addition to generating escalating demands for office space, the growth of the interlaboratory comparison programs, or Surveys, through the 1950s and 1960s also triggered a need for increased computer services to analyze data. The first Surveys offered by the College were evaluated by individuals in several institutions such as the Mayo Clinic. Beginning in 1966, the Surveys data was analyzed under a contract with Belfour and Stulen, a computer service company located in Traverse City, Michigan. In late 1971, the College purchased the company, which then became the Belfour-Stulen Division (BSD) of the College under the continued direction of former owners Al Belfour and Frank Stulen. This management arrangement continued until 1977, with the Belfour-Stulen Division operating in leased space in the Traverse City lakefront buildings owned by Belfour and Stulen. On several occasions, alternate sites for the Computer Center were considered, both in Traverse City and elsewhere. In 1979, the lakefront property housing the Computer Center was purchased by the College from Belfour and Stulen. In 1989, all computer operations were finally consolidated into the newly constructed CAP headquarters building in Northfield, Illinois, and the Traverse City property was subsequently sold.

Through the early 1970s, CAP staff and programs continued to grow steadily. The consequent need for additional office space, combined with rising costs in Chicago's central Loop business district, prompted the Board of Governors to seek an alternate location that would offer reduced expenses and greater convenience for a majority of the staff—as well as a possible opportunity for the College to become its own landlord. Traverse City was considered and rejected as a site, being deemed too remote, with resulting difficulty in travel arrangements for staff and volunteers. Washington, DC, was eliminated because of significantly higher rental and operating costs in the national capitol. The Board thus elected to keep the College headquarters in the Chicago area, and on December 9, 1974, the College headquarters was moved to the northern suburb of Skokie, Illinois, into a portion of the building at 7400 Skokie Boulevard. In late 1975, the property was purchased; and by early 1978, the entire building had been occupied by the College.

In 1983, a tract of land was purchased in Northfield, Illinois, as a potential site for a headquarters building. Despite a pressing need for more space, it was felt prudent to delay construction of a building at that time because of an atmosphere of uncertainty for pathologists generated by legislative actions limiting payment methods for pathology services. As an interim solution to space needs, the offices were moved in February 1985, into leased space at 5202 Old Orchard Road in Skokie, Illinois. The Computer Center remained in Traverse City, and the building at 7400 Skokie Boulevard was quickly sold.

The approaching expiration of the short-term lease on the space at 5202 Old Orchard Road prompted the Board of Governors to investigate construction on the Northfield property. A Building Committee was appointed in 1987; among its charges was evaluating whether the Computer Center should be consolidated into the proposed new building. After extensive study, it was recommended that a new headquarters be constructed on the Northfield, Illinois site at 325 Waukegan Road, and that the computer operations be moved from Traverse City into the new Northfield headquarters. The Northfield building was completed and occupied in October 1989 (Figs 2-9 and 2-10). (*Note: Photographs of all CAP headquarters office locations are included in Appendix H.*)

**Washington, DC Office** The passage by Congress of the Medicare Act in 1965 stimulated the CAP Board to consider establishing an office in the federal capitol to deal with legislative and regulatory issues. The initial proposal was for a joint Washington office with the American College of Radiology, but this arrangement was not pursued. The passage of the Partnership for Health Amendments, including regulation of interstate laboratories in a portion which became known as the Clinical Laboratories Improvement Act of 1967 (CLIA-67), gave another major impetus to the concept of a Washington office. The College's first Washington office



*Fig 2-9. The CAP's Northfield, Illinois headquarters, under construction in mid-1989. Then-President Loyd R. Wagner, MD appears at center.*



*Fig 2-10. The official ribbon-cutting at the Northfield building, April 19, 1990. Left to right: Thomas DiSilvio, MD, CAP Building Committee; Kenneth McClatchey, MD, CAP Board of Governors; the Rev. Robert Flinn, of Divine Word International, neighbor to the CAP headquarters; J. Scott Pennepacker, MD, CAP Building Committee; Howard E. Cartwright, retired Executive Vice-President; Leonard Franks, President, Northfield Chamber of Commerce; William Hamlin, MD, Chair, CAP Building Committee; and Loyd R. Wagner, MD, CAP President.*

was eventually approved in 1969, and opened in 1970 in a building at 1775 K Street, NW, across the street from the American Medical Association building and adjacent to the Washington Hospital Center. In November 1978, the CAP and ASCP Washington offices were joined for the first time in new space at 1333 New Hampshire Ave., NW. In 1981, the joint office was moved into Suite 401 of the new AMA building at 1101 Vermont Avenue, NW; it remained at this address for 12 years, meanwhile shifting from Suite 401 to Suite 604 in 1985. In 1993 the joint arrangement with ASCP came to an end, and the College occupied its current Washington, DC quarters at 1350 I Street, NW.

*The 1990s* Throughout the existence of the College, its success has been the result of innumerable hours contributed by a multitude of members who design and direct its programs. In the early 1990s, demands upon pathologists in their own practices raised fears that their voluntary contributions of time to the College would decrease. As a result, the role of committees was reassessed as part of the continuous planning process of the College, and several were discontinued. Others were realigned in an attempt to make more efficient use of volunteers' time; for example, the Councils on Pathology Practice and Education and Membership Services were combined into one. The CAP staff was also reorganized to bring it more in line with the volunteer

structure and to allow operation of the organization in a more businesslike fashion. With more effective strategic planning, embodied in a formal strategic plan adopted in 1993, the College is well-positioned to continue to meet the needs of its members, the profession, and the general public as it enters its second half-century of service.

## Notes

1. CAP Board of Governors Minutes, 1948 Oct 9-10:4. All subsequent references in this chapter to CAP Board of Governors actions are documented in the Board minutes unless noted otherwise.
2. CAP Board of Governors Minutes, 1949 Jan 16:4.
3. Queen FB. Letter to John R. Schenken, MD, 1957 Apr 22. CAP Archives.
4. CAP Board of Governors Minutes, 1963 Feb 24-27:218-219.
5. Private Practitioners of Pathology Foundation. Articles of Incorporation, 1959 Oct 21.
6. Neibel OJ. To CAP it off. *CAP Bulletin*. 1968;22:309-310.
7. Westmoreland MG. Oral history interview, 1985 Jun 4.

## Chapter Three

# Membership and Its Benefits

Loyd R. Wagner, MD  
James G. Carson, PhD

The tendency of individuals to band together for their common benefit appears to be inherent in virtually all animals. Fish form into schools, sheep into herds, and geese into flocks, apparently for protection against predators. Similarly, early humans found that they were more successful when they hunted together, thereby enhancing their chances for survival. Aggregations of individuals also provided opportunities for interactions to satisfy social needs.

As human society evolved, groups of all kinds assumed greater importance in increasingly complex cultures. Medieval craft guilds bestowed professional and social recognition upon their individual members, but also played a vital role in setting standards for the professions, ensuring that their practitioners were well qualified, well informed, and well trained. The Renaissance saw the formation of scientific societies or “academies,” such as the famed Royal Society (officially the Royal Society of London for the Improvement of Natural Knowledge), formed to promote and share new learning in the arts, sciences, and philosophy.

*The College of American Pathologists was founded to enhance both the scientific and the professional status of the specialty of pathology and of pathologists.*



Like tailors and philosophers, 20th-century professionals of all stripes, including pathologists, have found that many benefits are to be gained by association: more rapid sharing of scientific and technical knowledge, increased economic well-being, professional recognition, social interaction, and perhaps (in an age of escalating government regulation) even protection from predators. Thus, the College of American Pathologists, a 20th-century counterpart of the Medieval guild and the Renaissance academy, was founded to enhance both the scientific and the professional status of the specialty of pathology and of pathologists. Those services that benefit the individual pathologist ultimately benefit the profession; likewise, efforts that enhance the profession contribute to the welfare and success of the individual practitioner. And in both cases the ultimate beneficiary is, of course, the patient whose treatment is enhanced by state-of-the-art laboratory practice.

Subsequent chapters will describe in detail a number of specific College programs focused on enhancing the pathologist's scientific and technical knowledge and sophistication. This chapter details the evolution of a wide range of other professional benefits arising from membership in the College (Figs 3-1 and 3-2).

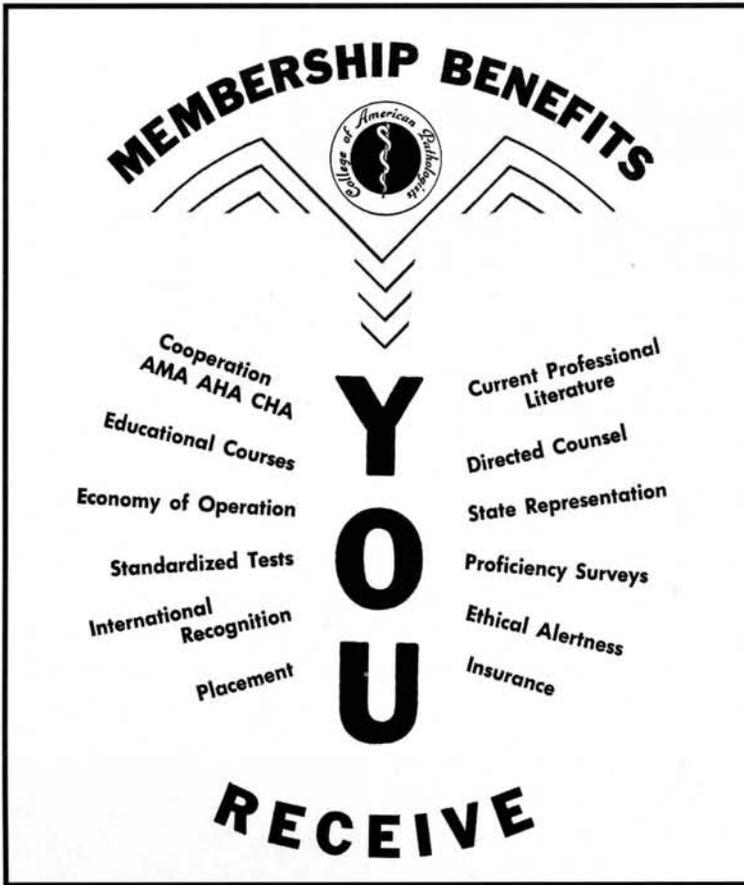


Fig 3-1. This graphic representation of CAP membership benefits appeared in the College's 1961 membership directory.

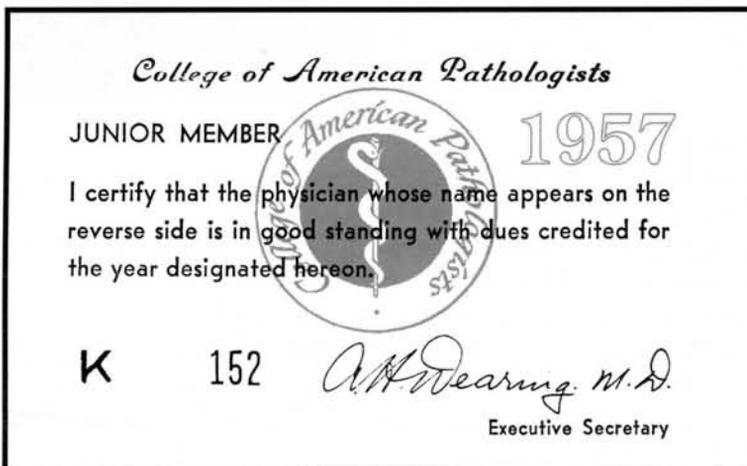


Fig 3-2. The earliest membership card in the CAP Archives collections.

*Membership Status* Membership in the College has always required a favorable vote by the Board of Governors following application by the prospective member. The basic category of "Member" was the one which the founding fathers of the CAP envisioned as the standard designation accorded to most pathologists affiliating with the College. From the beginning all members were required to be certified by the American Board of Pathology, thus ensuring at least a minimal level of professional competence on the part of those applying. With this requirement in place, merely being admitted to membership was seen as a mark of distinction in itself.

The original dues for the "Member" category were \$25 annually, and entitled each Member to all the usual privileges of membership in an organization, such as the right to vote for officers and governors, to hold office, to be appointed to committees, and to participate in any and all programs eventually offered by the College. As the College grew, however, the prestige of the "Member" category declined, and it was finally abolished in 1968.

The category of "Fellow" was also established in the original constitution. During the first two years of the organization's existence, applicants could request this designation, which would be granted with the payment of a higher level of membership dues (\$50

annually). After that time, "Fellow" status was to be awarded by the Board of Governors only in recognition of an individual's superior service to pathology, to medicine, or to the community. In 1950, however, the Board of Governors relaxed this requirement, so that applicants could request either "Member" or "Fellow" designation, as they felt their qualifications warranted. In 1953, Fellows of the College of American Pathologists were authorized to use the initials "FCAP" after their names as a public acknowledgment of their status in the profession.

Designation as a "Founding Fellow" was awarded to those pathologists who paid dues of \$100, twice the usual dues for Fellows, during the first year after the founding of the society. The category of "Life Fellow" was added in 1956. Life Fellows, in addition to the usual requirements for Fellowship, made a lump-sum dues payment (initially \$1,000) that, together with interest generated, was calculated to pay the annual dues for the lifetime of the member.



**Fig 3-3.** Ludvig Hektoen, MD (1863–1951), the College's first Honorary Fellow, inducted October 11, 1948. (Photo courtesy of American Medical Association Archives)

A category of "Junior Member" was also established in the original constitution. Residents in pathology could apply for this category after completion of the first two years of residency. Junior Member dues were \$5 per year. At first no restriction was placed on the length of time a physician could remain in this category, though Junior membership did terminate automatically if the member failed to achieve certification by the American Board of Pathology within five years after being elected to membership by the CAP Board of Governors. In 1950, the Board reached consensus on a requirement that a Junior Member must apply for "Member" status within one year of his/her certification; but this requirement was not added to the Constitution until 1954, with the deadline set at two years rather than one. Junior Members could not vote or hold office, but received all College publications and could participate in meetings and serve on committees.

Also established in the original constitution was the designation of "Honorary Fellow," to be awarded by the Board of Governors to persons making "outstanding contributions to the science of Pathology or to the College." The first Honorary Fellowship was granted to Ludvig Hektoen, MD, on October 11, 1948, for a "distinguished career...of outstanding service to pathologists" and particularly for "contributions in the field of pathologic anatomy."<sup>1</sup> (Fig 3-3) Dr. Hektoen was regarded by his colleagues "as a superb morphologic diagnostician and as a much sought consultant";<sup>2</sup> among his many other accomplishments, he was the founding editor (1926) of the *Archives of Pathology & Laboratory Medicine*, later to become the College's official journal.<sup>2,3</sup>

Ironically, George Papanicolaou, MD, PhD, now equally well known and highly respected, was refused Honorary Fellowship by the Board in 1950, on the grounds that such a distinction should be "extended only to those people of outstanding ability and those who have accomplished something unusual in the field."<sup>4</sup> Fortunately the Board eventually thought better of this action, and on April 23, 1956, elected Dr. Papanicolaou to Honorary Fellowship "in recognition of his outstanding work in the field of exfoliative cytology."<sup>5</sup>

In addition to Drs. Hektoen and Papanicolaou, nine other persons—some previously affiliated with the College, others not so affiliated—have been awarded Honorary Fellowship, the most recent award being in

1977. They include Robert E. Anderson, MD; William Boyd, MD; John F. Enders, MD; Thelma B. Dunn, MD; George M. Hass, MD; Howard T. Karsner, MD; U. Pentti Kokko, MD; Leonard W. Larson, MD; and George H. Whipple, MD. In most cases, though not all, the professional accomplishments which were recognized by these awards are recorded in contemporary minutes or publications.

The original constitution made provision for the designation of Emeritus Members and Emeritus Fellows, and the category of Emeritus Fellow has continued to the present with minor changes in qualifications. Currently, Emeritus Fellow status is granted to Fellows who have reached the age of 70, or have retired at an earlier age from active practice. The category of Affiliate Member, for pathologists certified and/or practicing in countries other than the United States, was added in 1961.

The requirements for membership in the various categories have changed over the years. However, as the Board made changes in its procedures for electing members, these changes were not always reflected in coherent and consistent fashion in the constitution. These inconsistencies led to a number of problems. For example, in 1955, it was discovered that certification by the American Board of Pathology was required for admission as a Member, but one could be a Fellow without certification. However, more than four years passed before the necessary constitutional change was made to rectify this incongruity.

One probable reason for the delay was a feeling on the part of some Board members that the inconsistency might in fact have been intentional—that “the writers of the Constitution...felt that Pathologists who were outstanding in the profession but not necessarily Diplomates of the Board [should] have an opportunity to be a Fellow [*sic*] of the College.”<sup>6</sup> This viewpoint in fact seems quite plausible in light of the original founders’ intention that the status of Member was to be the most commonly held, and that of Fellow an unusual honor. However, as the years passed and Fellowship became the most usual class of membership, this argument lost force, and the requirement of board certification came to be regarded as an appropriate one for Fellowship as well. This requirement was finally incorporated into the constitution in 1959.

Another provision added to the constitution at this time eventually proved problematic as well—namely, a requirement that applicants for membership belong to the American Medical Association (AMA), or an equivalent body for applicants residing outside the United States. In 1964, the legal counsel of the College pointed out to the Board of Governors that a new applicant for admission as a Fellow had to be an AMA member, but the same stricture did not apply when a Member requested transfer to Fellow status. This inconsistency apparently was never explicitly corrected; when the “Member” category was abolished in 1968, the requirement for AMA membership was added to the qualifications for Fellowship, only to be dropped entirely in 1971.

At the same time in 1959, when AMA membership began to be required, the constitution was also amended to provide for a maximum of three years in the status of “Member”—after which time the Member was required, on pain of automatic termination, to apply for Fellow status. A number of pathologists resigned to protest this change, but the Board stood firm on the issue.

***Recruitment and Training*** As early as 1949 the College was expressing concern over the fact that only 250 new pathologists were entering the profession each year.<sup>7</sup> Early in 1955, the College joined four other pathology societies in efforts to influence medical students to choose pathology as a career. Summer fellowships for students were suggested as one effective recruitment tool, but this proposal was not implemented until 1965, when the Board of Governors approved funding for five \$500 summer grants for sophomore medical students.

Whether due to the success of these efforts or to other factors, the CAP Committee on Recruitment was disbanded in 1973 because of a stated “lack of need for further pathology recruitment.”<sup>78</sup> Only a year later, however, the first of a series of joint manpower studies was undertaken by the CAP and the American Society of Clinical Pathologists (ASCP); the two organizations’ governing boards, if not others, feared a looming shortage of pathologists, and accurate forecasts were essential in order to maintain adequate funding for training programs. Other such studies have been conducted during the ensuing years, almost all of them causing controversy over the interpretation of the findings—particularly when the resulting forecasts of shortage were at variance with independent studies predicting a surplus of pathologists.

Alongside efforts to influence medical students to choose pathology as a career were those aimed at inducing residents to join the CAP and become active in the society. The Junior Member category was established in the original constitution specifically for this purpose. In 1971, the House of Delegates suggested that residents be named as observers to the House, and in 1972 a Junior Members’ Council was proposed, though never instituted. First-year residents were eligible for one year’s Junior Membership without dues from 1982 through 1988; in 1989, dues for Junior Members were abolished entirely. In 1986, the Board approved the addition of resident members to the CAP House of Delegates; these delegates were first seated in spring 1987. At the same time, the CAP began to send resident delegates to the AMA Resident Physicians Section. The CAP Residents Forum was established by the Board of Governors in February 1988 and held its first meeting in October of that year; in 1990, resident members were appointed to a majority of CAP committees. The chair of the Residents’ Forum was first invited as a guest to meetings of the Board of Governors in 1991, and in 1996 became a full voting member of the Board.

Among the benefits enjoyed by Junior Members in the College have been various programs intended to fill perceived gaps in the training of residents. As Junior Members of the College, residents have received such appropriate publications as the *Secretary’s Newsletter*, *Pathologist*, *CAP TODAY*, and *Archives of Pathology & Laboratory Medicine*. In addition, programs, seminars, and workshops for residents have been presented at both regional and national meetings, dealing with topics such as professional ethics, contract issues, laboratory management, and other economic and political matters. Most have been provided with no or minimal charge to the residents or their training programs.

**Education** Professional education was stressed as an important function of the College of American Pathologists by its founders, being mentioned in two of the three objects of the CAP listed in the constitution. Article II of the original bylaws was entitled “Education,” and there provision was made for the Regional Committees to address post-graduate, scientific education. When Sections were established in 1960, one of their specific functions was member education.

Educational programs, both scientific and socioeconomic in nature, have also been a consistent feature of the CAP national meetings. Early national programs were planned entirely by the Board of Governors, and the verbatim transcripts of Board minutes record circuitous, sometimes humorous, and occasionally acrimonious discussions of the topics, content, and structure of these programs. (Often the planning of social gatherings consumed as much discussion time as other topics!) One major priority was to avoid scheduling conflicts with the programs of the ASCP—a goal not always achieved.

Gradually, responsibility for national meeting programming has shifted to the various committees of the College. Problems discovered through the analysis of Surveys data frequently generate programs designed to correct problems in laboratory analysis. Similarly, discrepancies in anatomic pathology and cytopathology diagnosis identified through practice improvement programs may lead to educational events focused on

difficult diagnostic problems. The potential uses of the computer in pathology were recognized as early as 1962, when the first computer education programs were offered.

As early as 1953, education and/or program committees had begun to be appointed in order to coordinate educational activities and bring balance to those efforts. These committees have been able to identify emerging technology and problems in pathology and related branches of medicine, and rapidly design seminars which address these issues. Examples include programs on the Acquired Immunodeficiency Syndrome (AIDS) in the early 1980s and the resurgence of tuberculosis in the late 1980s and early 1990s.

During the 1960s, participation in and documentation of continuing medical education (CME) gradually became a common requirement for state licensing and/or hospital credentialing of physicians. Initially, the American Medical Association undertook the task of overseeing CME courses to assure that they were substantive and met measurable goals and objectives, and that attendance was documented. Subject to review, CAP courses were deemed acceptable by the AMA as long as they met these criteria. The independent Accreditation Council for Continuing Medical Education (ACCME) took over the supervision of CME programs from the AMA in 1981, and now accredits the College as a provider of CME courses. In 1974, the College established the Pathology Continuing Education Award, presented to those who completed a specified number of hours of CME within a three-year period. Record-keeping of credits for individual pathologists was centralized in the CAP office until 1983, when a combination of factors led to the discontinuance of this practice.



*Fig 3-4. Marjorie J. Williams, MD (b. 1919), played a pivotal role in the development of the CAP Workload Recording Method.*

Management of the laboratory is a subject rarely taught in pathology residencies, but lack of management skills is frequently a more serious problem for pathologists than lack of professional skills. The need for management training was recognized as early as 1960, when programs for both residents and practicing pathologists became part of the national and regional meeting formats. A series of Professional Administration Development Seminars, inaugurated in October 1969, was presented in cooperation with the Indiana University School of Business. The early warm reception for these two- or four-day seminars soon cooled, and a hiatus in management education ensued until late in the decade, when the gap was filled by the Professional Laboratory Management Institutes (PLMI) presented by CAP members. The PLMI were structured in half-day modules, with the entire course extending over several days, and were presented through the mid-1980s. Management education then languished again until the early 1990s, when seminars were resumed with faculty from recognized business schools.

An adjunct to management education was the Workload Recording Method. Spurred in part by earlier and only partly successful efforts among the armed services, the College began in 1963 to study a new system to address laboratory space allocation and forecast future need for technical personnel. The state-of-the-art system at that time was a simple tally of the total number of tests performed, which bore no relationship to the resource expenditures required for different types of procedures. The task of developing a more sophisticated method was assigned to the College's Committee on Laboratory Management and Planning, which had succeeded the earlier Committee on Laboratory Planning sometime between 1960 and 1963.

The committee's first efforts accomplished little more than standardizing the older counting system. In 1969, a renewed effort to update the system was undertaken under the leadership of Marjorie J. Williams, MD, who was named chair in January of that year (Fig 3-4). In the end, the committee adopted a system developed by the Canadian government which related test performance to time—that is, one minute of time equaled one workload unit. The first edition of the workload recording manual appeared in print in September 1970,<sup>9</sup> and a continuing process was undertaken to update the unit values periodically in conjunction with the Toronto Institute of Medical Technology. Development also commenced on a process for cost accounting in the laboratory. In 1971, the method was adopted by the American Hospital Association for use in its Hospital Administrative Service, offered on a subscription basis to 3,000 participating hospitals.

From its inception, accurate and up-to-date values for the workload system were a continuing concern, and a process using time studies in volunteer laboratories soon replaced the exclusive use of the Toronto Institute. The system was periodically plagued by problems with consistency of time studies and with adequate sample sizes for statistical accuracy, but it nevertheless was widely accepted in laboratories, and the workload recording manual became a best-seller among College publications. Continuing efforts to improve the system involved liaisons from other laboratory groups and a Computerized Workload Recording System, which began in 1972. The computerized system not only processed data submitted from participant laboratories, but was also designed to use these data to refine the unit values on an ongoing basis.

The Workload Recording Committee presented numerous seminars, both regional and national, to teach the proper and consistent use of the method—including, perhaps unfortunately, its application to cost accounting. The latter adaptation was always imperfect; the system was frequently used for government reimbursement purposes for which it was never intended, and there were recurring challenges to the validity of the unit values. In 1992, the Workload Recording Method was abandoned and replaced by a system developed by the Laboratory Fiscal Management Committee. This system, the Laboratory Management Index Program (LMIP<sup>®</sup>), is based on a standardized chart of accounts that more accurately identifies all costs, and from which have been developed a series of ratios to measure management performance.

In response to the rapid emergence of new laboratory techniques throughout the 1980s, the College developed a program to allow interested pathologists to learn such techniques in laboratories that had them already in place. This scheme, begun in the late 1980s, is referred to as a "Practicum" or "Micro-Fellowship" and generally involves a one- to two-week period of intensive study.

**Promoting the Science** Promotion of the science and practice of pathology has always been among the central objectives of the College. Many programs have been developed that set standards for the quality practice of laboratory medicine and pathology. Daily quality control, proficiency testing, laboratory accreditation, and several other programs will be discussed in separate chapters later in this volume. One major avenue of improvement in practice has been interlaboratory comparison of data, as occurs in the CAP Surveys Program. In other instances, improvement comes as a result of scientific presentation and consensus building.

A prime example of the consensus-building process is that embodied in the continuing series of CAP Conferences.<sup>10</sup> During the late 1960s, some of the College's resource committees, which support the Surveys program by overseeing the distribution of proficiency testing materials and the evaluation of results, began to recognize the need for consensus in certain poorly defined areas of laboratory practice in order to improve performance. Out of this realization evolved the concept of invitational conferences of experts, meeting in a

retreat-like atmosphere to deliver presentations on these problem areas, participate in discussion, and then prepare a manuscript for publication. Thus were born the CAP Conferences, the first of which was approved by the Board of Governors in August 1974.

This first conference in the series, organized by the Microbiology Resource Committee and entitled “Clinical Relevance in Microbiology,” was held in 1975 in Aspen, Colorado.<sup>11</sup> Several early conferences were held at the same site, and this led to an informal custom of referring to the entire series as “Aspen conferences.” Other venues were also used; however, and because of the resulting confusion, the more straightforward designation “CAP Conferences” was adopted in 1982.

By 1979, the invitation-only makeup of these conferences had come to be viewed as “elitist,” and a limited number of observers were allowed to attend in addition to the invited participants. At this writing, 30 CAP Conferences have been held, with the most recent, entitled “Quality and Liability Issues with the Papanicolaou Smear,” held in June 6-9, 1996, with approximately 400 participants.<sup>12</sup>

The benefit of the earliest conferences was largely confined to the attendees and the sponsoring resource committee. To widen the dissemination of the discussions, the Board of Governors mandated that the proceedings of the 1977 conference on hematology and all subsequent conferences were to be published in book form to create a series.<sup>13</sup> The proceedings of the two previous Aspen conferences were also to be evaluated for possible publication (both were in fact published).<sup>14,14</sup> Unfortunately, details of the kind often involved in the book-publishing process became more the norm than the exception, and the march of science frequently made the information in a given volume obsolete by the time it became available. None of the 12 volumes of proceedings of these conferences reached the best-seller list. Since 1988, CAP Conference proceedings have been published in part or in full in the *Archives of Pathology & Laboratory Medicine*, making

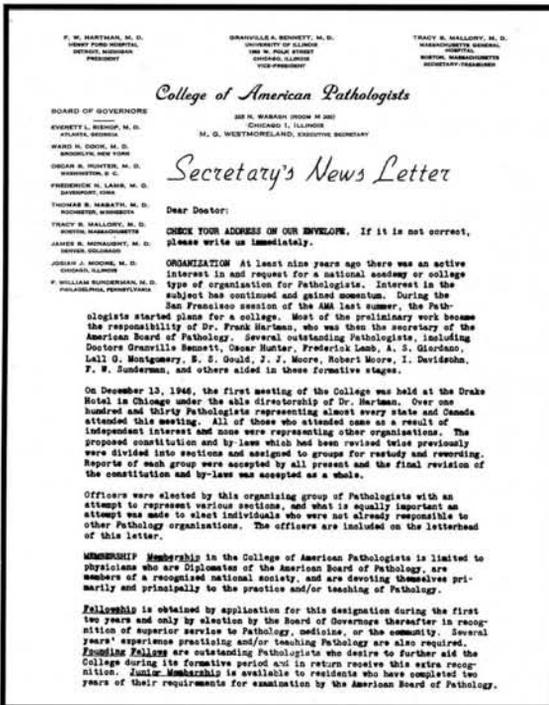


Fig 3-5. The first Secretary's News Letter, May 1947.

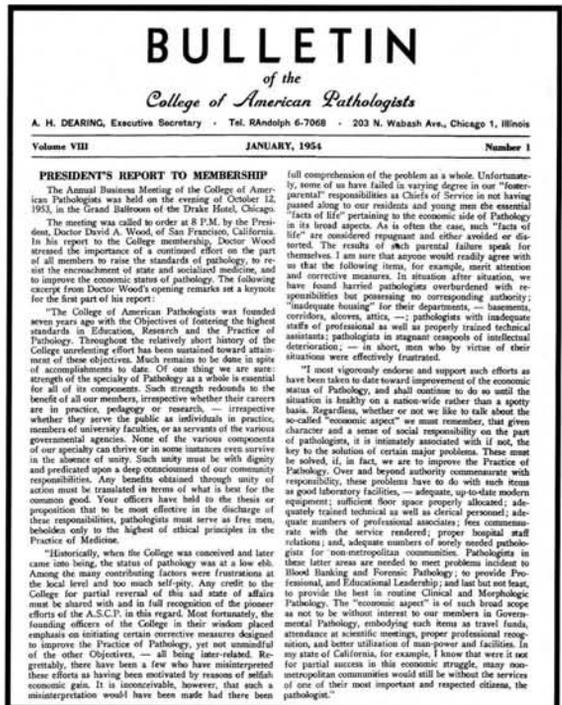


Fig 3-6. Inaugural issue of the Bulletin, January 1954.

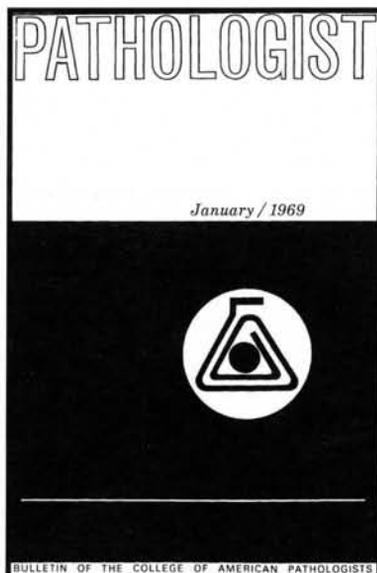
the articles and findings available in the indexed medical literature. In addition to more timely dissemination, this procedure has also allowed for further refinement of the manuscripts through the journal's customary peer review process.

**Communications** With CAP members spread throughout the United States—and indeed the world—the efficient transfer of information, both scientific and practical, is vital if the College is to be successful in its role as advocate for the profession and individual pathologists. This need has been recognized from the outset; the first publication sent by the College to all members was a letter from Frank W. Hartman, MD, the first president, dated February 13, 1947, which described the organizational meeting of the College. Shortly thereafter, in May 1947, Executive Secretary Melbourne G. Westmoreland, MD, initiated the monthly *Secretary's News Letter*, which contained a listing of members, reports of the Board of Governors, and other informational items considered to be of interest to the members (Fig 3-5). Support for the *News Letter* was not universal among the members of the Board of Governors, as some feared that information published there could “[reach] the hands of individuals who might work against the College.”<sup>15</sup>

In October 1953, the Board approved changing the title of the *News Letter* to *The Bulletin of the College of American Pathologists*. The first issue of the *Bulletin*, eight pages in length, was published in January 1954 as Volume 8, No. 1, continuing the sequential numbering begun with the first *News Letter* (Fig 3-6). In 1957, “appropriate” advertising was first allowed in the *Bulletin*; the Publications Committee was charged with reviewing all advertising prior to publication. By the end of 1959, the *Bulletin* generated sufficient revenue to become virtually self-supporting.



**Fig 3-7.** Martin J. Valaske, MD (1928–1987), served as editor of the *Bulletin and Pathologist* for 17 years, from 1965 through 1982.



**Fig 3-8.** The new CAP logo and a new title, *Pathologist*, January 1969.

Initially, the *Bulletin* was edited by Executive Secretary Arthur H. Dearing, MD, who replaced Westmoreland late in 1953. By July 1957, the executive secretary's other duties had made the editorship too burdensome, and S.E. Gould, MD, the first pathologist editor, took over from Dearing and served until his replacement by Dennis Dorsey, MD, in January 1961. George Milles, MD, assumed the editorship in March 1963; in July 1965, Martin J. Valaske, MD, was named editor, a position he held until June 1982 (Fig 3-7).

In 1969, the name of the *Bulletin* was again changed, this time to *Pathologist*, with “Bulletin of the College of American Pathologists” as a subtitle (Fig 3-8); the subtitle was dropped in January 1976. During the 1970s and early 1980s, scholarly scientific articles appeared in *Pathologist* with increasing frequency, alongside the society's informational materials. Dr. Valaske and subsequent editors began to press for conversion of *Pathologist* from a



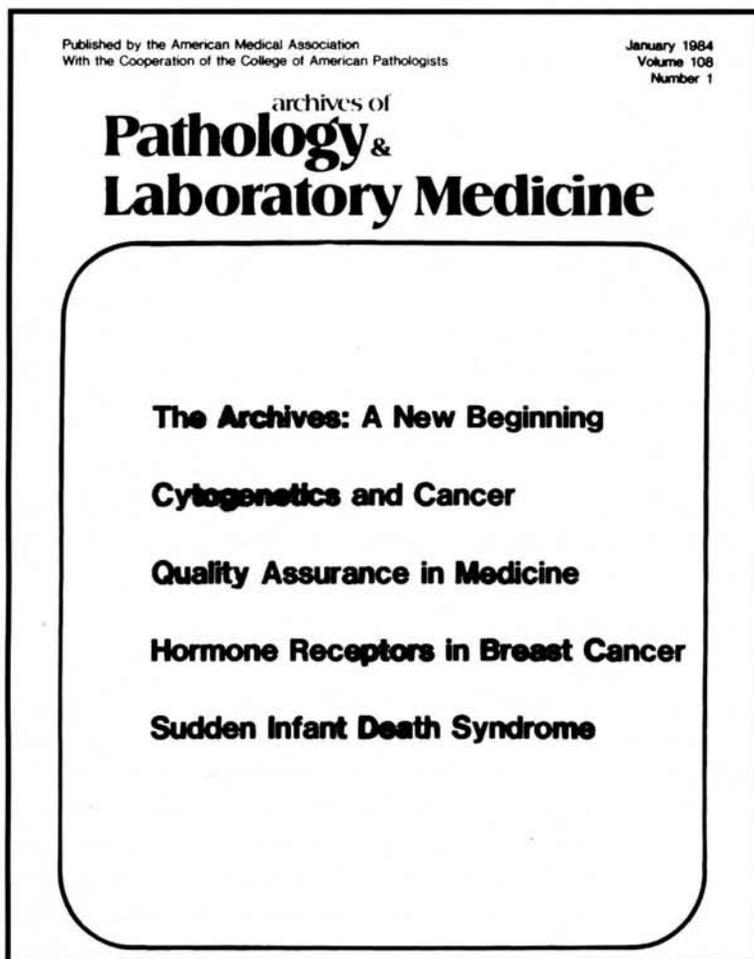


Fig 3-10. CAP joins AMA in publishing the Archives of Pathology & Laboratory Medicine, January 1984.

sponsor *Human Pathology* was also considered but came to naught. Another proposal for co-sponsorship of the AMA *Archives of Pathology & Laboratory Medicine* was defeated by the CAP Board of Governors by a single vote in 1980; but in 1982 a year of intense negotiation with the AMA began. In October of that year, agreement appeared to be unlikely, and the Board voted to convert *Pathologist* to a refereed journal. Having received a revised proposal from the AMA in November, the Board agreed to re-open negotiations, and in May 1983, agreement was reached for the CAP to provide financial support to the *Archives of Pathology & Laboratory Medicine*, although the AMA retained ultimate fiscal and publication responsibility for the journal.<sup>21</sup> Joint publication began in January 1984. The logo of each society was displayed on the cover of the journal (Fig 3-10), and the editorial board was selected jointly. At this point, publication of the AJCP supplements was discontinued.

Under the editorial leadership of William W. McLendon, MD, the quality of the journal has been greatly enhanced. The co-sponsorship agreement was intended, in part, to allow a more ambitious schedule of publications "resulting from such CAP activities as the laboratory improvement programs and on such topics as laboratory management, the role of the laboratory in the practice of medicine, and the utilization of

elected as the CAP's first Honorary Fellow. (Interestingly, the phrase "and Laboratory Medicine" was part of the publication's original title; it was dropped for unknown reasons in 1928, and reinstated to mark the journal's 50th anniversary in 1976.)<sup>2,16</sup> Early in 1969, the Standards Committee proposed the publication of an annual supplement to the AJCP to include all such articles. The first AJCP supplement was published in September 1970;<sup>17</sup> succeeding supplements appeared annually from 1974<sup>18</sup> through 1983.<sup>19</sup> One additional article based on Surveys data, but not designated as a "supplement," appeared in 1972.<sup>20</sup>

Even with the AJCP supplements, access to the indexed medical literature for CAP-generated articles was perceived to be too limited. In 1974 and 1975, the AMA was again consulted about cooperative use of the *Archives of Pathology* for such articles; a proposal for the College to co-

information science and computer technology in the care of patients.”<sup>21</sup> Under this expanded mandate, the *Archives of Pathology & Laboratory Medicine* now publishes complete or partial proceedings of CAP Conferences; several of these special issues have gained wide circulation in the medical community as definitive discussions of important issues.



Fig 3-11. *Archives of Pathology & Laboratory Medicine* becomes the CAP's official journal, January 1995.

The College's financial support of the journal increased each year, but in 1993 the AMA served notice that it would cease publication of *Archives of Pathology & Laboratory Medicine* unless it could at least break even. At that time, the CAP Board agreed to explore complete ownership and support of the journal by the College. The joint publication arrangement with the AMA was eventually extended through December 1994. In January 1995, the CAP assumed full fiscal and publication responsibility for the journal, and it became the Official Journal of the College of American Pathologists (Fig 3-11).<sup>16</sup> It remains, however, a part of the AMA's family of specialty journals, and the *Archives* editor continues to serve on the editorial board of the *Journal of the American Medical Association* (JAMA).

**Public Relations** Alongside the vital role of communication among its membership and the larger laboratory community, the CAP also recognizes a continuing need to improve the image of pathology and its practitioners in the eyes of the general and medical public. Efforts along this line date back almost to the founding of the College. The Board of Governors considered enlisting professional assistance as early as June 1948, when three public relations firms were inter-

viewed; however, there is no evidence that any of the three was hired. Shortly thereafter, the College found itself seizing opportunities to influence popular media portrayals of pathology, with mixed results. A 1949 article on the autopsy in *Collier's* was written by former *Look* editor Margaret Blake Ewing with guidance from the CAP Autopsy Committee, and carried the following endorsement from the College's Editorial Committee:

*We have reviewed the article on autopsy and are glad to see this information being brought to the public. We would like to congratulate the editors on being courageous enough to approach the subject which has for so long been neglected. We are certain that publicizing this information will encourage greater reliance upon this type of study by the public and thereby advance medical education, as well as result in better medical service for all of us.*<sup>22</sup>

On the other hand, author Greer Williams was alleged to have ignored suggestions from both the College and the ASCP in preparing a 1951 *Saturday Evening Post* piece on pathology; though the article had reportedly been approved by the AMA, its impending publication seems to have been causing some sleepless nights among CAP and ASCP members at the time of the CAP's January 1951 Board of Governors meeting. At that meeting the Board went on record as "willing to approve the article if certain modifications were made."<sup>23</sup> Apparently those modifications were not forthcoming; there is no documentary record of the Board's reaction to the piece after it was finally printed in the *Post's* March 3, 1951 issue, but it did not carry any statement of endorsement by the profession.<sup>24</sup>

Other efforts to improve the public image of pathology were largely cooperative in the 1950s. The College endorsed a motion picture entitled "Surgical Histology" planned by Technicon Corporation in 1954; in 1956

it gave its blessing to a series of films on forensic pathology produced by the AMA, and to a documentary film on pathology made by the Armed Forces Institute of Pathology. The Board of Governors in 1955 approved the production of 13 television programs dealing with general and forensic pathology. Unfortunately, no copies of any of these films are known to have survived.

In 1957, the College joined the American Society of Clinical Pathologists, the American Association of Pathologists and Bacteriologists, the International Academy of Pathology, and the American Society for Experimental Pathology to incorporate the Intersociety Committee on Pathology Information (ICPI). Stimulated by a survey which revealed that 72 percent of the public believed that pathologists had no degree (28% thought they had “a degree of some sort”), the CAP Board voted an initial contribution of \$5,000 to ICPI, which was charged with motivating pathologists to become involved in educating the public about pathology and recruiting residents into the specialty—a huge undertaking! Among the early successes of ICPI was the production of an informative brochure on cervical cytology, which was widely circulated in the United States and Canada. ICPI continues to publish a pathology recruitment pamphlet, which has been broadly distributed over the years.

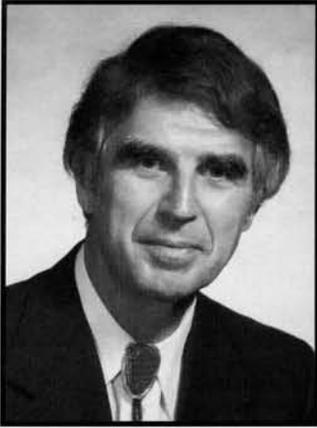
A public relations department within the College was approved by the Board in 1965, with a budget of \$20,000, but another two years elapsed before Howard E. Cartwright, a seasoned public relations professional, joined the staff as assistant to the executive director late in 1967. Other public relations activities were sporadic at best. One modest program, originating in 1977, was focused largely on other health care professionals; a somewhat more ambitious effort began in 1980 at the urging of the CAP Foundation and the House of Delegates. In 1984, with pathologists still perceived as having virtually no public image, a comprehensive public relations effort finally began with a budget of \$275,000. A Commission on Public Services was chaired by Pierre Keitges, MD, and William Kuehn, PhD, became the first full-time director of public services in the College.

Today, the public relations efforts of the College feature monthly public service television releases, press releases, training for members in public speaking, and major television documentaries. Several CAP documentaries have received national awards from prestigious public broadcasting and public service organizations. In 1992, the Commission on Public Services was converted to the Council on Public Affairs, a move that stressed the importance of these efforts.

**CAP Foundation** According to its 1988 Silver Anniversary report, the CAP Foundation was established “to enhance the role of the pathologist in the provision of medical care; to advance pathology through the education of the medical community; [and] to encourage the clinical application of research developments.” These goals are complementary to the public relations program and related endeavors of the CAP itself.

The CAP Foundation was established in 1963, following the failure of efforts to form a similar joint organization with the other major pathology societies, and funded with an initial contribution of \$2,000 by the CAP Board in April 1964. Founded as a tax-exempt 501(c)(3) corporation under the Internal Revenue Service code, the CAP Foundation receives tax-deductible contributions from members and others. (The Foundation’s 501(c)(3) status allows it to receive tax-deductible contributions and prohibits it from engaging in substantial political advocacy activities. The College itself is a 501(c)(6) corporation, and is thus unable to receive tax-deductible contributions, but is permitted to carry on a lobbying program.)

The CAP Foundation’s earliest efforts were devoted to the funding of research grants and the sponsorship of keynote speakers at CAP Fall Meetings. In 1981 the Foundation began sponsoring invitational conferences



**Fig 3-12.** Herbert Lansky, MD (1925–1985), was CAP secretary-treasurer from 1979 until his untimely death, and is commemorated in the CAP Foundation's Herbert Lansky Memorial Award.



**Fig 3-13.** Geraldine Colby Zeiler (1925–1990), memorialized by the CAP Foundation's Zeiler Professorship in Cytopathology.



**Fig 3-14.** John H. "Jack" Rippey, MD (1934–1994), honored in the John H. Rippey Memorial Fund for Laboratory Quality Assurance.

to identify and suggest solutions to problems facing pathology, such as the decline in the prestige and use of the autopsy. Proceedings of these conferences, like those of the CAP Conferences, have been published in *Archives of Pathology & Laboratory Medicine*. Since the Fall of 1992, the Foundation has also presented a seminar at each CAP/ASCP Fall and Spring national meeting.

Among other significant Foundation activities is the CAP Foundation Scholars Program, designed to support the research activities of young pathologists in the hope that this research will have eventual application in the clinical laboratory. By early 1996, the individual grants of \$25,000 each under this program had reached a total of \$700,000. The training of pathologists in new technologic areas is fostered by the CAP Foundation Technology Award and the Informatics Award.

The CAP Foundation also administers several memorial funds. The Lansky Award memorializes Herbert Lansky, MD, an active and highly respected leader of the CAP who died in a 1985 traffic accident while serving the College as secretary-treasurer (Fig 3-12). This award is presented to a young pathologist who best represents the ideals of the College of American Pathologists and has made a significant contribution to pathology.

The Geraldine Colby Zeiler Professorship in Cytopathology was established through the Foundation at the Mayo Medical School, from contributions by the family and friends of the wife of William B. Zeiler, MD, CAP president from 1987 through 1989 (Fig 3-13). Mrs. Zeiler was a cytotechnologist trained at the Mayo Clinic, and the Geraldine Colby Zeiler Awards for Students of Cytotechnology are also administered by the Foundation.

The John H. Rippey Memorial Fund for Laboratory Quality Assurance was funded by a grant from the former Southeast Regional Quality Control Group. This fund honors John H. "Jack" Rippey, MD, a pioneer of the CAP Surveys Program and a stalwart supporter of the College's mission (Fig 3-14).

**Insurance** Many, if not most modern medical societies, have found it an appropriate expression of their missions to provide insurance coverages of various sorts to their members. In this respect, as in many others, the CAP has been in the forefront. The first discussion of possible group insurance policies for CAP members took place at a meeting of the Board of Governors in October 1948, and led to the appointment of the College's first Insurance Committee the following year. Group health and accident coverage was first offered in 1954, and has continued without interruption to the present, although terms, rates, and underwriters of the policy have all changed periodically.

Group term life insurance was instituted in 1960. On several occasions, for example, in 1974, a one-year \$12,500 policy was offered without cost to each new Fellow and Junior Member as an inducement to join the College. Malpractice insurance coverage has been provided intermittently under the auspices of the College: from 1954 through 1958 by Lloyd's of London; from 1981 through 1986 by CIGNA; and since 1986 by the Doctor's Company of California. Long-term nursing-home care coverage is also provided.

Administration of the College's insurance programs was for many years in the hands of the Association Service Office of Philadelphia. In 1996 this responsibility was transferred to Jardine's Group Services Corporation.



**Fig 3-15.** Roger A. Côté, MD (b. 1928), edited the first edition of the *Systematized Nomenclature of Pathology (SNOP)* and contributed greatly to its subsequent development as the *Systematized Nomenclature of Medicine (SNOMED)*.

**Benefits to Medicine—Medical Nomenclature and the Development of SNOMED®**

Along with its many services to its own members and the general laboratory community, the College can point with pride to its leading role in a major effort resulting in tremendous benefit to the entire universe of health care professions—namely, the standardization of medical terminology now embodied in the *Systematized Nomenclature of Medicine (SNOMED)*. Several early leaders of the College—notable among them David A. Wood, MD, president from 1953 through 1955—viewed with alarm the confusion and inconsistency which then existed in the diagnosis and terminology of disease.<sup>25</sup> In 1953, the College's newly created Committee on Nomenclature and Classification of Disease was charged to develop a standard classification system for pathology. The work of this committee was supported in part by a grant from the National Institutes of Health, which had begun work on the classification of all morphologic changes in *homo sapiens*; one of the original members made the charmingly understated and eminently safe prediction that “the work envisioned will require meetings and discussion.”<sup>26</sup>

In fact the process eventually entailed a full decade of “meetings and discussion.” One former Governor of the College has recalled that the nomenclature project “got off to a very slow start....production by volunteers from the membership in committee action proved less than cost efficient.”<sup>27</sup> At several points throughout the 1950s, the Board of Governors minutes record complaints about the slow progress and high cost of this undertaking. Finally it was decided that the nomenclature project had to be brought under the purview of a single editor if it were to be successfully completed. That editor was Roger A. Côté, MD, then associated with the US Veterans Administration Hospital at Wood, Wisconsin, who shepherded the first edition of the *Systematized Nomenclature of Pathology (SNOP)* to publication in January 1964 (Fig 3-15).

At this stage, funds were committed by the Board to maintain SNOP and to cooperate with the Council of International Organization of Medical Science (CIOMS) to gain acceptance of the system worldwide. This effort was at least partially successful, for permission was granted in 1967 for translations of SNOP into Japanese, German, and Italian. In 1972, the Board authorized the conversion of SNOP into the more comprehensive SNOMED, which was readied for field testing by 1975—again largely under the aegis of Dr. Côté, who remained at the helm of the project until 1979. The College's proposals to the US Health Care Financing Administration for use of SNOMED in several components of the Medicare program were rejected, but the system has won gradual acceptance in other parts of the world and in other branches of medicine.

In 1979, the chair of the SNOMED Editorial Board was taken over by David J. Rothwell, MD, who served until 1988; at that time Dr. Côté returned to the chair and is still serving at this writing. In the meantime, an electronic version of SNOMED has been prepared, and microglossaries for some segments of the system are also available, e.g. in surgical pathology and veterinary medicine. To date SNOMED has been translated, in whole or in part, into 13 languages other than English. In 1995, the Board approved a major commitment of funds to position the College as a player in the development of standards for electronic patient records based on SNOMED.

In sum, then, the College has succeeded admirably in balancing its efforts in the service of individual pathologists, the profession of pathology, the larger laboratory and health care communities, and the general public. Its distinguished record thus far gives clear promise of continued leadership in the pursuit of excellence on all these fronts as the CAP enters its second half-century.

## Notes

1. CAP *Secretary's Newsletter*. 1948 Dec;2:4; CAP *Bulletin*. 1954 Nov;8:1.
2. Wissler RW. A trip through time to visit four scholarly pathologists I have known: First four editors of the *Archives of Pathology and Laboratory Medicine*. *Arch Pathol Lab Med*. 1993;117:743-747.
3. Gruhn JG, Steigmann FS. Ludvig Hektoen, 1863-1951: Founding editor of the *Archives of Pathology and Laboratory Medicine*. *Arch Pathol Lab Med*. 1993;117:748-753.
4. CAP Board of Governors Minutes, 1950 Feb 5:6. Hereafter cited as "Minutes."
5. CAP *Bulletin*. 1956 Oct;10:1.
6. Minutes, 1955 Feb 5–6:20.
7. CAP *Secretary's Newsletter*, 1949 Mar;3:3.
8. Minutes, 1973 Jun 26:5.
9. *A workload recording method for clinical laboratories*. Chicago, Ill: College of American Pathologists; 1970.
10. Langdell RD. The College of American Pathologists Conferences. *Arch Pathol Lab Med*. 1988;112:319. Editorial.

11. Dolan CT, Gavan TL, King JW, et al, eds. *College of American Pathologists Conference I (1975): Clinical Relevance in Microbiology I*. Skokie, Ill: College of American Pathologists; 1976.
12. Austin RM, McLendon WW, eds. College of American Pathologists Conference XXX on Quality and Liability Issues with the Papanicolaou Smear. *Arch Pathol Lab Med*. 1997;121:205-342.
13. Koepke JA, ed. *College of American Pathologists Conference III (1977): Differential Leukocyte Counting*. Skokie, Ill: College of American Pathologists, 1978.
14. Elevitch FR, ed. *College of American Pathologists Conference II (1976): Analytical Goals in Clinical Chemistry*. Skokie, Ill: College of American Pathologists; 1977.
15. Minutes, 1948 Jan 17:1.
16. McLendon WW. The *Archives of Pathology & Laboratory Medicine*, the American Medical Association, and the College of American Pathologists: A journal in transition. *Arch Pathol Lab Med*. 1995;119:13-15. Editorial.
17. Eilers RJ. Total quality control for the medical laboratory: The role of the College of American Pathologists Survey Program. *Am J Clin Pathol*. 1970;54:435-436, and following articles.
18. King JW, ed. College of American Pathologists Survey. *Am J Clin Pathol*. 1974;61:899-998.
19. Batsakis JG, Lawson NS, eds. Report on the Quality Assurance Programs of the College of American Pathologists, 1983. *Am J Clin Pathol*. 1983;80:551-647.
20. Copeland BE, Skendzel LP, Barnett RN. Interlaboratory comparison of university hospital referee laboratories and community hospital laboratories, using results of the 1968 College of American Pathologists Clinical Chemistry Survey. *Am J Clin Pathol*. 1972;58:281-296.
21. McLendon WW. The *Archives of Pathology & Laboratory Medicine*: A new beginning. *Arch Pathol Lab Med*. 1984;108:13-14. Editorial.
22. Ewing MB. Autopsy. *Collier's*, 1949 Jul 23:30,40.
23. Minutes, 1951 Jan 27-28:9.
24. Williams G. Who checks up on doctors? *Saturday Evening Post*. 1951 Mar 3;223:32-33ff.
25. Wood DA. Oral history interview, 1987 Apr 1.
26. Queen FB. Minutes, 1953 May 30-31, Exhibit P.
27. Pontius EE. Oral history interview, 1985 Nov 3.

## Chapter Four

# Laboratory Standards

Loyd R. Wagner, MD

No action taken by the early pioneers of the College of American Pathologists has had greater long-term impact on the organization than the creation of the Committee on Standards, subsequently known as the Committee on Laboratory Standards and the Clinical Pathology Standards Program Committee. Virtually all of the laboratory improvement programs developed by the College can be traced directly or indirectly to this committee and the dedicated pathologists who served on it. The breadth of that impact could hardly have been foreseen by even the most visionary of the early CAP leaders. In 1966, Dennis Dorsey, MD, later to become president of the College, wrote of the Standards Committee, “The primary standards program, the certification program, and the Surveys conducted by this committee....have encouraged us to abandon the security of the ‘paraffin curtain’ and helped us become clinical pathologists and laboratory directors in fact as well as in name.”<sup>1</sup>

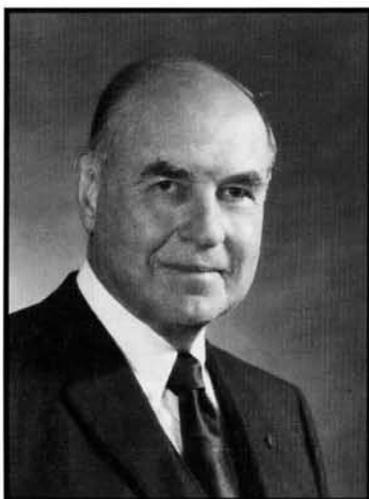
The Standards Committee’s initial mission was to oversee the production of carefully standardized solutions for use in laboratory procedures, a need that was made starkly apparent by surveys of laboratory performance during the late 1940s. The 1950s witnessed the evolution of several new roles for the Standards Committee. As projects proliferated, the need for members with expertise in the various specialty areas of clinical pathology became apparent. In 1958, several sub-committees were formed and charged with responsibility for specific areas of activity. These sub-committees would eventually become free-standing—the precursors of the present resource committees that oversee the quality control programs of the College.

*The primary standards program encouraged us to abandon the security of the ‘paraffin curtain’ and helped us become clinical pathologists and laboratory directors in fact as well as in name.*



In May 1961, the Board of Governors amended the charge of the Committee on Clinical Pathology Standards to read: “The purpose of the committee shall be to develop and maintain the highest possible technical standards in the field of clinical pathology. This is to be accomplished primarily by evaluation, certification, and survey.” In discussing the new charge with the Board, Donald Brown, MD, a member of the Standards Committee, stated “it is time that the medical profession in general and all involved paramedical interests be made aware that pathologists are both willing and qualified to set standards for the practice of laboratory medicine.” This mandate of the Board of Governors to evaluate, certify, and survey firmly established the standards program, set the stage for the growth of Surveys, and soon led to the Laboratory Inspection and Accreditation Program. Proceeding on parallel courses, these programs would come to define the College of American Pathologists as a leading proponent of laboratory quality in the United States and the world.

As the programs initiated by the Standards Committee matured, responsibility for their operation was delegated to independent committees, such as the Surveys and Resource Committees and the Commission on Laboratory Accreditation. Finding itself now dealing chiefly with “standards in a bottle,” the Standards Committee began a search for a broader mandate. In 1969, the Standards Committee redefined “standard” for its purposes to include not only chemical materials, but methods, procedures, and test management as well. The committee’s interest in other “standards” was exemplified by its support of the consensus process of the National Committee for Clinical Laboratory Standards (NCCLS), which was formed in 1967. Since that time, proposed NCCLS standards have been routed to the Standards Committee for review and comment, ensuring CAP input into the process. By 1996, the various programs originated by the Standards Committee had grown to require the oversight of a network of nearly 40 commissions and committees.



**Fig 4-1.** F. William Sunderman, MD (b. 1898), the only surviving member of the original Board of Governors, coordinated the first CAP survey of laboratory performance in 1949, which provided the impetus for the standard solutions program.

**Standard Solutions and Materials Program** Shortly after World War II, a small group of pathologists who had formed the Clinical Pathology Section of the Philadelphia County Medical Society distributed unknown chemical samples among themselves to evaluate their accuracy. Among them was F. William Sunderman, MD, who prepared the samples and analyzed the results<sup>2</sup> (Fig 4-1). Alarmed by the findings of this survey, the Committee on Laboratories of the Medical Society of the State of Pennsylvania conducted a statewide survey in 1946 to evaluate the accuracy of some common chemical laboratory measurements. Again under the direction of Dr. Sunderman, carefully prepared solutions of hemoglobin, glucose, urea nitrogen, chloride, calcium, total protein and albumin were distributed in two separate mailings to participating laboratories for analysis. When the responses were evaluated, unsatisfactory results outnumbered the satisfactory, without a single laboratory attaining a perfect score. A follow-up questionnaire was sent to the participating clinical pathologists seeking reasons for the poor performance. Nearly 80 percent of the respondents cited inadequate numbers of technicians and their poor training, while more than 50 percent listed poor equipment as a contributing factor. The results of the Pennsylvania survey were published in a now classic article by William Belk, MD, then chair of the committee, and Sunderman in the *American Journal of Clinical Pathology*.<sup>3</sup>

Based on the Pennsylvania experience, the CAP Standards Committee submitted a proposal to the College’s Board of Governors in November 1947, for a national survey of 100 to 200 laboratories, also refereed by Dr. Sunderman, to assess the accuracy of laboratory determinations, in anticipation of the later distribution of standards for calibration of equipment and methods. By the time this first Survey was mailed in 1949, the program had expanded to 650 participants. The samples provided to the laboratories for analysis included water-based solutions of glucose, urea, chloride, and calcium, and a chloroform-based solution of cholesterol, each supplied at two levels. Some 500 participants returned their results to the College. When the results were compiled, the analytical variations were so large that the Board of Governors decided to delay publication of the results until methods for improving performance were determined.

This wide variation in analytic results initially moved the Board to consider approaching several commercial firms to produce accurate standards for laboratories to use for calibration and standardization of methods. Instead, a CAP Bureau of Standards was proposed for the preparation and distribution of standards, and in

# College of American Pathologists

## SECRETARY'S NEWS LETTER

M. G. WESTMORELAND, M.D., *Executive Secretary*, 203 N. Wabash Avenue, Chicago 1, Illinois

Volume V

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Number 8

### COLLEGE BUREAU OF LABORATORY STANDARDS

#### BUREAU GETS UNDER WAY

Once more pathologists are engaging in a program to increase the efficiency of laboratory determinations. This is the second time that an organized effort has been made to improve laboratory service to patients, physicians and the public. About fifteen years ago the pathologists undertook the first improvement. This was in the field of serology and dealt with the complete standardization of the Wassermann tests. At that time the pathologists were concerned over the inaccuracies in reports from different laboratories when the same blood was tested in several laboratories. After developing a method that greatly increased accuracy and anticipated an even greater uniformity in results from all laboratories, the pathologists urged U.S.P.H.S. to assume responsibility for the continuation of the method used to standardize this group of tests. Unfortunately the basic role of the pathologist was soon forgotten in the continued development of this first improvement in the accuracy of laboratory determinations.

have embarked upon the second organized effort to improve the reliability of the laboratory which will be of material benefit to patients, physicians and the public.

#### Accurate Solutions Now Available

All members of the College of American Pathologists who direct or are responsible for clinical pathology are urged to request the standard solutions prepared for the first distribution. These will include three containers of a dextrose standard and three containers of a nitrogen standard which will be distributed **without charge** in order of receipt of requests until the supply is exhausted. One thousand boxes are available for this purpose. Requests will be taken care of until October 1, 1951, at which time any remaining boxes will be mailed to those who have asked for duplicate sets.

The dextrose and nitrogen standards represent values commonly found in human blood. Since higher values have been selected for these standards it is possible to use

Fig 4-2. Announcement of the first standard solutions, August 1951.

October 1950, \$12,000 was authorized to fund a PhD chemist and a technician-secretary to staff such a CAP Laboratory of Clinical Standards. The laboratory was to be under the direction of Dr. Sunderman, and to operate in conjunction with the Communicable Disease Center (now the Centers for Disease Control and Prevention) and with Emory University in Atlanta, Georgia. However, negotiations to establish the laboratory failed, and in mid-1951 the program was redirected to provide standards manufactured by commercial firms. The first standards were available late in 1951. Before release for distribution, samples of each batch of standard were submitted to three independent analysts; if the three assays agreed within defined limits of tolerance, they became CAP Certified Standards.

Under the overall designation of the "Clinical Pathology Standards Program," the first standards produced were for dextrose (glucose) and nitrogen (urea nitrogen) (Fig 4-2). An introductory price of \$.50 per box of six ampules of standard was established. Following soon thereafter were standards for chloride, calcium, phosphate, uric acid, creatinine, and tyrosine. Standards for cholesterol and bilirubin were considered, but were deemed inadvisable at the time because of the difficulty of obtaining pure materials. By 1953, standards for sodium and potassium by flame photometry were for sale, and the feasibility of producing a protein standard was under consideration.

While the CAP Certified Standards were at first sold by laboratory supply firms, in 1952 the Board of Governors brought the distribution of standards into the College. Initially, only members of the College could purchase standards, but in 1955 sales were opened to all physicians (Figs 4-3 and 4-4). At the same time, educational activities were linked to standards in order to solve problems discovered in the earlier surveys of laboratory proficiency.

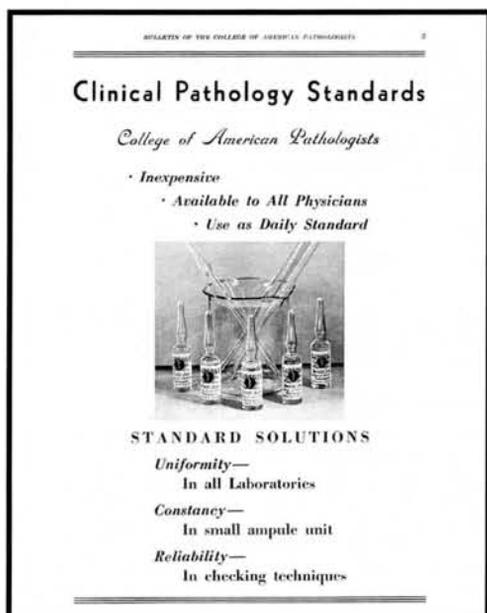


Fig 4-3. This display advertisement for standard solutions appeared in the CAP Bulletin in September 1957.



Fig 4-4. The standard solutions room in the CAP headquarters suite at Chicago's then-new Prudential Plaza, 1957.

Although the Committee for Clinical Pathology Standards was concentrating on providing standards for calibration, it was also conducting additional surveys of laboratory accuracy. The second chemistry survey was conducted in 1954, with 562 participants returning 473 results for analysis. The data thus collected served to focus the committee's activities on the design of specific projects to accomplish needed improvements in laboratory performance.

As activities of the Committee expanded, a number of its members expressed the need for a laboratory in which to carry out projects dealing with certification of materials. Though the Board of Governors agreed in principle that such a laboratory would be desirable, economic factors at first deterred any action. Then serendipity brought the need for such a laboratory into sharper focus, and economics changed to make its establishment possible.

In 1950, the generally unsatisfactory performance of hemoglobin determinations in American laboratories had led the CAP and ASCP to co-sponsor a symposium on this subject at the national meeting of the two groups.<sup>2</sup> The results were published as a symposium in the *American Journal of Clinical Pathology* in 1953.<sup>4</sup> In 1955, the National Research Council (NRC) formed an ad hoc Committee for the Establishment of a Hemoglobin Standard, in conjunction with the Hematology Section of the National Institutes of Health. The deliberations of this ad hoc group led to the recommendation of the cyanmethemoglobin method as the first choice for routine hemoglobin analysis. Two commercial firms began production of a standard under the implied regulation of the National Research Council, but in fact there was no actual oversight mechanism. In April 1957, Dr. Margaret Sloane of the NRC raised the possibility of a certification program for hemoglobin standards operated by or in conjunction with the College. At the 1957 annual meeting of the CAP, the Board of Governors accepted responsibility for such a certification program, the specifications for which were published in 1958.<sup>5</sup>

In order for the College to fulfill this responsibility, the need for a laboratory in which to carry out the necessary testing became acute, and an agreement was secured for use of the laboratory then operated by the American Medical Association. In addition to the initial certification, monthly follow-up analysis was to be performed to determine shelf life and stability of the materials, which bore the label "Certified by the College of American Pathologists."

The first standards had hardly been released when the AMA closed its facility, leaving the committee and the College with no laboratory in which to perform the required analyses. Consequently, the Board of Governors established the CAP Reference Laboratory in rented space in downtown Chicago. A DU spectrophotometer and other laboratory equipment were purchased from the AMA, and the AMA's former analyst was also hired to staff the facility.<sup>6</sup>

Concurrently, efforts were under way to establish an international standard for cyanmethemoglobin, and in 1965 the CAP Certification Laboratory was selected as one of five in the world designated to analyze specimens for the certification of this material. On January 1, 1967, the criteria for the cyanmethemoglobin standard certified by the CAP were brought into compliance with the new international standard.

In mid-1964, concerns about inadequate space and supervision led to a proposal by the Standards Committee to relocate the CAP Reference Laboratory and redefine its mission. The laboratory was moved to the Division of Pathology at the Cleveland Clinic Foundation in Cleveland, Ohio, and renamed the "CAP Certification Laboratory." It remained at the Cleveland Clinic until 1983, when CAP certification of standards ended.

Over the years CAP chemical standards were gradually refined and became more widely used and accepted. Calcium standards were purchased by at least one instrument manufacturer and provided to its customers for calibration purposes. The production of standards for other analytes was undertaken, notably for coagulation studies and cholesterol analysis. At the urging of the federal government, the first crystalline bilirubin standard was produced and certified by the College in late 1963.

In December 1967, surplus materials from the 1966 and 1967 Surveys Programs were offered to the subscribers as "true value samples." This represented the first laboratory use of materials validated through the Surveys process for calibration and/or daily quality control purposes. These materials eventually became known as "Survey Validated Reference Materials" (SVRMs), although it is uncertain exactly when this name was given. In 1981, the Standards Committee began a study aimed at replacing all aqueous standards with protein-based materials. As a result, in 1983 SVRMs, previously available only to Surveys participants, were made available for purchase by all laboratories as a protein-based reference material. A fresh frozen liquid standard for cholesterol was introduced in 1992.

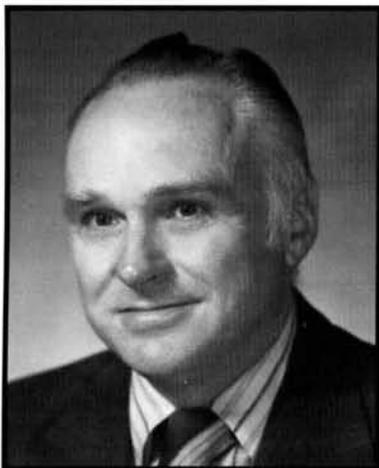
Standards for calibration of specific protein fraction analysis were not readily available until the early 1980s. In the mid-1970s, the World Health Organization (WHO) prepared stable standards for a limited number of protein fractions, and in December 1977, the WHO Expert Committee on Biological Standards established one freeze-dried pool of human serum as the "WHO International Reference Preparation for Six Human Serum Proteins." Another lot of the same pool of material was accepted as the "United States Reference Preparation for Specific Human Serum Proteins," calibrated in international units. In collaboration with the Centers for Disease Control, the Standards Committee, under the direction of Robert M. Nakamura, MD, then oversaw production of the CAP Reference Preparation for Serum Proteins. This preparation, calibrated in mass units, was announced in the July 1981 issue of *Pathologist*.<sup>7</sup> The scientific report of the value-assignment process was published in the January 1982 issue of the *American Journal of Clinical Pathology*.<sup>8</sup>

More esoteric standards have been introduced over the years. Standards for coagulation and rubella are among recent examples of what has become a wide selection of materials for calibration of laboratory determinations.

**Product Evaluation** In March 1961, several members of the Committee on Clinical Laboratory Standards met with representatives of some 15 producers of laboratory instruments and reagents to discuss the possibility of creating a mechanism to evaluate chemical procedure kits. Concerns had arisen because many of the kits then on the market failed to meet their advertised performance specifications. The committee proposed a program to verify the performance of various products; it did not envision writing specifications for, or actual endorsement of, such products.

Once the design of the program was set, manufacturing companies were approached regarding CAP verification of their claims, and product evaluation was under way. This program, in the words of Donald A. Nickerson, MD, CAP president in 1963, would “give members a sound basis for judgment of products offered for their use by manufacturers.”

In 1964, the committee adopted a statement of operating procedure for the Product Evaluation Program.<sup>9</sup> Manufacturers desiring to have their products evaluated would submit data to the committee on the expected performance of a product. The Subcommittee on Product Evaluation would then conduct a series of tests under typical clinical laboratory conditions, using the laboratories of committee members and other selected pathologists. Each manufacturer provided an instrument and reagents, and frequently paid labor costs to the testing laboratory in addition to the application fee paid to the College. Studies included verification of day-to-day reproducibility, recovery studies, and comparability to other methods. By February 1965, the first evaluation had been completed, and the manufacturing company was permitted to cite CAP verification of its claims on labels, literature, and advertising.



**Fig 4-5.** Russell J. Eilers, MD (1925–1985), played a pivotal role in the establishment of the National Committee for Clinical Laboratory Standards in 1967, and served as its first chair.

In 1966, the College published “A Suggested Guide for Manufacturers for Preparation of Manuals of Operation for Laboratory Instruments.” Included in the guide were instructions on unpacking of equipment, environmental requirements, electrical and electronic descriptions, system specifications, initial operational checks, and drift. By the early 1970s, an independent Product Evaluation Committee had evolved and verification protocols had been refined.

Eventually the use of the CAP logo by companies participating in the Product Evaluation Program became controversial, although acceptable uses of the logo had never been clearly defined by the Board of Governors. In 1980, a review of the program was ordered by the Board, following which the committee was restructured and charged with redesigning the program; however, the program was instead discontinued in early 1981.

**Cooperative Standards Programs** In early 1967, members of the Standards Committee, then chaired by Russell J. Eilers, MD, met with manufacturers’ representatives regarding industry-wide standardization of reagents and materials (Fig 4-5). In a report of the committee’s activities, Dr. Eilers noted “it is evident there is a need for a supra-National Standards Committee and the Board has given its approval

for the Standards Committee of the College to take this initiative.<sup>10</sup> By December of that year, a Provisional National Committee for Clinical Laboratory Standards, with Dr. Eilers as temporary chair, had been formed by a coalition of laboratory and industry groups. Its purpose was to deal with reagent and consensus standards, excluding accreditation, personnel standards, proficiency testing, and certification of standard materials. In 1968, this body became the National Committee for Clinical Laboratory Standards (NCCLS). The College has continued as an active participant in NCCLS throughout its existence, and a number of CAP Fellows have served the NCCLS as officers or members of the Board of Directors. Many other CAP Fellows have chaired or served on various area committees or sub-committees dealing with specific topics. NCCLS documents frequently serve as references for checklist questions in the Laboratory Accreditation Program.

Also during the 1960s, in the process of certifying cyanmethemoglobin standards in the CAP Reference Laboratory, several analytical problems were traced to imprecise wavelength calibration of the spectrophotometer. Accurate wavelength filters were then obtained from the National Bureau of Standards to calibrate the CAP equipment, and were later made available for use by individual laboratory directors. In June 1967, an informal discussion was held at the National Bureau of Standards (NBS) concerning the need for absorbance and wavelength standards for spectrophotometers. The College was represented by Bradley Copeland, MD, at this meeting, which was assessed by the editor of the *CAP Bulletin* as "an important step in cooperative joint efforts to improve laboratory reference standards."<sup>11</sup> Later, the NBS agreed to furnish many organic and inorganic standards for the clinical laboratory, and in 1968, provided a new cholesterol calibration standard that was widely used.

Cooperation between the College and the NBS expanded after 1970. In 1972, a joint study of temperature standards was undertaken. In 1978, an NBS Research Fellowship was established by the College, primarily to develop definitive analytical methods and then to validate the values in Surveys materials established through analysis of participant results. Michael Welch, PhD, was selected as the first research fellow. In 1981, the NBS Research Fellowship was renamed in honor of the late Roger Gilbert, MD, one of the pioneers of the CAP Surveys Program. At this writing, two Fellows and two assistants who are College employees work at the renamed National Institute of Standards and Technology (NIST).

In the early 1980s, the Standards Committee began to develop a "CAP Archive of Standards." This was envisioned as an encyclopedic listing of all national and international, written or physical, standards having any application in the clinical laboratory. They were to be classified into five categories: materials and preparations, building codes, devices, procedures and guidelines, and miscellaneous. The listings were to include the names and addresses of all organizations that had developed the standards. The document was to serve as a reference source only, without CAP republication of the standards. Published under the title "Archive of Standards: A Practical Guide for the Medical Laboratory," the 1984 edition encompassed 178 pages and was dedicated to past CAP President Dennis Dorsey, MD, who chaired the Standards Committee during the early phases of this project.

In the early 1980s, the National Reference System in Clinical Chemistry (NRSCC) was formed in response to an initiative by federal Centers for Disease Control staff to dominate standard setting in clinical chemistry. Strong representation by Roger Gilbert, MD, Roy N. Barnett, MD, and others at an organizational conference in Atlanta resulted in the creation of the NRSCC as a component of NCCLS, having an organizational relationship with that body similar to that of NCCLS area committees. Early meetings of this group reportedly were relatively unfocused and accomplished little.



**Fig 4-6.** (left) Tyra T. Hutchens, MD (b. 1921) served as president of the CAP in 1977-79 and of the World Association of Societies of Pathology (Anatomic & Clinical) (WASP) in 1989-1991.

**Fig 4-7.** (right) Kenneth McClatchey, MD (b. 1942) served as chair of the CAP International Committee and greatly enhanced the international role of the WASP Commission on World Standards.

However, in February 1981, a proposal was forwarded to NCCLS by the CAP Council on Quality Assurance which provided for rotating the chair of the NRSCC among the chair of the CAP Standards Committee, the equivalent individual from the American Association for Clinical Chemistry, and the chair of the NCCLS Area Committee on Clinical Chemistry. Dr. Dorsey, in his position as chair of the CAP Standards Committee, was instrumental in establishing an orderly operating procedure for the NRSCC, defining affiliated organizations, and preparing for its expansion to other disciplines to become the National Reference System for the Clinical Laboratory (NRSCL). By 1985, the role of the NRSCL was focused on reference and definitive methodologies for a prioritized set of laboratory analytes.

The growth of international travel, improvement in world-wide communications, and the development of a global economy have had substantial impact on pathology and the College, most notably since the 1970s. World trade led to efforts to standardize the criteria for the manufacture of equipment and other products, and the clinical laboratory was not immune. Leaders of the World Association of Societies of Pathology (Anatomic & Clinical) (WASP) recognized the need for international harmony in the clinical laboratory relatively early, and formed the Council on World Standards (COWS). However, due to lack of funding and other material resources, many of the activities of WASP and COWS depended heavily on the dedication of individual pathologists, rather than the constituent societies. With the encouragement of Tyra T. Hutchens, MD (CAP president in 1977-1979), the concept of Secretariats was developed, by which individual member societies would assume responsibility for implementing WASP programs (Fig 4-6). In 1986, the College of American Pathologists assumed responsibility for the COWS Secretariat. Under the leadership of Kenneth McClatchey, MD, a much more proactive agenda evolved, providing input into international standard-setting organizations and monitoring such activities worldwide. As chair of the CAP International Committee, Dr. McClatchey also coordinated COWS activities with those of the College (Fig 4-7).

In setting standards for production of equipment and reagents, for the operation of proficiency testing programs, and other areas that affect the clinical laboratory, cooperation with other societies and organizations with interests in the field has become increasingly critical. In addition to the NCCLS and the other organizations already mentioned, CAP relationships have developed with such United States organizations as the American National Standards Institute (ANSI), the American Society for Quality Control (ASQC), the Health Industry Manufacturers Association (HIMA), and the AMA Biomedical Sector of the American National Metric Council. Through its relationships with ANSI and COWS, the College also has access to the

International Standards Organization (ISO), which deals with a wide array of standards beyond the clinical laboratory, and is supported by the governments of many nations.

Clearly the impact of the original Standards Committee has been enormous. From the early provision of materials in a bottle, to an active international role in determining standards of all types, the committee and its successors have remained consistently in "pursuit of excellence," and the enhancements in laboratory accuracy that its efforts have made possible have benefitted both practitioners and patients.

## Notes

1. CAP *Bulletin*. 1966;20:451.
2. Sunderman FW. Twenty-five years of proficiency testing for clinical laboratories. *Ann Clin Lab Sci*. 1972;2:420-424.
3. Belk WP, Sunderman FW. A survey of the accuracy of chemical analyses in clinical laboratories. *Am J Clin Pathol*. 1947;17:853-861. Reprinted in *Arch Pathol Lab Med*. 1988;112:320-326.
4. Sunderman FW, et al. Symposium on clinical hemoglobinometry. *Am J Clin Pathol*. 1953 Jun:23.
5. Cannon RK. Proposal for a certified standard for use in hemoglobinometry. *Am J Clin Pathol*. 1958;30:211-215.
6. Brown DE. CAP *Bulletin*. 1968;22:278-279.
7. Nakamura RM, Hanson DJ, Keitges, PW, et al. Development of the CAP Reference Preparation for Serum Proteins. *Pathologist*. 1981;35:377-379.
8. Reimer CB, Smith SJ, Wells TW, et al. Collaborative calibration of the U.S. national and the College of American Pathologists reference preparations for specific serum proteins. *Am J Clin Pathol*. 1982;77:12-19.
9. CAP *Bulletin*. 1964;18:202.
10. CAP *Bulletin*. 1967;21:148-150.
11. CAP *Bulletin*. 1967;21:266.

## Chapter Five

# The Surveys Program

Loyd R. Wagner, MD

The activities of the Committee on Laboratory Standards during the first years after the founding of the College of American Pathologists are recounted in Chapter 4 and need not be repeated in detail here. Following the first survey of accuracy in clinical laboratories in 1949, the efforts of the committee were directed at providing standards for calibration of methods. It was not until 1953 that the second national survey in chemistry was conducted, showing little or no improvement in laboratory accuracy during the interim. In June 1954, the Board of Governors approved surveys in bacteriology, hematology, and parasitology. For reasons which are not recorded, the bacteriology survey was not carried out until 1958, and there is no evidence that the other two were ever conducted. A third chemistry survey followed in 1960.

Meanwhile, the concept of “proficiency testing,” or “PT,” was emerging in other sectors of the laboratory community. In a number of laboratories, processes were developed to monitor continuing performance by submitting “unknown” samples to the analysts for comparison with known values in the sample. The first continuing “external” proficiency assessment program began in 1949, when the Virginia Pathology Society approached F. William Sunderman, MD, PhD (a founding member of the CAP Board of Governors), to provide monthly samples with which to conduct ongoing surveillance of laboratory performance in that state. Soon expanded to Indiana and Alabama, Dr. Sunderman’s Proficiency Testing Service (PTS) grew to more than 1,000 laboratory participants, and continued until 1985. It was then purchased by the American Society of Clinical Pathologists (ASCP) and became known as the ASCP Technical Improvement Service. An educational component was an integral part of the PTS, with a current review of pertinent methodology and a bibliography being returned to each participating laboratory along with an analysis of their testing results.<sup>1</sup>

*In the early 1960s, the Standards Committee established Surveys as a regular periodic external interlaboratory comparison program.*



Initially, CAP national surveys were conducted only sporadically, and were intended primarily to assess the general state of the art and identify areas for improvement with other CAP programs. However, in May 1961, the Board of Governors adopted a new statement of the Standards Committee’s mission, which was defined in part as “to develop and maintain the highest possible technical standards in the field of clinical pathology...by evaluation, certification and survey.”<sup>2</sup> In response to the mandate to “survey,” Donald E. Brown, MD, then chair of the Committee, established Surveys as a regular periodic external interlaboratory comparison program.<sup>11</sup> Surveys were no longer restricted to CAP members, but were opened to all laboratories, with invitations to subscribe being extended to more than 9,000 laboratory directors.

The CAP Surveys of that time were not educational, nor were they intended to be. In fact, the ASCP was provided with Survey results in order to focus the educational activities in its Check Sample Program on

**TABLE 10**

EVALUATION OF PERFORMANCE OF PARTICIPATING LABORATORIES: SERUM SODIUM PROCEDURES

Sodium Method	Percent within $139 \pm 3$ mEq./l.*	Percent within $139 \pm 6$ mEq./l.†
All methods	73.1	91.7
Flame photometer, direct flame type	71.2	90.9
Flame photometer, internal standard with lithium	78.3	94.0

\* These arbitrary limits represent the average and one standard deviation based on the gaussian estimate  
 † Average and two standard deviations based on the gaussian estimate

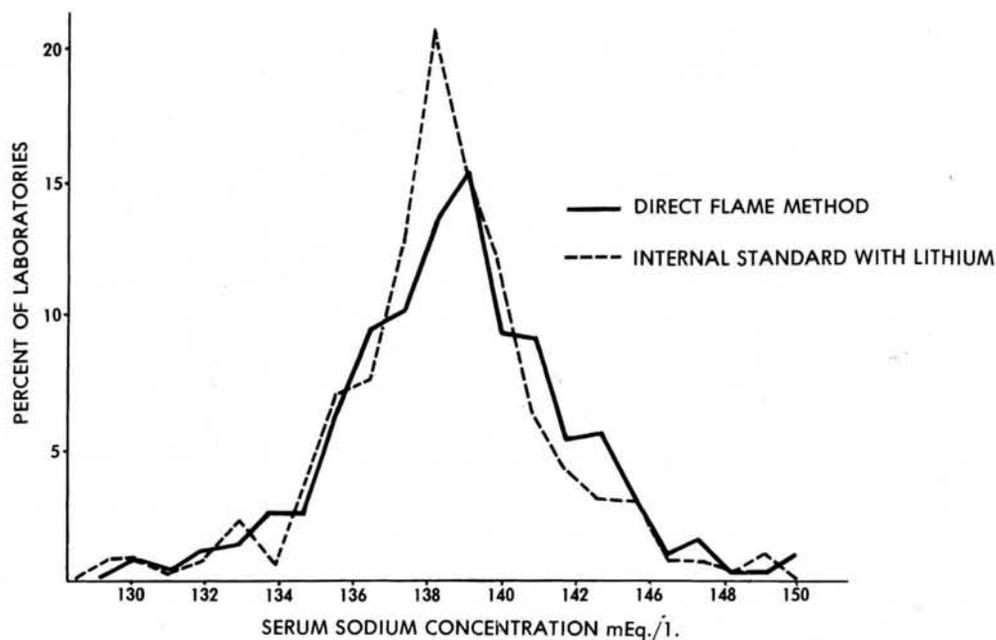


Fig 5-1. Sample serum sodium results from the report of the first Comprehensive Survey, 1963.

analytic problems discovered in Surveys. (The ASCP Technical Improvement Service also was subsequently developed to improve the technical performance of laboratories.) Educational materials were first incorporated into a 1962 prothrombin survey, which was sent to participants with a commitment to return results with a critique on improvement of prothrombin measurements. Educational materials rapidly became an adjunct of most, if not all, other Surveys.

During 1962, the operational details of the Surveys process were defined. In September of that year, the Standards Committee adopted the following description of procedures for the new program:

*Announcing*

**1964**

**NATIONAL COMPREHENSIVE  
LABORATORY SURVEY**

The College of American Pathologists will conduct its second annual National Comprehensive Laboratory Survey this spring with the first official invitation for participation in the 1964 Survey being mailed to the Pathologists after March 1, 1964.

The Survey will be provided in 3 KITS, which may be purchased individually or collectively in a Series of three

**KIT 1 — CHEMICAL**

- Bilirubin
- Chloride (2 samples)
- Total Protein
- Uric Acid (3 samples)
- Amylase
- Alkaline Phosphatase
- Glutamic Oxalacetic Transaminase
- Urea Nitrogen

**KIT 2 — BLOOD BANK, HEMATOLOGY & URINALYSIS**

- Blood Smear Evaluation (3 slides)
- Hemoglobin
- Blood Grouping—Typing—Crossmatch (3 samples)
- Urinalysis

**KIT 3 — BACTERIOLOGY, PARASITOLOGY & SEROLOGY**

- Bacteria Identification (2 samples)
- Parasite Identification
- Serologic Tests for Syphilis
- Anti-Streptolysin Titer
- Febrile Agglutinin Titer

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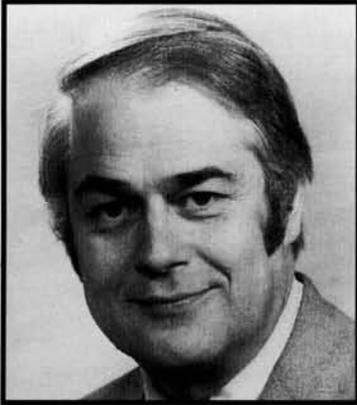
KIT 1 — Chemical.....	\$10.00
KIT 2 — Blood Bank, Hematology & Urinalysis.....	12.00
KIT 3 — Bacteriology, Parasitology & Serology.....	15.00
KITS 1, 2, 3 purchased at the same time in a Series (a savings of \$4.25).....	\$32.75

Fig 5-2. This advertisement for the recently-introduced Comprehensive Surveys appeared in the March 1964 issue of the CAP Bulletin.

- “1. After an adequate publicity program, the unknown sample and a statement of the criteria used by the Committee in evaluating the results will be sent to the hospitals participating in the survey. Participants will be told when the value of the unknown and the results obtained in the survey will be available.
2. A week to ten days after the unknown has been sent, the expected values of the unknown will be mailed to the participants. At this time, a brief annotated bibliography dealing with methodology will also be provided.
3. Three months after the unknown sample is sent the participant will receive the information derived from an analysis of the results of the survey.
4. Approximately one year after the survey, the participants will receive a report on the evaluation of the results of the survey by the Committee on Clinical Pathology Standards along with the comments of an Advisory Committee appointed to review these results.”<sup>3</sup>

The sample materials provided to laboratories in the initial Surveys were either water- or chloroform-based, which were adequate to assess the general state of the art at the time. As the Surveys were reconfigured into a proficiency testing mode, however, samples more closely simulating actual patient materials were needed, and these were provided with the first multi-disciplinary “Comprehensive Surveys” introduced in 1963 (Figs 5-1 and 5-2). Slightly more than 1,200 laboratories participated in this Survey. Analytes included serum bilirubin, cholesterol, sodium, potassium, carbon dioxide, urea, hemoglobin, blood grouping, blood smear evaluation, parasite identification, spinal fluid protein and chloride, and stool culture. The data returned to participants grouped results by method, and included the means of all results with standard deviations. The reference laboratories’ means and ranges of values were also provided, along with each individual laboratory’s results for comparison of performance.

In late 1965, the “Small Hospital Survey” for hospitals with less than 100 beds was approved by the Board of Governors. This included constituents most commonly analyzed in smaller hospitals, making Surveys more economical for these laboratories. The first Small Hospital Survey was conducted as a pilot in June 1966. A newly-designed reporting format listed each analyte with the laboratory’s result, method of analysis, range of acceptable performance based on reference laboratory values, and a notation which indicated whether the participant’s value was acceptable or unacceptable. The results of this pilot study demonstrated very good performance in small hospital laboratories; their publication in the *New England Journal of Medicine* marked the first time that data from Surveys appeared in the indexed medical literature.<sup>4</sup> The “Small Hospital Survey” was renamed the “Basic Survey” in early 1967.



*Fig 5-3. Roger K. Gilbert, MD (1930–1981) was among the scientific “fathers” of CAP Surveys, and played a pivotal role in enhancing cooperation between the Surveys program and the National Bureau of Standards.*

The conversion of Surveys to a regular proficiency testing format created a need for enhanced computer services to analyze data. Belfour and Stulen, a Traverse City, Michigan, computer firm, was chosen in 1966 to provide these services under contract. The firm was selected by Laurence P. Skendzel, MD, a member of the Surveys Committee and a resident of Traverse City, reportedly by the simple expedient of checking the local phone directory. Eventually the steady growth of data processing needs led to the acquisition of the firm in 1971 and the consequent establishment of the Belfour/Stulen Division of the College. (This development is discussed more fully in Chapter 2.)

As Surveys matured into a true extra-laboratory comparison (that is, proficiency testing) program, refinements were added to the operational processes and additional goals were identified. In the mid-1960s, laboratories began to be notified by air mail special delivery when their Survey results varied so widely from the expected values that continued testing without investigating the causes of failure was thought to constitute a threat to patient welfare. Beyond monitoring accuracy of analysis, the goals of the program were broadened to include the identification of national testing trends as influenced by standards, differing methodologies, and/or the impact of different instrumentation.

It soon became apparent that the aggregate data from many participants analyzing the same material could effectively determine the “true” value of the individual analytes in those solutions. Consequently, in 1966, excess materials from Surveys were made available to participants, at cost, as well-documented reference materials—the first Surveys Validated Reference Materials (SVRMs). Cooperation between the College and the National Bureau of Standards (NBS) soon led to further verification of the accuracy of these values. Spurred by Roger K. Gilbert, MD, who was responsible for many of the concepts behind Surveys (Fig 5-3), negotiations between the CAP and the Bureau began in 1974 to have Surveys materials analyzed by definitive methodologies at the NBS. Serum with analyte levels verified by definitive methods at NBS was envisioned as creating the “gold standard” in reference and calibration substances. In 1975, the concept of a CAP-funded Research Fellowship at NBS was approved by the Board of Governors to continue this process. Actual funding followed in 1977, and the first CAP Research Fellow, Michael Welch, PhD, was appointed in mid-1978. (This development is treated in more detail in Chapter 4.)

A number of significant events in the history of Surveys occurred in 1967. The Board instituted the first requirement that CAP-accredited laboratories enroll in Surveys, and at this writing participation in

proficiency testing is still required for each analyte for which a Survey exists. (In 1994, the Board agreed to accept proficiency testing results from other PT providers; the implementation of this policy awaits installation of new computer hardware and software scheduled for early 1997.) Also instituted in 1967 were quarterly mailings of Survey specimens with the same analytes in varying concentrations provided in each mailing. While previously a particular analyte might be included only once during a Survey cycle (that is, one year), quarterly mailings allowed better contemporaneous monitoring of accuracy. For the first time, each subscribing facility received a certificate of Survey participation, and the National Committee on Clinical Laboratory Standards (NCCLS) was born, as described in the preceding chapter.

1969 witnessed the introduction of the Office Laboratory Proficiency Evaluation Program (PEP), a Survey originally proposed as the "Petite Survey" and designed for the physician's office laboratory. PEP was renamed EXCEL® (External Comparative Evaluation of Laboratories) in 1980. Soon endorsed by other physician groups, the program was offered jointly offered by the CAP with the American Society of Internal Medicine (ASIM) and the California Society of Internal Medicine in 1971. Based on the principle that the College would cooperate with any other organization interested in the improvement of laboratory quality, other joint programs shortly emerged. Examples include the Medical Laboratory Evaluation program of the ASIM, called ASIM/MLE, from 1986-1995; the American Academy of Family Practice beginning in 1989; the American Academy of Pediatrics in 1992; and the American Osteopathic Association in 1993. Other joint proficiency testing programs are listed in Table 5-1.

<b>Joint Proficiency Testing Programs Offered by CAP and Other Organizations</b>		
1970	Blood Banking	American Association of Blood Banks
1972	Hepatitis B Surface Antigen	American Association of Blood Banks
1986	Blood Lead	American Association for Clinical Chemistry
1989	Parentage Testing	American Association of Blood Banks
1991	Lyme Disease	Wisconsin State Health Department
1991	Alpha Fetoprotein	Foundation for Blood Research
1993	Genetic Testing	American Society of Human Genetics American Board of Medical Genetics
1994	Histocompatibility	American Society for Histocompatibility and Immunogenetics

*Table 5-1.*

Widespread recognition of the contribution of Surveys to quality laboratory performance was evidenced by the participation of more than 5,000 subscribers in 1969. Analytes were steadily added to the Surveys, with Enzymology and Instrumentation Surveys introduced in 1969, followed by Toxicology and Virology Surveys in 1971. Delineation of the hormone dependence of breast carcinoma led to hormone receptor assay Surveys in the early 1980s; similarly, the advent of DNA testing led to the development of the Forensic Identity and Parentage Testing Survey in 1992.

In the early days of nuclear imaging, an estimated 25 percent of physicians active in the discipline were pathologists. Several College members were national leaders in this specialty, among them Tyra T. Hutchens, MD (president of the CAP 1977-1979), who was one of the founders of the Society of Nuclear Medicine. Others such as Nilo Herrera, MD and Frank DeLand, MD, spearheaded efforts to extend proficiency testing

into this emerging field of diagnostic medicine. In 1975, the first Nuclear Medicine Survey was introduced, evaluating both the technical production of organ images and their interpretation by the physician. The first Surveys used “phantom” organs such as the thyroid, liver, brain, and lung. The images and interpretations were returned to the Nuclear Medicine Resource Committee for evaluation and critique. Eventually mechanical devices simulating dynamic heart actions were developed for such studies as the calculation of ejection fractions. The resource committee responsible for this Survey included liaison members from the Society for Nuclear Medicine (SNM) and the American College of Nuclear Physicians (ACNP). As the number of pathologists active in this field declined, accreditation and Survey functions in nuclear imaging gradually shifted to the ACNP, which assumed full responsibility for the programs in 1994.

**Grading** The evaluation or “grading” of Survey performance has undergone steady change and refinement. Results of the earliest quantitative Surveys were reported to participants simply with the individual laboratory’s values and target values as determined by several reference laboratories. The next evolutionary step was the calculation of participant means with standard deviations, to determine acceptable ranges of laboratory performance. Method comparisons and peer group evaluations were initiated in 1970.

As methodologies improved, the standard deviations of many analyses became so narrow that their precision exceeded clinical usefulness. Resource committees began to define the limits of clinical relevance and move to fixed criteria to judge acceptable proficiency, for example  $\pm 10$  percent of the actual value. Correlation with definitive methods at the NBS (now renamed the National Institute for Standards and Testing [NIST]) was also included; but as methods changed, definitive methods tended not to correlate as well as previously. Matrix effects in proficiency testing materials can affect analysis, and on-going studies have attempted to define these effects in order to avoid penalizing laboratories for factors beyond their control. Although other proficiency testing providers and government agencies have not always agreed with the College’s grading methods, the CAP evaluation system has always been based on well-documented science and statistics, and on the principles of medical utility and a national accuracy base.

**International Activities** From its inception, interest in the Surveys Programs as a means of improving laboratory accuracy has extended beyond the confines of the United States. In 1961, 30 laboratories in Australia and others in Canada participated in Surveys, and requests for enrollment were received from laboratories in Peru, Colombia, and the Sudan. In 1963, CAP materials were provided for an international glucose evaluation by the International Academy of Pathology.

Further extension of international Surveys participation was identified as a CAP goal in the early 1970s. However, it was soon recognized that Surveys configurations appropriate for the United States might not meet the needs of foreign laboratories. Thus, a procedure was developed for shipping materials in bulk to a foreign pathology society, along with the data generated in the United States. The foreign society would ship samples to their laboratories and analyze participant data. Societies in several countries still participate in this manner.

Scientific programs based on Survey data have been presented at a number of foreign meetings, including those of the World Association of Societies of Pathology (Anatomic & Clinical) (WASP) beginning in Munich, Germany in 1972.

**Resource Committees** The data and information generated from Surveys have become the stimulus for changes in the structure of the College and for the development of other related “Programs of Excellence.” One of the first changes was in the size and operation of the Standards Committee itself. Several sub-committees were formed to oversee specific activities and provide the scientific expertise for programs under the

purview of the Standards Committee. The concept of such sub-committees in fact dates back as far as February 1948, when the Laboratory Standards Committee report in the *Secretary's Newsletter* carried a listing of 13 projected "central committees...to represent all subdivisions of medical laboratory practice." Included in this list were chemistry, hematology, transfusion practice, and several other areas still represented among the resource committees of 1996.

A listing of the Standards Committee members and the ad hoc sub-committees and chairs for 1964 will illustrate the diversity of this committee's activities. Readers will recognize the names of dedicated pathologists who played significant roles in plotting the course of the College, many of whom are still active in practice and in College activities.

The composition of the Standards Committee included Rudolph J. Muelling, Jr, MD, chair; Bradley E. Copeland, MD, vice chair; Laurence P. Skendzel, MD, secretary; with Roy N. Barnett, MD; Gerald S. Dean, MD; Daniel J. Hanson, MD; and Arthur E. Rappoport, MD, as members. The various sub-committees and their chairs were:

Administration of Laboratory—*Douglas W. Heustis, MD*  
Bilirubin Certification—*Russell J. Eilers, MD*  
Certification of Coagulation Reagents—*John B. Miale, MD*  
Hemoglobin Certification—*Bradley E. Copeland, MD*  
Contracts—*Daniel J. Hanson, MD*  
Grants—*S. Brandt Rose, MD*  
International Survey—*Donald W. Penner, MD*  
Microbiology—*S. Brandt Rose, MD*  
Product Evaluation—*Roy N. Barnett, MD*  
Serological Certification—*Victor N. Tompkins, MD*

Later in the 1960s the various sub-committees became free-standing and were designated as "resource committees" for the various clinical laboratory disciplines. They not only provided scientific expertise for the Surveys Programs, but were responsible in many instances for operational details as well. These latter responsibilities ceased in 1973 when an independent Surveys Committee was charged with the "business" details of the program. The 13 present resource committees are now grouped under the Commission on Clinical Pathology, reporting through the Council on Scientific Affairs to the Board of Governors. The duties of other 1964 sub-committees listed above have also been transferred to other committees in the College; in some cases the programs for which they were responsible, such as Product Evaluation, have been abandoned.

As an adjunct to Surveys, the Standards Committee in 1968 announced the introduction of a national longitudinal pool for chemistry procedures, to allow a laboratory to compare its results on the same pool of serum during a period of three to five years. Computer programs were developed to receive data from users to provide analyte trend data to the individual subscribers. This program was designated the Quality Assurance Service (QAS). At the time of its establishment, at least two regional pools had been in operation for several years, and utilized CAP computer services to process data. The QAS program, which is scheduled to be discontinued in 1997, is discussed in more detail in Chapter 7.

***Surveys and Regulations*** As the benefits of external proficiency testing became apparent, several state regulatory agencies incorporated proficiency testing into their procedures for monitoring the performance of laboratories. The first recorded request for proficiency testing data for this purpose was made by the

Michigan State Health Department in 1963. Later that year, though concerned about the problems of state-by-state analysis of Survey results, the CAP Board of Governors agreed to furnish data to state health departments, provided that they would pay any extra costs involved, and that directors of laboratories agreed to the release of their data to the state agency. In 1966, the Board authorized the provision of CAP Survey material to state health agencies for use in their regulatory activities, with the proviso that CAP identity of materials be maintained whenever they were used. In late 1967 Illinois, Oregon, and Washington purchased the Basic Survey for use in their state proficiency testing programs; by December of that year, 22 states had indicated similar interest.

During the debate over Medicare in the mid-1960s, public controversy erupted over the accuracy of laboratory determinations. Allegations were made by the Federal Communicable Disease Center (later the Centers for Disease Control) and by New York State Health Department officials, among others, that 25 percent of laboratory tests in the United States were inaccurate. These charges were refuted by data from the 1966 CAP Surveys showing that 95 percent of testing was medically useful. In response to statements by Morris Schaeffer, MD, of the New York Department of Health, Bradley E. Copeland, MD, wrote that “for almost two years a smoke screen of untrue statements, exaggerated charges, incorrect statistics, misleading reports, and incredible claims plus a repetition of all these—has settled over these truths [of medical usefulness] hiding them and almost choking them.”<sup>5</sup> While the CAP data was persuasive, the passage of the Partnership for Health Amendments of 1967, which became known as the Clinical Laboratories Improvement Act of 1967 (CLIA-67), marked the entry of the federal government into laboratory regulation, focusing heavily on proficiency testing.

In 1968, the Department of Health, Education, and Welfare (HEW) declared that the Basic, or Small Hospital, Survey met the specifications for proficiency testing for interstate laboratories under its jurisdiction. Changes were made in other Surveys to meet CLIA-67 requirements, such as increasing the number of challenges for each analyte to three in each mailing. Eventually all CAP Surveys were recognized in the final CLIA-67 regulations as meeting the proficiency testing requirements for laboratories engaged in interstate commerce. Surveys were also accepted by the Health Care Financing Administration (HCFA), and by various state regulatory agencies.

The College has always maintained that proficiency testing is only one parameter in ensuring quality laboratory analyses, along with daily quality control, properly trained personnel, procedure manuals, and voluntary inspection and accreditation. The passage of the Clinical Laboratories Improvement Amendments of 1988 (CLIA-88) once again focused attention on the role of proficiency testing in laboratory regulation. The College made vigorous efforts to keep proficiency testing in proper perspective, but ultimately the CLIA-88 regulations incorporated PT criteria that required major changes in CAP Surveys. The number of testing events was reduced from four to three per year, but the number of challenges in each event increased from three to five. The count of five challenges per testing event allowed the imposition of a percentage grading system and an arbitrary 80 percent pass-fail criterion for most analytes to facilitate federal monitoring of laboratory performance.

*Surveys Operations* The operation of the Surveys Program entails numerous administrative functions distinct from the scientific involvement of the resource committees. Contracting for materials, pricing of Surveys to participants, and marketing are all issues with which the College has had to deal, and the processes for these activities frequently developed through trial and error. The lack of a good business plan prompted one Board member to comment in 1970 that while Surveys had become a \$1,250,000 a year operation, it was run “like the back room of a shoe store.”<sup>6</sup>

Fair and equitable pricing of Surveys is critical to the success of the program. In the 1960s, inexperience, inadequate cost accounting data, and cost increases from material suppliers after prices had been set frequently resulted in financial losses to the College. Of historical note, the price of the 1963 Comprehensive Survey was \$40, or \$20 for either of two kits ordered separately; its 1964 counterpart was priced at \$32.75, a savings of \$4.25 over the cost if components were ordered individually. Cost accounting became better defined when William E. Williamson Sr., now retired as vice president for Laboratory Improvement, joined the CAP staff and assumed responsibility for Surveys in May of 1978.

Marketing of Surveys has been carried out almost entirely through direct announcements to members of the College or to directors of laboratories, with orders coming to the CAP. In the late 1960s, however, they could also be ordered from the supplier of most of the testing materials, which was given permission to market the product in sparsely populated areas with few pathologists. Promotional materials were prepared almost entirely by Surveys staff, until the establishment of a Marketing Department at CAP headquarters in the late 1980s.

Reagent manufacturers have supplied the majority of Surveys testing materials under contract with the College, although some of the more esoteric Surveys have been supplied by members or the institutions with which they were associated. An exclusive long-term contract for most chemical materials, signed with one vendor in the late 1960s, continued until 1987, although several other vendors began supplying materials as new Surveys were developed. The College's inability to control escalating costs under these contracts prompted the Board of Governors in 1985 to appoint a Survey Contract Development Committee to evaluate multiple vendors and shorter contract terms. Contracts now in place with multiple suppliers, with terms of one to three years, have resulted in significant cost savings to the College and consequently to Surveys subscribers.

Increased operational support by Surveys staff has paralleled the increase in the number of laboratories participating in the program. The 1971 acquisition of the CAP computer facility in Traverse City, Michigan, was predicated on the need for analysis of Survey data. The consolidation of computer services into the Northfield, Illinois, headquarters office in 1989, and the explosive growth of Surveys participants and programmatic changes resulting from CLIA-88, placed heavy burdens on administrative operations. A special Task Force in 1994 recommended major changes in how the program operated, especially with regard to computer support. Replacement of computer hardware and a complete rewrite of the Surveys software was approved by the Board of Governors in 1995, and is continuing at this writing.

<b>Statistical Growth of Surveys Programs 1966, 1976, 1986, and 1996</b>				
<u>Year</u>	<u>Number of Modules</u>	<u>Number of Analytes*</u>	<u>Number of Subscriptions</u>	<u>Number of Subscribing Labs</u>
1966	6	20	(unknown)	2,600*
1976	17	125	22,659	7,810
1986	63	250	58,900	14,000*
1996	135	500	178,224	29,823

\*approximate

Table 5-2.

**Conclusion** The acceptance of Surveys by the laboratory community has been demonstrated by the steady growth of the program. As of September 1996, the Surveys Program encompassed 135 different Survey modules covering approximately 500 analytes, with 178,224 individual subscriptions representing 29,823 laboratories. Corresponding statistics for previous decades are shown in Table 5-2.

The improvement of laboratory performance resulting from these Surveys is well documented in the medical literature in numerous scientific articles, authored by the resource committees and/or their individual members. Following the first publication of the Small Hospital Survey pilot study results in the *New England Journal of Medicine*,<sup>4</sup> many of these articles were published in supplements to the *American Journal of Clinical Pathology*. (These publications are treated in greater detail in Chapter 3.) From 1971 through 1975, a series of year-end Surveys summaries was written by Roger Gilbert, MD. In 1981 *DATA ReCAP* was published as a compendium of results for the preceding decade,<sup>7</sup> documenting marked increases in the precision of analyses. Many CAP Conferences have been generated by issues identified through the Surveys process, leading to published proceedings in the form of separately bound volumes (through 1987), and since 1988 in the *Archives of Pathology & Laboratory Medicine*, which also includes articles based on Survey data in a special section entitled “CAP Laboratory Improvement Programs.”

From the modest goal in 1949 of evaluating 100 to 200 laboratories, Surveys have grown to encompass the largest array and volume of proficiency testing materials in the world. The continued successful “Pursuit of Excellence” by the College of American Pathologists would be impossible without them.

## Notes

1. Sunderman FW. Twenty-five years of proficiency testing for clinical laboratories. *Ann Clin Lab Sci*. 1972;2:420-424.
2. Brown DE. *CAP Bulletin*. 1968;22:277-281.
3. Skendzel LP. Report of the secretary of the Standards Committee. *CAP Bulletin*. 1963;17:20-21.
4. Skendzel LP, Muelling RJ Jr. Report on small hospital laboratories. 1966 survey of the College of American Pathologists. *N Engl J Med*. 1967;277:180-185.
5. *CAP Bulletin*. 1968;22:39.
6. CAP Board of Governors Minutes, 1970 Apr 28:2.
7. Elevitch FR, Noce PS, eds. *DATA ReCAP, 1970-1980: A compilation of data from the College of American Pathologists' clinical laboratory improvement programs*. Skokie, Ill.: College of American Pathologists, 1981.

## Chapter Six

# Laboratory Accreditation

William B. Hamlin, MD  
John K. Duckworth, MD

*The Origins, 1946–1962* It is apparent from surviving CAP historical documents that the initial idea of a laboratory accreditation program dates back to the very origins of the College. The first CAP bylaws, adopted in December 1946, empowered the Board of Governors to “establish standards for the adequacy of hospital laboratories and issue certificates therefor.” Among the original CAP committees formed by the Board of Governors in January 1947 was a Committee on Evaluation of Hospital Laboratories whose charge was to define a variety of parameters, such as personnel, space, and equipment, that were essential for quality laboratory services. A number of America’s most prominent pathologists were involved in the conceptual planning of this undertaking, among them William P. Belk, MD; F. William Sunderman, MD; Israel Davidsohn, MD; Arthur H. Sanford, MD; and Edward A. Gall, MD. During this early phase, discussions relating to the creation of a standards or surveys (proficiency testing) program were intermixed with discussions of an accreditation program. The primary goal at the outset was to develop a program to evaluate the “efficiency” of laboratories—i.e., their ability to accurately measure analytes on unknown external samples. There had not been any previous attempt to evaluate laboratory performance on a national scale.

By late 1947, planning was underway for “a test run of chemical unknowns,” and the Committee on Evaluation of Hospital Laboratories engaged the services of an experienced biometrician with special expertise in laboratory investigations. By early 1948, the College had become keenly interested in exploring laboratory methods in a critical manner, and sought assistance from the National Bureau of Standards toward that end. There were also discussions concerning the wisdom of developing a CAP “approved official methods” booklet; and contact was made with the World Health Organization (WHO) in an effort to assist that organization’s efforts toward worldwide evaluation and standardization of laboratory services. The Committee on Laboratory Evaluation concluded that programs of laboratory standards (surveys or proficiency testing) and overall laboratory evaluation (accreditation) could serve as a bimodal method for elevating the practice of laboratory medicine. Late in 1948, preparation of an outline of basic requirements for a laboratory in a modern hospital was almost complete; and the Laboratory Standards Committee had recommended establishing a “bureau of standards” within the CAP structure. In January 1949, the initial draft of “The Basic Requirements of a Department of Clinical Pathology in a Modern Hospital” was submitted by the Committee on Laboratory Standards to the CAP Board of Governors, who referred the material to three different committees for evaluation and comment! A questionnaire, which was designed to survey hospital laboratories throughout the country, dealt primarily with space and staff requirements.

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By mid-1949, the various involved committees were emphasizing the importance of improving the “efficiency” of laboratory procedures, and were attempting to outline the technical, personnel, physical, and other factors which influenced a laboratory’s efficiency. Later in 1949, renewed emphasis was placed on the earlier idea of creating a CAP “bureau of standards,” and in October of that year, a report on evaluating laboratories and surveying the adequacy of laboratory facilities was submitted to the Board of Governors. In October 1950, the Board, following lengthy discussion, adopted the draft report entitled “Basic Requirements of a Department of Clinical Pathology in a Modern Hospital,” presented the previous year by the Committee on Laboratory Standards. This document included detailed specifications concerning space, location, facilities, and equipment for hospital laboratories, and delineated the duties of a laboratory director, including responsibilities in teaching, research, and staff governance. Additionally, it suggested duties and qualifications for other laboratory personnel, deplored the practice of decentralizing laboratory work by installing small “splinter” laboratories throughout a hospital, stressed the need for promptness in reporting results, and indicated a need for procedure and ward manuals. The Board delegated to the Executive Committee the task of determining how and how widely to disseminate the report; it was finally published as a pamphlet in 1951. By 1952, the Board of Governors had agreed that a manual outlining the basic requirements for a private clinical pathology laboratory should be developed as an adjunct to the one just developed for hospital laboratories.

In 1952, a CAP liaison committee was established to meet with representatives of the Joint Commission on Accreditation of Hospitals (JCAH—in 1979, this liaison committee was renamed the CAP/JCAH Working Group). In February 1955, the CAP Committee on Laboratory Evaluation was abolished by the Board of Governors, who had concluded that such activity was outside the purview of the College. Only two years later, however, the Board of Governors reviewed the subject of evaluating pathology services, and there was considerable discussion about whether the College should be involved in such activity, and if so, whether the focus should be on evaluating individual pathologists’ competency or on assessing the laboratory as a whole.

During the latter 1950s, there appears to have been little officially documented CAP activity relating to laboratory accreditation. However, it is unlikely that discussions ceased during that period, in light of the many thoughtful, influential American pathologists who had given serious thought to a voluntary national laboratory accreditation program over the preceding ten years. Indeed, a December 1959 letter by future CAP President William J. Reals, MD, suggests “that a national group, probably a pathology group, should undertake in the very near future a program of laboratory accreditation.”<sup>1</sup> Less than a year later, on November 12, 1960, the CAP Assembly (now the House of Delegates) passed a resolution to the Board of Governors, authored by Dr. Reals and another College President-to-be, James D. Barger, MD, requesting that “the CAP initiate a study of the feasibility of a nation-wide, voluntary program for laboratory accreditation.” This resolution was apparently referred by the Board to the Plans and Scope Committee then chaired by John R. Schenken, MD. That Committee’s report to the Board of Governors in May 1961 indicated that “a critical study should be made as to the feasibility of a voluntary inspection and accreditation program to avoid compulsory statutes and regulations which are sooner or later bound to result.” This appears to be a remarkable case of clairvoyance, in view of the subsequent enactment of Medicare (1965), the Clinical Laboratories Improvement Act of 1967 (CLIA-67), and the Clinical Laboratories Improvement Amendments of 1988 (CLIA-88), all of which had a major effect on laboratory practices. Fortunately, the groundwork laid by those pioneering pathologists blunted the impact of these laws upon CAP-accredited laboratories.

To follow up the recommendation of the Plans and Scope Committee, an Ad Hoc Committee on Laboratory Accreditation was appointed by the Board and charged to develop a plan for the accreditation of

laboratories. The members of this committee, chaired by Francis C. [Frank] Coleman, MD, were Hollis N. Allen, MD; Victor B. Buhler, MD; Donald H. Kaump, MD; and Ernest E. Simard, MD. The Ad Hoc Committee report proposed the establishment of a Laboratory Accreditation Program encompassing several specific features:

- Laboratories would be accredited for a period of three years.
- Participation would be open on a voluntary basis to all hospital and private office laboratories.
- The supervision and direction of the program would be entrusted to a Commission on Laboratory Inspection and Accreditation.
- The Commission would be appointed by the president with approval of the Board of Governors.
- The Commission would be answerable directly to the Board of Governors.
- The Commission would consist of a chair and 10 members, one from each of 10 designated geographic regions in the United States.
- The Commission would be charged with responsibility for developing standards for accreditation to be submitted to the Board of Governors for consideration and approval.
- The standards would define parameters relating to physical plant, laboratory organization, equipment, technical personnel, quality control, and record-keeping.
- An annual fee (the amount initially was not specified) would be assessed for participation in the accreditation program.
- There would be no "grandfathering."<sup>2</sup>

There was considerable debate as to whether or not a carefully selected group of laboratories would be accredited under a "grandfather" clause, i.e. without application and inspection. Initially this idea was thought to be acceptable, but eventually it was decided that no laboratories would be accredited through "grandfathering."

### **COLLEGE ACCREDITATION PROGRAM**

The College is instituting an accreditation program for clinical laboratories. This program will be voluntary in that each laboratory desiring accreditation must ask for it. A survey of the facilities, equipment, personnel and performance of the laboratory will be made following a request for accreditation to determine whether the laboratory meets the standards which must be met for accreditation. Laboratories in hospitals and pathologists' private laboratories will be eligible to participate in the program.

Fig 6-1. This introductory advertisement for the accreditation program appeared in the November 1961 issue of the CAP Bulletin.

The first recorded publicity for the Laboratory Accreditation Program was contained in the *Pathology Daily News* of October 3, 1961, during the CAP's annual meeting in Seattle. A dignified advertisement for the Program also appeared in the November 1961 issue of the *CAP Bulletin* (Fig 6-1). In February 1962, the Board of Governors approved the Ad Hoc Committee report with the understanding that the Accreditation Program would be implemented as rapidly as possible. Standards and questionnaires designed to capture essential data for laboratories applying for accreditation were then developed.

The College's initial contacts with the Joint Commission on Accreditation of Hospitals (JCAH) seemed to indicate that the Commission would be willing to recognize CAP Laboratory Accreditation in the context of the JCAH institutional accreditation program. Shortly thereafter, however, a joint liaison committee of the CAP and the Catholic Hospital Association (CHA) encountered major objections to JCAH recognition of the CAP program, based on the multiplicity of inspection and accreditation programs to which hospitals were being subjected. The same sentiments were expressed by representatives of the American Hospital Association (AHA), and the AHA publication, *Hospitals*, criticized the College program because it was not tied into the JCAH accreditation program. By 1965, the JCAH's enthusiasm for the CAP program had clearly waned, and its expressed willingness to recognize CAP accreditation was a thing of the past.



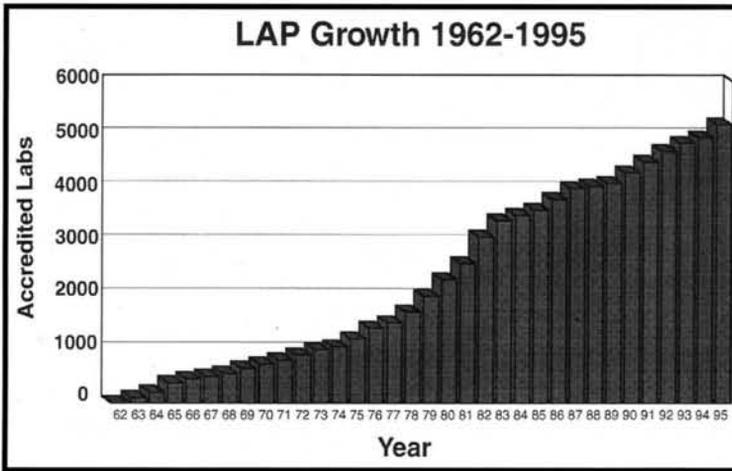
**Fig 6-2.** Hollis N. Allen, MD (1900-1988), chaired the new Commission on Laboratory Inspection and Accreditation when it was established in 1962.

*The Launch and Early Years, 1962–1969* The report of the Ad Hoc Committee on Laboratory Accreditation recommended that the Inspection and Accreditation (I&A) Program operate under the direction of a Commission consisting of a chair and 10 regional commissioners. The commissioners were to be appointed by the president, with the approval of the Board of Governors, and the Commission was to report directly to the Board. Dr. Hollis N. Allen was appointed as the first chair of the new Commission on Laboratory Inspection and Accreditation (Fig 6-2).

The Commission's initial task was the development of standards for accreditation which covered a laboratory's physical plant, organization, efficiency of service, space, equipment, personnel, quality control, and record-keeping. The initial accreditation fee was set at \$100; accreditation was to be valid for a period not to exceed three years.

The first group of laboratories to undergo inspection and accreditation were those of the 10 newly appointed regional commissioners. Once these laboratories were inspected and accredited, the commissioners were empowered to select other volunteer pathologists to serve as inspectors. By the fall of 1963, 222 laboratories had submitted applications for inspection and accreditation, and 55 of these had been inspected and approved for accreditation (Fig 6-3). The first accreditation certificate was issued in January 1964 to the Medical Laboratory Associates of Birmingham, Alabama, directed by Joseph A. Cunningham, MD, the program's first Gulf Region commissioner.

The CAP leadership was able to organize and implement the Laboratory Accreditation Program single-handedly through its own resources, despite opposition from various other medical organizations and institutions such as JCAH. In an effort to assure a more uniform application of the standards, one of the regional commissioners, Dr. Dennis B. Dorsey, developed the first checklist to be used by inspectors; the first edition of this checklist was published in 1965 (Fig 6-4). In 1966, the standards were revised so as to be more specific and to include explanatory notes. In this revision, much greater emphasis was placed on participation in interlaboratory surveys (proficiency testing) and internal quality control systems.



**Fig 6-3 (left).** Growth in numbers of LAP-accredited laboratories, 1962–1995. **Fig 6-4 (right).** Dennis B. Dorsey, MD (b. 1912) designed the first inspection checklist; as chair of the Commission on Laboratory Inspection and Accreditation in 1967 and 1968, he also played a critical role in maintaining liaison with other organizations and agencies having an interest in laboratory standards. Dr. Dorsey served as CAP president from 1975 through 1977.

Early in 1965, Dr. Allen resigned as the Commission chair because of illness. The CAP President, Dr. Ernest E. Simard, then appointed Arthur E. Rappoport, MD as chair of the Commission on Laboratory Inspection and Accreditation “until a suitable replacement could be found.” This temporary assignment lasted for two and a half years.

With the enactment of federal Medicare legislation in 1965, the interest of government agencies in standards of care intensified, particularly with respect to clinical laboratory performance. In addition to detailed provisions governing reimbursement of services by hospital-based physicians, including pathologists, Medicare regulations also included specific requirements for participation in the plan by independent laboratories.<sup>3</sup> In spring 1967, the JCAH announced that it intended to revise its laboratory standards, as part of a general updating of its regulations, and notified all clinical laboratory-related societies that it would be willing to consider outside suggestions. In response to this initiative, CAP representatives presented the College’s newly published detailed Inspection and Accreditation Standards and Check List. Subsequently Dr. Dorsey, who later became chair of the Commission on Laboratory Inspection and Accreditation, served as a JCAH consultant on laboratory standards. This collaboration resulted in the issuance of identical published standards for laboratories by both JCAH and CAP.<sup>4</sup>

In summer 1967, the federal Communicable Disease Center (CDC) invited a diverse group of laboratorians to meet in Atlanta with the mission “to devise an acceptable laboratory evaluation program and plan for its implementation.” It was implied that this document was to replace the Medicare regulations for independent laboratories; but in fact it was intended to be the basis for implementing CLIA-67, subsequently passed in December of that year, inaugurating federal regulation of clinical laboratories operating in interstate commerce—i.e., receiving specimens for analysis across state lines.

The legislation recognized the CAP Inspection and Accreditation Program, provided that its standards were “equivalent to, or more stringent than” the regulatory requirements developed by CDC to implement the federal statute. Under the Act, a laboratory accredited by the CAP could apply for a Letter of Exemption from the CDC in lieu of federal licensure. When CDC implemented CLIA-67 in July 1969, the CAP

Inspection and Accreditation Program was presented to the CDC-sponsored Medical Laboratory Services Advisory Committee, and was determined to be indeed equivalent to or more stringent than the federal regulatory requirements. In 1968, successful participation in CAP Comprehensive Surveys (proficiency testing) became a requirement for CAP accreditation; this requirement provided an integrated laboratory surveillance system comparable to that mandated in CLIA-67.

In late 1967, Dr. Dorsey was appointed as the chair of the Commission. While serving in that capacity, he also was a member of the Medical Laboratory Services Advisory Committee at CDC, and a consultant to JCAH. As such, he was instrumental in maintaining a close liaison with those programs so that similar standards and regulations were developed by all of the accrediting entities. Dr. Dorsey, working with officials of the JCAH, developed versions of the standards and checklist which were acceptable to both organizations and were proposed for implementation as of January 1, 1969. Soon after, the Commission agreed to accept applications from laboratories having PhD directors who satisfied the federal requirements for a laboratory director.



**Fig 6-5.** Maj. Gen. Joe M. Blumberg, MC, USA Ret. (1909–1984) chaired the Commission for a decade, from 1969 through 1978, and presided over a period of explosive growth and increasing sophistication in the administration of the Inspection and Accreditation Program.

Late in 1969, a decision was made to conduct educational workshops for potential laboratory inspectors at the regional level. The Commission was recruiting and instructing additional deputy commissioners and inspectors to assist with an ever-increasing workload; in order to maximize the efficiency of data handling within the program, it also began to use the services of Belfour and Stulen, Inc., the Traverse City, Michigan computer services firm that had begun processing CAP Surveys data in 1966, and which would subsequently become the CAP Computer Center. By 1969, the CAP accreditation program had become international; the records indicate that the first overseas laboratory to be inspected and accredited was in Bombay, India. Also in 1969, on July 1, final implementation of CLIA-67 had occurred. From that time on, all laboratories engaged in interstate commerce had to be either inspected and licensed by the US Department of Health, Education, and Welfare (HEW), or exempted via accreditation by the CAP Inspection and Accreditation Program—the only program at the time that satisfied the requirements of CLIA-67.

*The Expansion Years, 1969–1987* Following the appointment of Major General Joe M. Blumberg, MC, USA Retired, as the chair of the Commission on Laboratory Inspection and Accreditation in 1969 (Fig 6-5), a decade of progress and improvement ensued under his leadership. The number of accredited laboratories tripled. Through Blumberg's personal contacts and persuasion, he convinced many influential and important pathologists to have their laboratories accredited and to participate fully in the program by serving as inspectors and/or regional commissioners. He also conceived the idea of having state commissioners assist regional commissioners, and urged that many of the tasks involved in the management of the program be delegated to these new state commissioners.

With the rapid growth of the program, General Blumberg recognized the need for educational programs to teach pathologists how to inspect laboratories and determine whether they met the standards for accreditation. Various forms of seminars and workshops were initiated to achieve this. The first three laboratory improvement seminars were held in Philadelphia (1969), Atlanta, and Kansas City. The CAP reimbursed

pathologist attendees for their expenses in order to encourage them to attend; in return, participants were requested to accept assignment to inspect one or two laboratories. The seminars used a didactic method and were designed to familiarize inspectors, other pathologists, technologists, and laboratory administrators with the program. Workshops were also offered, either in conjunction with seminars or independently; they frequently took the form of having two or three trainees assist with an actual on-site inspection under the supervision of an experienced inspector. A variant of the workshop format was the preceptorship, in which one inexperienced inspector was assigned to accompany an experienced inspector on an inspection; this provided one-on-one training and proved to be especially effective. All of these training techniques continue in use today but with considerably more frequency.

To supplement educational events such as workshops and seminars, a publication program was also undertaken, beginning with the first *Inspector's Manual*, compiled in 1969. This guide for inspectors continues in use and has been regularly revised and updated over the years. In 1972, the *I & A Newsletter* (later the *Laboratory Accreditation News*) was conceived with the purpose of informing accredited laboratories about developments in the program such as new standards, common deficiencies, and the like. Dennis J. Carlson, MD, the Northeast regional commissioner, was its first editor. Israel Diamond, MD, then the Northeast regional commissioner, became editor in 1977. Also in 1972, the Commission's first *Policy Manual* was written, and the first reagent grade water manual was published. The third revision of the checklist was published in 1973, sectionalized by specialty and color-coded for convenient use. The Commission also published the *Instrument Maintenance and Function Verification Manual* in 1973. A pilot computer program, the Instrument Maintenance Program, was initiated in 1974, but later abandoned because of a lack of subscribers.

Under General Blumberg's leadership, liaisons were also continued and/or developed with federal agencies and other professional organizations. These included the US Centers for Disease Control, Health Care Financing Administration, Joint Commission on Accreditation of Hospitals, Indian Health Service, Veterans Administration, the various branches of the armed forces, Association of Pathology Chairmen, and American Association of Blood Banks.

Where special projects or problems warranted attention, General Blumberg would appoint a "Special Commissioner" to address the issue. From 1973 through 1976, Dr. Carlson served in this capacity and was responsible for keeping the checklist up to date and developing an inspection checklist for physician's office laboratories, as well as continuing his previous work on the *I & A Newsletter*. From 1976 through 1978, the late Lester J. Kiefer, MD, served as special commissioner, assuming Dr. Carlson's responsibilities for the maintenance of the checklists, and developing liaisons with the CAP's scientific resource committees with whom he frequently met.

The Survey Surveillance Summary (later the Cumulative Survey Management Report, currently the Proficiency Testing Exception Summary) was developed in the late 1960s as a tool to monitor laboratory surveys (proficiency testing) performance. Initially designed by Dr. Carlson to review performance of interstate laboratories in compliance with equivalency obligations, the Summary rapidly became a valuable tool that was adopted by the Commission in 1983 for use in evaluating all accredited laboratories.

During the 1970s and early 1980s, the CAP Computer Center in Traverse City, Michigan, developed a variety of software support programs designed to facilitate paper flow, speed the handling of each laboratory's application, and preserve and report certain historical information vital to the program. These accomplishments included the complete storage, documentation, and retrieval of the entire checklist and commentary; the Cumulative Survey Management Report; recording and tracking of common and/or

recurrent deficiencies; listings and updates of qualified inspectors; and a history of each laboratory's performance in the program.

Since the inception of the program, the standard accreditation period had been three years following the date of inspection. An exception had been made for laboratories engaged in interstate commerce; these laboratories underwent an annual inspection under the terms of CLIA-67. In 1973, the accreditation period was changed from three to two years for all laboratories, interstate and non-interstate, with provision for an interim year self-evaluation. This modification was motivated by a detailed study performed by the Commission, comparing the performance of laboratories having annual and triennial inspections. The frequency of inspections and duration of the accreditation period had been hotly debated within the Commission since its inception; General Blumberg often commented that if annual inspections became mandatory, the College would be better off if the Program were moved to the planet Saturn, since then inspections would only occur every 500 days instead of every 365 days!

In 1976, the position of interstate commissioner was developed to provide for consistent monitoring of CAP-accredited laboratories engaged in interstate commerce. An additional step was incorporated into the regular accreditation process by having the interstate commissioner review the responses to cited deficiencies for all laboratories using CAP accreditation in lieu of federal licensure under CLIA-67.

As the program continued to grow, the Commission periodically reviewed its overall direction, goals, and philosophy. In 1975, a report entitled "Expansion of the Inspection and Accreditation Program" was prepared, and in 1977, the Commission carefully reviewed possible mechanisms for accommodating a significant increase in applicant laboratories should such an increase occur. Plans for increasing the number of inspectors and enhancing the Commission's administrative support were developed. A four-day meeting conducted in 1978 was devoted entirely to a structured planning process, in which goals and objectives were developed by the Commission and forwarded to the Board of Governors for approval. Since that time, similar planning meetings of shorter duration have been held approximately every two years.

In 1978, under the guidance of Frank M. Townsend, MD, then the South Central regional commissioner, the Commission developed a position paper proposing that continuing medical education (CME) credit be awarded to laboratory inspectors. Application was made to the American Medical Association Committee on Continuing Education, and in late 1979, AMA granted Category 1 credit to inspectors (designated Category A-1 by the CAP).

At the 1978 fall meeting of the CAP House of Delegates, the House adopted a resolution in support of the Inspection and Accreditation Program, urging participation in the program and strongly encouraging delegates to serve as inspectors. The resolution stated "BE IT RESOLVED that the College of American Pathologists strongly urges all members to actively support and participate in the Inspection and Accreditation Program by (1) achieving accreditation of each member's laboratory, and (2) gaining knowledge and experience so as to serve as an effective inspector, and (3) promoting the Inspection and Accreditation Program among future members (residents) and BE IT FURTHER RESOLVED that the College of American Pathologists urge other pathology organizations and each state pathology society to endorse this resolution or pass comparable resolutions."

In anticipation of the pending recognition of CAP accreditation by JCAH, the Commission held a planning session in late 1978 and scheduled a meeting of all the regional, deputy, and state commissioners in Atlanta in January 1979. The meeting program dealt with expanded recruitment and improved training of inspectors, recognition and rewards, recruitment of new laboratories, better administration of the program, and

expediting the inspection process from the perspective of the deputy and state commissioners. This meeting coincided with the retirement of General Blumberg as the chair of the program, and a recognition dinner was held in his and Mrs. Blumberg's honor; all of the then-current commissioners and many supporters and past commissioners attended.

Following General Blumberg's retirement, John K. Duckworth, MD, became chair of the Laboratory Accreditation Program. His tenure featured continuing revision of the standards, characterized by numerous drafts and iterations; a special commissioner was also appointed to keep the checklist up to date, and an inspector evaluation form was created so that each accredited laboratory could critique its inspector and the inspection it had undergone. During 1979, the Joint Commission on Accreditation of Hospitals officially recognized CAP laboratory inspections, and indicated that it would no longer inspect laboratories in JCAH-accredited facilities if those laboratories held CAP accreditation.



**Fig 6-6.** William E. Williamson Sr. (b. 1945) was the staff “guardian angel” for the Laboratory Accreditation Program from 1979 until his retirement from full-time service in 1994.

In May 1979, William E. Williamson Sr. was assigned staff responsibility for the Laboratory Accreditation Program, which remained under his purview until his retirement from full-time service in 1994 (Fig 6-6). During this period, more overseas laboratories were applying for accreditation. Emphasis was also placed upon recruiting university-affiliated laboratories; Frank Townsend, MD, was instrumental in orchestrating this effort, and worked closely with academic pathology chairs to bring university laboratories into the program. This initiative also led to more active involvement and training of pathology residents in the accreditation program.

A Safety Resource Committee, appointed by the Commission in fall 1979, was charged to seek and maintain a liaison with the National Fire Prevention Association, to develop checklist questions with appropriate commentary, and to update the safety manual by Dennis Carlson, MD, first published in 1972. In a later revision, this manual ultimately became an approved NCCLS guideline<sup>5-7</sup> Also during this period, the federal Indian Health Service (IHS) became interested in having all its laboratories accredited, and negotiations for a contractual arrangement between the CAP and IHS were initiated and completed. Increasing numbers of “special function” laboratories, often not under

a parent laboratory's administration, also began applying for accreditation, and special procedures were established to deal with these types of facilities.

In 1979, proficiency testing standards for laboratories enrolled in the inspection and accreditation program were adopted. The Commission also approved a policy for establishing equivalency relationships with state governments that licensed laboratories. A program was developed to track the history of deficiencies for each laboratory, thus allowing the performance of a laboratory to be tracked over time in terms of recurrent deficiencies.

In the educational arena, more and more pathology residents were being trained and serving on inspection teams. Kodachrome slide preparations for workshops and seminars were developed. In 1979, the name of the Inspection and Accreditation Program was changed to the Laboratory Accreditation Program, and the Commission became the Commission on Laboratory Accreditation.

In 1980, a JCAH task force was created to conduct a comparative study of a group of JCAH- and CAP-accredited laboratories to ensure that the two programs were in fact comparable, and the results were reported to both organizations. During this period, several states also announced the acceptance of the CAP accreditation program for purposes of meeting state licensure requirements.

As early as 1981, the Commission was discussing quality control for “ward” testing (now referred to as “point of care” testing) by nurses and other non-laboratory personnel. In 1982, a “small laboratory” checklist was developed by Dr. Townsend, and procedures developed to accommodate these laboratories. Late in 1981, a concerted effort was also undertaken to reorganize the checklists and reduce the number of questions. This effort was completed in 1983 with a more consistent, more easily used checklist format, and a 30 percent decrease in the number of questions.

Late in 1982, the US Department of Justice voiced concern regarding the LAP standard governing qualifications for directors of medical laboratories. Following a meeting between representatives of the Department and the CAP, minor modifications of the relevant language in LAP Standard I were made to clarify that appropriately trained doctoral scientists were qualified to serve as laboratory directors. These modifications satisfied the expressed concerns of the Justice Department.

In 1983, partly in response to a House of Delegates report, the Commission began to place increased emphasis on support for the volunteer regional commissioners, with more regional office support and an effort to centralize as many activities as possible in the CAP headquarters office. By 1985, this effort had led to the establishment of a training program for the regional commissioners’ clerical and administrative assistants. Also about this time, a microcomputer hookup to the regional commissioners’ offices was developed and initiated.

By 1984, discussions were underway regarding the development of voluntary accreditation and proficiency testing programs for forensic urine drug testing (FUDT) laboratories. In 1986, the Commission approved a mechanism for joint inspection by CAP and the American Association of Blood Banks (AABB) of blood banks that desired both CAP and AABB accreditation. By 1987, an appeal mechanism was developed for laboratories that had been denied CAP accreditation. A revised draft of the director standard (Standard I) was developed, and was adopted by the CAP Board and House of Delegates in 1988. This revision effort was intensive and time-consuming, and involved extensive discussion in order to accommodate the multitude of situations that prevailed in the laboratories being accredited by the College at that time. During the late 1980s, major emphasis on the concept of “quality assurance” was incorporated into the accreditation program, and a standard dealing with this concept was incorporated into the revised Standards for Laboratory Accreditation.

By the mid-1980s, the Commission on Laboratory Accreditation had liaisons and active dialogue with a wide variety of organizations such as the AABB, the American Society of Microbiology, the American Society of Clinical Pathologists, the American Association of Clinical Chemists, the National Committee for Clinical Laboratory Standards, the National Fire Prevention Association, the Central Office of the Veterans Administration, and the Joint Commission on Accreditation of Hospitals. This activity was undertaken to obtain scientific information and suggestions from these organizations in order to improve the accreditation process with respect to specialty areas such as microbiology, chemistry, and safety. A genuine and ongoing effort was made to incorporate suggestions and ideas from these groups into the CAP accreditation program.

*Recent History, 1987–1996* John Batjer, MD, was appointed as the chair of the Commission in November 1987. As of January 1988, there were 4,059 accredited laboratories in the program. Because of the burgeoning workload, the program was restructured in 1988 with the reconfiguration of the original 10 geographic regions into 14, thus expanding the Commission with the addition of four new regional

commissioners. Additionally, two new special commissioners were appointed to the Commission for Education and Forensic Urine Drug Testing (FUDT).

A new, separate accreditation program for FUDT laboratories was established in 1989; however, this program remained under the jurisdiction of the Commission on Laboratory Accreditation, with a special commissioner serving as a member of the Commission. Between 1989 and 1993, similar new accreditation programs were also established for athletic drug testing laboratories and reproductive biology (in-vitro fertilization) laboratories; each was managed by an appointed special commissioner with special expertise in the appropriate field. Both these programs, as well as the FUDT program, were initiated with the assistance and cooperation of other professional organizations, especially the American Association of Clinical Chemists and the American Fertility Society.

In October 1988, Congress enacted the Clinical Laboratories Improvement Amendments of 1988 (CLIA-88). This statute required that any clinical laboratory providing test results for the diagnosis and treatment of human disease be licensed by the federal government. The responsibility for developing implementing regulations and enforcing the new law was then assigned to the Secretary of Health and Human Services (HHS), and thence to the Centers for Disease Control and the Health Care Financing Administration (HCFA). The initial proposed regulations were published in the *Federal Register* in May 1990.

The comments received by the government during 1991 in response to the proposed regulations were voluminous. The CAP, with extensive input from the Commission on Laboratory Accreditation, submitted a comprehensive paper listing specific objections to some of the regulations and outlining suggestions for improvement. The "final" regulations published in February 1992 contained some modifications suggested by the CAP and other commenting organizations, but were still very similar to the original proposed version. A planned "final-final" version incorporating additional modifications was to be published at "at a later time." The CLIA-88 regulations were eventually implemented effective September 1, 1992.

In June 1991, the CAP Board of Governors voted to seek "deeming authority" as an "approved accrediting organization" as provided for in the CLIA-88 statute, provided that the accreditation program would not be required to alter its basic principles or implement major revisions in its operations. The regulations for this aspect of the law were published by HCFA in mid-1992. The CAP then submitted its application to be an "approved accrediting organization"; following a comprehensive review of the accreditation program by HCFA and CDC, and numerous meetings with those agencies to negotiate and resolve perceived inconsistencies between the CAP Program and the federal regulations, the accreditation program was recognized as an "approved accrediting organization" in early 1994.

Meanwhile, in 1990, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO, successor to JCAH) had requested that a verbal agreement in effect between the two organizations since 1979, which recognized CAP laboratory accreditation for purposes of JCAHO institutional accreditation, be formalized into a written contract. A series of negotiating meetings ensued, which culminated in a formal contractual agreement in late 1993. As part of this agreement, the Commission agreed that at least 90 percent of all CAP-accredited laboratories would have their biennial on-site inspections within the 30 days prior to each laboratory's specified anniversary date, and that the JCAHO would receive the CAP accreditation report no later than 120 days after the date of the inspection. An additional provision of the agreement was that the JCAHO would monitor the CAP Laboratory Accreditation Program by having a JCAHO surveyor accompany the CAP inspection team for a certain percentage of laboratory inspections to be selected by JCAHO.

In 1993, William B. Hamlin, MD was appointed as the chair of the Commission on Laboratory Accreditation. A task force appointed by the Board of Governors in 1992 had recently reviewed the entire accreditation structure and process, and submitted its report to the Board in February 1993. This report recommended that the LAP continue to seek, and once granted, to maintain deeming authority under CLIA-88; strengthen and improve inspector training; require accredited laboratories to provide inspection teams in order to continue to be accredited; streamline and improve the inspection process; and reorganize operations to decrease nonessential volunteer activities by delegating them to staff wherever possible. These recommendations were adopted by the Board, and the Commission on Laboratory Accreditation was charged to report progress on a regular basis to the Council on Scientific Affairs.

In addition to this Board of Governors action, new pressures on the Program were expected because of JCAHO contractual obligations and because of increased responsibilities stemming from CLIA-88 deemed status, including more aggressive PT monitoring, expanded complaint investigation requirements, and a major increase in reporting requirements. All of these factors resulted in a major effort to increase the efficiency and effectiveness of the accreditation program. In late 1993, it became apparent that the dramatically expanded role and responsibilities of the program, as well as its close alliance with the CAP Surveys Program, could not be supported without a major improvement in support from the Information Services (data processing) Division of the CAP headquarters office. A comprehensive study was therefore undertaken to define the system requirements for the development of this increased support, an activity which continues at this writing.

As of January 1996, the Laboratory Accreditation Program was accrediting more than 5,000 laboratories worldwide (Fig 6-3). The Commission on Laboratory Accreditation consisted of a chair, vice chair, 15 regional commissioners, and seven special commissioners. More than 70 pathologists serve as deputy, state and division commissioners. There are more than 3,500 pathologists who volunteer as inspectors, and thousands more laboratorians who serve on inspection teams. All of these individuals serve without pay on a volunteer basis.

The current challenges facing the Commission are difficult, but in principle no more formidable than those of 30 years ago. Current vexing questions include these: How can the program manage to inspect the myriad of very small clinic, physician office, and other laboratories that are now being drawn into amalgamated institutions and vast managed-care organizations? These large organizations desire one entity to accredit all their facilities and do not wish to deal with multiple accrediting agencies. How can the program deal with the immense pressures to comparatively “grade” laboratories by assigning subspecialties a percentage or other “score?” How can the program accommodate laboratories who wish to subscribe to other than CAP Surveys for purposes of accreditation? The latter issue involves highly complex considerations relative to monitoring PT performance and ensuring that all accredited laboratories are enrolled in “equivalent” PT programs.

Despite this current atmosphere of uncertainty, there is not the least doubt that the ideas conceived in 1946, developed through the 1950s, implemented in the early 1960s, and pursued through the 1970s, 1980s, and 1990s have had a definite impact in improving laboratory performance and patient care. There is no other program in the world like the CAP Laboratory Accreditation Program, and its history of success will pose a formidable ongoing challenge to future CAP leaders in their continuing pursuit of excellence.

## Notes

1. Reals WJ. Letter to John R. Schenken, 1959 Dec 10. CAP Archives.
2. Coleman FC. Early history of CAP's Inspection and Accreditation Program. *CAP Bulletin*. 1975;29:85-89.
3. Coleman FC. The coming of Medicare—a turbulent time for pathology. Part II. *Pathologist*. 1981;35:272-276.
4. Dorsey DB. Evolving concepts of quality in laboratory practice: a historical overview of quality assurance in clinical laboratories. *Arch Pathol Lab Med*. 1989;113:1329-1334.
5. Hawk WA, Hoeltge GA, Sodeman TM. *Guidelines for Laboratory Safety in the Clinical Laboratory*. Skokie, Ill: College of American Pathologists; 1984.
6. Hoeltge GA, Alpert L, Arvin D, et al. *Manual for Laboratory Safety*. Skokie, Ill: College of American Pathologists; 1989.
7. National Committee for Clinical Laboratory Standards [NCCLS]. *Clinical Laboratory Safety: Approved Guideline*. Villanova, Pa: NCCLS; 1995 (NCCLS Document GP17-A).

## Chapter Seven

# Quality Assurance Service

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**D**evelopment of QAS Committee The Quality Assurance Service (QAS) was created in 1970 by the College of American Pathologists in response to a need for professional guidance and management of internal quality control practices in clinical laboratories.<sup>1</sup> The 1960s had witnessed rapid and significant expansion in the awareness and application of these practices; and the development by industry of large pools of lyophilized stable homogeneous control materials provided a vehicle for continuous inter- and intra-laboratory monitoring of daily quality control performance. Through regional quality control, QAS was able to provide interlaboratory data allowing laboratories to assess their performance for both bias and precision. QAS thus offered a tool for daily monitoring of performance in terms of both random and fixed error, as well as benchmarks of performance for quality assurance and improvement.

The formal entry of CAP into the area of internal quality control was a logical extension of its role in external quality control under the Surveys Program. The QAS program was organized primarily by Russell Eilers, MD; Tyra T. Hutchens, MD; Pierre Keitges, MD; and Laurence Skendzel, MD.<sup>1,2</sup> Initially, the program operated under the College's Standards Committee, chaired by Dr. Eilers with Roy N. Barnett, MD, as vice-chair. A subcommittee of the Standards Committee was formed to manage the QAS program, and subsequently became a freestanding committee under the Council on Quality Assurance. With the establishment of QAS, it was hoped that data on daily quality control would be correlated with Surveys results, CAP laboratory inspections data, and workload information "to define in a much better way a number of parameters of clinical laboratory proficiency and efficiency."<sup>3</sup>

*QAS offers a tool  
for daily monitoring  
of performance in terms  
of both random and fixed error,  
as well as benchmarks  
of performance for  
quality assurance  
and improvement.*



The impetus for extending coordinated internal quality control to large groups of clinical laboratories had occurred at the state and regional level, predominantly through state pathology societies. In the late 1960s, regional quality control programs were formed, initially in Colorado by Joseph Preston, MD, and subsequently in New York and New England.<sup>4</sup> These programs served to aggregate participating laboratories into co-operating groups; to arrange with manufacturers to provide large pools of shared control materials; and to obtain data processing services yielding comparative interlaboratory information on laboratory performance for bias (e.g. standard deviation interval [S.D.I.]) and precision (group coefficient of variation [C.V.]).<sup>4,5</sup>



**Figs 7-1 and 7-2.** Charles Blumenfeld, MD (1905-1992) of California [1] and Jerald R. Schenken, MD (b. 1933) of Nebraska [2] initiated the first Regional Quality Control Programs (RQCPs) using QAS data analysis in 1971.

In 1971, the California Society of Pathologists under Charles Blumenfeld, MD, and a Nebraska group under Jerald Schenken, MD, organized the initial Regional Quality Control Programs using QAS data analysis.<sup>2,6</sup> (Figs 7-1 and 7-2) During the 1970s, QAS grew both through the formation of new Regional Quality Control Programs affiliated with the CAP, and by the conversion of existing programs from industry-sponsored data processing. Programs that were thus added to QAS included Great Lakes (Michigan, Ohio, Indiana); Southeast (Kentucky, Tennessee, Georgia, Florida, and South Carolina);

Tristate (Alabama, Louisiana, and Mississippi); New York; Massachusetts;<sup>7</sup> Pennsylvania;<sup>8</sup> Illinois; and New Jersey groups. Initially applied to chemistry data,<sup>9</sup> the program expanded to include other quantitative disciplines of coagulation and general hematology in 1974,<sup>10,11</sup> platelet counting and ligand assay in 1976,<sup>12,13</sup> and therapeutic drugs in 1978.<sup>14</sup> A novel interlaboratory program in microbiology sensitivity testing, not generally considered to be a quantitative discipline, had been initiated in 1973.<sup>15</sup>

**Features of the QAS Program** The QAS program and its related professional activities have contributed significantly to the development of key quality control practices in laboratory medicine (Table 7-1). QAS has consistently emphasized the importance of using two or three levels of quality control rather than a single level. Two levels were sufficient to “stress” the analysis across a meaningful analytic range, and to measure performance at key clinical concentration levels. Additionally, with multilevel data, one could distinguish various types of error, such as fixed vs. random and proportional vs. constant. A second important practice traceable to the program was the setting of reasonably consistent analyte concentration levels in control materials, through the specifications of the Regional Program pools. These specifications tended to focus on clinically important decision levels.

The program also contributed to improved quality control performance by simplifying and standardizing methodology for reporting and documentation, and by providing data analyses across a wide spectrum of analytic disciplines and clinical laboratories. QAS, in addition, developed interlaboratory data comparisons by general and specific method, and was influential in emphasizing the application of simple “common sense” quality control algorithms, such as the one 3-standard deviations ( $1_{3s}$ ) and two 2-standard deviations ( $2_{2s}$ ) multi-rules.<sup>16</sup> Wall charts from the program were adjustable—that is, laboratories could set target values and limits as fixed or recalculated according to multiple options. A default option was provided, consisting of lot-to-date means as a target value, and limits of  $\pm 2$  and 3 standard deviations. These gave participants a simple visual, graphic plot on which simple multi-rules could be applied. This option was selected by a great majority of laboratories, creating a de-facto standard wall chart. Finally, the QAS program for interlaboratory comparison in microbiology sensitivity testing developed into the largest existing intra-laboratory data base on performance for Kirby-Bauer methodology.<sup>17</sup>

## **Significant Contributions to Quality Control Practices by the CAP QAS Program**

### **Regional Quality Control**

- Expanding concept
- Logistics
- Applications
- Scientific data
- Vendor-neutral (generic) quality control

### **Emphasis on multilevel (2 and 3 level) controls**

### **Emphasis on analyte concentrations at key clinical decision levels**

### **Emphasis on simple multirules for run acceptance/rejection**

### **Standardized methodology**

- Data input
- Method grouping - coordinated with CAP Survey
- Data analysis
- Outlier screening
- Reporting

### **Data sorting by general and specific methods for reagents and instruments**

### **Shared Pools with CAP Surveys for target value selection and bias calculation**

### **Publications—Categories**

- Performance (CV) vs concentration benchmarks
- Analyte stability in control materials
- Performance (CV) in multiple disciplines
- Analytic biases with different control materials
- Multiprogram characterization of laboratory performance (QAS, Survey, Inspection)

Table 7-1.

*Scientific Contributions of QAS* The QAS program has generated a substantial body of scientific publications on such topics as stability and matrix effects of control materials, program organization, state of the art for analytical performance, the Shared Pools program (operated jointly with CAP Surveys), multiprogram characterization of laboratory performance, and review articles on quality control and regional quality control. A list of key publications derived from the QAS program is presented in Table 7-2, and selected examples are reviewed in this chapter. In addition, the QAS Committee sponsored the first CAP consensus conference to be organized by a committee other than a Surveys resource committee. This conference, entitled *Quality Assurance in Physician Office, Bedside and Home Testing*, included representatives from pathology and laboratory medicine, various medical specialty societies involved in primary care, and legal and government professions who achieved consensus on effective quality assurance for remote site laboratory testing.<sup>55</sup> (*Text continues on page 82.*)

### Selected Landmark QAS Publications

<b>Year</b>	<b>Author</b>	<b>Comment</b>
1976	Lawson NS, Haven GT <sup>4</sup>	Review of history and growth of regional quality control programs (RQCP) in U. S. Some 5,700 laboratories participating in RQCP, with 1,700 in professionally coordinated groups.
1976	Ross JW, Fraser MD <sup>18</sup>	Initial comprehensive description of effect of analyte concentrations on performance (CV) in chemistry. Data presented as polynomial regression equations of median CVs versus concentration. Significant dependence of CV on concentration for most analytes.
1977	Haven GT, Lawson NS <sup>19</sup>	Performance data on QAS Ligand Assay Program presented with comparison of Surveys versus QAS performance, and QAS performance (CV) for 17 analytes.
1977	Lawson NS, Haven GT <sup>20</sup>	Classification and characterization of regional quality control programs. Attributes of programs including materials, participants, pool usage rates.
1977	Lawson NS, Ross JW <sup>21</sup>	Description of performance criteria (CV) for 29 analytes in five regional quality control programs and QAS Ligand Assay Program. Strong influence of concentration on performance. Inclusion of data on commonly measured enzymes.
1977	Lawson NS, Haven GT, Moore TD <sup>22</sup>	Initial use of monthly QAS data to study preconstitution analyte stability in control serum. Study included enzymes, inorganic analytes, total protein. Consistent minimal increase in sodium. Decrease in inorganic phosphorus. Very close correlation of phosphorus change with Survey data for pools from same manufacturer.
1977	Ross JW, Fraser MD <sup>23</sup>	Performance (CV) in relation to concentration updated and expanded. Mean performance exceeding medical needs for 13 of 14 chemistry analytes.

Table 7-2, beginning

<u>Year</u>	<u>Author</u>	<u>Comment</u>
1978	Lawson NS, Haven GT, Moore TD <sup>24</sup>	Documentation of prereconstitution instability of glucose in a significant proportion of lyophilized quality control pools.
1979	Gilbert RD, Rosenbaum JM <sup>25</sup>	Review of strategies for providing participant target values for determination of accuracy in external and regional quality control.
1979	Ross JW, Fraser MD <sup>26</sup>	State of the art in performance (CV) for 29 analytes in chemistry, ligand assay, therapeutic drugs, coagulation, hematology. Average performance meets analytic goals for 28 analytes.
1979	Haven GT, Lawson NS, Moore TD <sup>27</sup>	Stability of organic analytes in lyophilized control serum. Consistent pattern of instability not identified.
1979	DiSilvio TV <sup>28</sup>	Description of strategies employed to evaluate stability of control serum used for regional quality control.
1980	Knowles RC, Moore TD <sup>17</sup>	State of the art in antibiotic sensitivity testing. Data representing 2.4 million observations. Comparison with published National Committee for Clinical Laboratory Standards (NCCLS) control limits.
1980	Ross JW, Fraser MD, Moore TD <sup>29</sup>	State of the art in concentration-related performance (CV) for 31 analytes in chemistry, ligand assay, therapeutic drug measurement, coagulation, hematology. Significant trends of improving performance over time. Documented tolerance limits for achieving specified percentile rankings determined at clinically significant concentrations.
1980	Lohff MR <sup>30</sup>	QAS Therapeutic Drug Program data describing performance (CV) for normal and elevated concentrations of theophylline, phenytoin, and phenobarbital.
1980	Lawson NS, Haven GT, Ross JW <sup>31</sup>	Summary of established data studies from regional quality control. Attention focused on important future studies involving QAS data.

Table 7-2, continued

<b>Year</b>	<b>Author</b>	<b>Comment</b>
1981	Platt R, Batsakis JG <sup>32</sup>	Good correlation of intralaboratory precision for calcium and sodium between QAS and Surveys for a cohort of laboratories.
1981	Lawson NS, Haven GT, DiSilvio TV, Gilmore BF <sup>33</sup>	Confirmation of tendency, published previously, for minimal increase in measured sodium concentration over time in a portion of lyophilized pools.
1981	Knowles RC, Gilmore BF <sup>34</sup>	Updated state-of-the-art performance for Kirby-Bauer antibiotic sensitivity testing, based on approximately two million observations from 155 laboratories.
1982	Ross JW, Fraser MD <sup>35</sup>	State of the art in performance (CV) for 31 analytes in chemistry, ligand assay, therapeutic drug measurement, coagulation, hematology. Tolerance limits with percent of laboratories meeting specified percentiles of performance at clinically important concentrations. Development of medical precision index indicating 97 percent of results meeting medical usefulness based analytic goals.
1982	Lawson NS, Haven GT, DiSilvio TV, Gilmore BF <sup>36</sup>	Data from 2.5 million glucose measurements confirming previously reported decreasing glucose concentration in a significant proportion of quality control pools.
1982	Lawson NS, Haven GT, Williams GW <sup>37</sup>	Literature review of prereconstitution stability of control materials. QAS data comprises largest element of reported data. Suggested approaches toward defining limits of acceptable instability.
1982	Lohff MR, DiSilvio TV, Ross JW, Gilmore BF <sup>38</sup>	Analyte performance for common enzymes as a function of enzyme activity.
1983	DiSilvio TV, Lawson NS, Haven GT, Gilmore BF <sup>39</sup>	Documented changes in magnesium and iron concentration in control serum over time due to methodologic factors.
1983	Howanitz PJ, Howanitz JH, Lamberson HV, Tierston D, Lansky H <sup>40</sup>	Comparison of matrix associated biases for eight analytes, lyophilized versus liquid control material. Tendency for biases to be greater for liquid material and proportional to concentration.

Table 7-2, continued

<b>Year</b>	<b>Author</b>	<b>Comment</b>
1985	Rosenbaum JM <sup>41</sup>	Bias measured in the Massachusetts Regional Quality Control Program compared favorably to comparable data using definitive and reference methods for common analytes.
1983	Knowles RC, Gilmore BF <sup>42</sup>	Summary of laboratory performance by QAS Microbiology participants with Kirby-Bauer method versus NCCLS published standards. Discrepancies documented for antibiotics versus <i>E. Coli</i> and two antibiotics versus <i>S. Aureus</i> .
1983	Kafka MT <sup>43</sup>	Estimates of bias derived from regional quality control programs greater than those seen in Surveys for the same analytes. Many methods for calcium, creatinine, cholesterol failed to meet analytic goals. Glucose methods generally met analytic goals.
1988	Lawson NS, Gilmore BF <sup>44</sup>	Interprogram data correlations between laboratory improvement programs. Documented relationships between QAS and Surveys performance statistics for AST, glucose, inorganic phosphorus, potassium.
1991	Barnett RN, et al <sup>45</sup>	Approved NCCLS Guideline, with significant QAS input in various areas including numbers of specimens, purpose of quality control, materials, concentrations, use of data, regional quality control.
1991	Lawson NS, Ross JW, Long T <sup>46</sup>	Descriptions of theory and application of QAS-Surveys shared quality control pools in laboratory medicine.
1991	Lawson NS, Cembrowski GS <sup>47</sup>	Use of Surveys assayed shared pools for internal quality control. Documented improvement of performance within framework of total quality management.
1994	Arkin C <sup>48</sup>	Improvement in interlaboratory CV for coagulation testing in New England Regional Quality Control Program, using a shared pools control product.

Table 7-2, continued

<b>Year</b>	<b>Author</b>	<b>Comment</b>
1994	Arkin C <sup>49</sup>	Review of regional program data on seven analytes for human versus bovine controls. Tendency for greater method related bias with bovine controls.
1995	Lawson PL, Lawson NS, Ross JW <sup>50</sup>	Data describing performance with shared pools; documentation of satisfactory analyte stability. Concentration shifts traceable to analytic methodology. Open methods generally more stable than closed methods.
1995	Ross JW, Lawson NS <sup>51</sup>	State of the art for performance (CV) as a function of concentration for 37 analytes. Continued overall improvement in performance over time. Tolerance limits for performance at given percentile rankings provided for clinically important analyte concentrations.
1995	Tetrault GA <sup>52</sup>	Key applications in clinical laboratory quality control to be incorporated into the practice of clinical pathology.
1995	Lawson NS, Williams TL, Ross JW <sup>53</sup>	Evolution and status of shared pools concept. Role of shared pools in accuracy based quality control.
1996	Westgard JO, Ross JW, Lawson NS <sup>54</sup>	Level related performance (CV) in QAS used to predict performance in proficiency testing using CLIA-88 guidelines.

Table 7-2, continued

The state of the art for performance on analytic precision in clinical laboratories has been addressed in several publications.<sup>8,18,21,23,26,29,35,38,50,51</sup> A key contribution of QAS has been the work of Ross and Fraser in characterizing the mathematical relationship between analytic precision and analytic concentration, and descriptions of achieved performance percentiles at key analyte concentrations.<sup>18,23,26,29,35</sup> Such data have served both as benchmarks against which laboratories could measure their own performance, and as assessments of the state of the art in precision for the clinical laboratory community.

QAS data have also been employed to study control materials. The stability of control materials has been widely analyzed, using trending of monthly means from regional control data.<sup>22,24,27,37,39</sup> Some instability with glucose and certain enzymes, and minimal increases in sodium, were noted in a proportion of lyophilized chemistry pools from the 1970s and early 1980s; more recent materials, however, have only rarely been determined to pose stability problems.<sup>50</sup> DiSilvio also has reported on the methodology of specimen stability assessment, using regional quality control data.<sup>28</sup> The analytic biases in various types of control sera have been described by Howanitz et al<sup>40</sup> and Arkin.<sup>49</sup>

In 1989, the CAP pioneered the concept of shared pools between Surveys and QAS, to allow for a large intra-laboratory data base to set target values for daily quality control materials. The Shared Pools program combined the most desirable features of Surveys and QAS into an integrated product. Its major benefits

include testing and validation of single-vial multidiscipline control products for Surveys and QAS, providing thoroughly assayed controls for costs approximating those of unassayed materials, and inserting a key link for accuracy-based quality control. Multidiscipline lyophilized controls for chemistry, ligand assay, and therapeutic drug analysis initially were employed as unknowns in CAP Surveys. Shared multidiscipline pools were employed in the Great Lakes and Southeast Regional Quality Control Programs, whereas special products were used for the Ligand Assay, Therapeutic Drug Analysis, and Coagulation Surveys. A shared pools program, within a context of total quality management, has been shown to improve laboratory performance.<sup>47</sup>

The Shared Pools programs' scientific success has not been paralleled by commercial success, however. Because they were viewed as significant competition by control manufacturers, the programs did not receive the vendor support necessary to assure long-term success, and thus are scheduled to be discontinued in their present form as of 1997.

No single attribute of laboratory behavior is sufficient to characterize overall performance. Among Dr. Hutchens' original goals for the QAS program was that it provide descriptions of interprogram or multiprogram performance targets.<sup>3</sup> In line with this vision, QAS data have been included in studies that have demonstrated significant correlation between performance in Surveys and QAS, and performance in Surveys and QAS as a function of participation in the CAP Laboratory Accreditation Program.<sup>44</sup> Platt and Batsakis have reported on correlation of precision estimates between Surveys and QAS,<sup>32</sup> and Westgard et al have used QAS data on precision to calculate predicted performance in proficiency testing.<sup>34</sup>

During the 1980's, CAP implemented the QAS Today program, providing an electronic interface between participants and the CAP Computer Center. With QAS Today, laboratories could upload and download information directly to and from the program. QAS has achieved success in that a significant percentage of large laboratories in the United States were using QAS by the late 1980s. At its peak, the program was used by approximately 2,300 participants, who were operating approximately 140,000 analyte-level data files. Currently, the program has approximately 1,300 participating laboratories.

*Limitations of QAS* From its inception, the QAS program was handicapped by inherent limitations which affected its popularity in the clinical laboratory community. These included the need for major ongoing voluntary effort by physicians at the regional level; the lack of "industrial strength" marketing techniques and budgets; competing regional quality control data programs provided by manufacturers of control serum; lack of a CAP-vended control serum; differences in cost-accounting methodology between industry and CAP, which left the College at a cost disadvantage; and the increasing emergence of "tie-in" sales, whereby control materials were sold by manufacturers along with instruments, thus diminishing the ability of laboratories to choose unrelated controls which would use CAP data processing. (A notable exception is the successful program operated with Beckman Instruments controls, wherein the manufacturer has elected to employ QAS for its participants rather than initiate and maintain a data processing program of its own.)

This combination of factors has consistently limited the CAP's ability to achieve greater adoption of QAS, and to operate the program on a sound financial basis. Nonetheless, over the years, the program's considerable success has reflected a working combination of organizational stewardship, business acumen, and high professional and scientific quality.

The direct data processing component of QAS is scheduled to be maintained through 1997. The CAP is reengineering QAS to maintain the educational and scientific components of the program, while relying increasingly on relationships with vendors for access to daily quality control data. At this writing, the

specific details of the reengineering are incomplete; but we are confident that QAS will continue to make important educational and scientific contributions to the laboratory profession in the future as it has in the past.

*Origin of Q-PROBES* During the 1970s and early 1980s there was a general perception that for laboratory testing, quality control and quality assurance were synonymous. However, in the early 1980s a few publications began to describe the laboratory test as extending beyond the traditional analytical or measurement step to include preanalytical and postanalytical phases, regardless of the physical location of any of these steps.<sup>56</sup> This broader definition of the laboratory test began with the physician deciding which test to order, ended with the physician evaluating the result of the ordered test, and included a number of intermediate steps. This new definition implied an expanded scope of quality assurance that now involved each of the steps of the laboratory test; and because many of these steps occurred outside the laboratory, quality assurance became formalized as a process having both intralaboratory and extralaboratory components. As a result, this definition also entailed that traditional laboratory quality control was confined solely to the measurement step, and thus, analytical laboratory quality control became only one of a number of quality assurance measures.

In 1986, the Joint Commission on Accreditation of Healthcare Organizations (Joint Commission), under the new leadership of Dennis O'Leary, MD, announced its "Agenda for Change," under which decisions on hospital accreditation were to be based less on structural and procedural aspects of patient care and more on actual, measured outcomes of care. One of the cornerstones of this initiative was an accreditation and surveys program which emphasized the use in the accreditation process of clinical and organizational "indicators," described as characteristics and management activities that most directly affected quality of patient care.<sup>57</sup> The Joint Commission's position was enhanced by a simultaneous movement in medicine toward evaluating outcomes by comparing treatments and technologies to determine which produced the best results for patients.

Shortly thereafter, more stringent federal regulations for clinical laboratory testing appeared in the form of the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88).<sup>58</sup> Among many important revisions promulgated by this legislation and its implementing regulations, one required that quality assurance be performed at each step of a laboratory test. The combined aggregate of all these steps was formally referred to as "The Total Testing Process" under these regulations.

Many of the CAP's QAS Committee members were leaders in these changes in quality control and quality assurance, and in this evolving regulatory environment they perceived a new opportunity for the CAP. In 1986 the QAS Committee conceptualized and began to develop a quality assurance program that would fulfill the potential requirements of the Joint Commission and emerging government regulations, as well as the CAP's own Laboratory Accreditation Program. To develop such a program, it was necessary for the committee to include individuals expert not only in hematology, chemistry, and microbiology, but also in transfusion medicine, surgical pathology, autopsy pathology, cytology, and laboratory management. When fully constituted, this committee functioned as a consensus group of experts who identified indicators of quality for pathology and laboratory medicine; designed studies using these indicators for participants in the program, now named Q-PROBES; worked with CAP statisticians to interpret study data; and wrote critiques to guide participant improvement. Additional scientific expertise was provided by members of Surveys resource committees and other CAP committees, who helped design many Q-PROBES studies and co-authored a few as well.

The Q-PROBES program succeeded in the 1980s and 1990s because it provided appropriately designed "off-the-shelf" quality improvement studies that drew on the best available expertise, developed quality

benchmarks for participants, and offered concrete suggestions on improving performance. These attributes made it easy for participants to implement a state-of-the-art program in their laboratories with minimal expenditure of resources. At the same time, the program educated participants on how to develop and improve their own programs.

As first developed, this subscription program provided studies that all participants performed simultaneously according to a previously tested format. Participants then sent their results to the CAP for analysis, and within a short period of time received critiques written by experts that compared their performance to benchmarks established by the study. Most of these studies were cross-sectional studies that evaluated participants' performance for a given indicator of quality (e.g. reporting errors, phlebotomy complications) on a one-time basis. However, a number of studies were repeated at a later date to measure improvement. Because of the early success of the Q-PROBES program, the Joint Commission's own quality assurance program concentrated on hospital departments other than pathology and laboratory medicine. The operational details of Q-PROBES studies have previously been described in a 1990 article in *Archives of Pathology & Laboratory Medicine*.<sup>39</sup>

In 1988, a field evaluation of the first six indicators of quality was conducted, and in 1989, the first year of operation, three studies for anatomic pathology and five studies for clinical pathology appeared. In 1990, because of the increasing success of the Q-PROBES program, the QAS Committee was divided into two committees, one with members expert in quality control (QC), and a second specializing in quality improvement (Q-PROBES), with the committees designated QAS-QC and QAS-QA, respectively.

During the next few years, the QAS-QA Committee increased the number of Q-PROBES studies, and in 1993 provided studies in anatomic pathology and clinical pathology expressly for small hospitals. Between 1988 and 1995, 76 Q-PROBES studies were offered for pathology and laboratory medicine (Fig 7-3). The number of studies offered in 1996 has been decreased in expectation of the release of a new product, Q-Track, which will provide ongoing quality assurance monitoring—as distinct from the one-time studies used by Q-PROBES—and will feature remote software to be used by participants to collect, analyze, and transmit information to the CAP, as well as to receive updated benchmark data from the College. Studies for the managed care environment are also being considered for development.

Figure 7-4 shows the numbers of participants in the Q-PROBES program since its inception. Beginning with more than 800 participants in the first year, the number of institutions has more than doubled during the next six years to more than 1,600 in 1995. Although the majority of participants have been from the United States, laboratories from Canada, New Zealand, Australia, Hong Kong, England, Mexico, Brazil, Israel, Singapore, Scotland, Belgium, and Saudi Arabia have participated in the Q-PROBES program. In 1996, the QAS-QA Committee ended its previous reporting relationship with the CAP Council on Scientific Affairs and began to report instead to the Council on Practice Management. In 1997, the QAS-QA Committee will change its name to "Quality Practices Committee."

**Q-PROBES Studies** The major feature of Q-PROBES in its first seven years of operation is that it provides a standard against which laboratories can measure themselves. Because of the large number of participants, their practice patterns can be established with great certainty and the best-performing participants identified. The best practice standards are called benchmarks, and the process of comparing participants to such standards (benchmarking) is one of the most powerful tools now used in the quest for quality improvement.

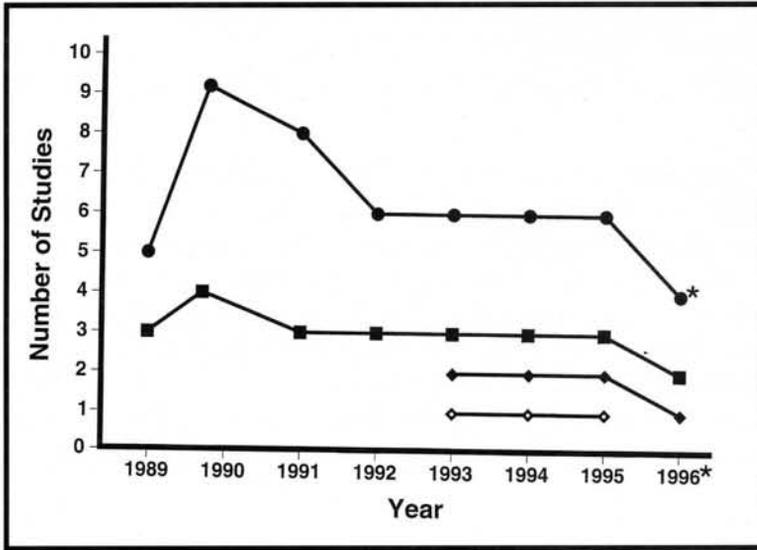


Fig 7-3. Number of yearly Q-PROBES studies. Circles (●) are clinical pathology studies, squares (■) are anatomic pathology studies, closed diamonds (◆) are small hospital clinical pathology studies, and open diamonds (◇) are small hospital anatomic pathology studies.

\* Indicate that some small hospital studies were combined with large hospital studies.

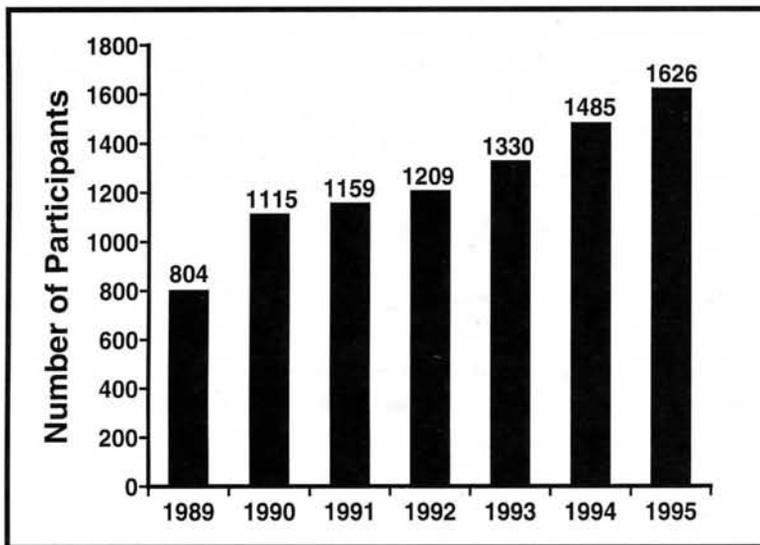


Fig 7-4. Number of Q-PROBES participants by year.

Although benchmarking results in comparative performance measures, it also describes how exceptional performance is attained. Practices that lead to exceptional performance from benchmarking studies are called enablers. Thus the process of benchmarking from Q-PROBES results in two types of outputs: benchmarks, or measures of comparative performance, and enablers, both of which are integral parts of the information provided to participants by each Q-PROBES study. Listed in Table 7-3 are some important benchmarks established by Q-PROBES studies for each of the steps of the laboratory test, as well as the amount of time laboratories spend on QA per month. These benchmarks are derived from studies conducted during the first four years of the program; the lead author for each study is listed. The studies shown in this table also cover each of the principal disciplines of pathology and laboratory medicine. By the end of 1996, the Q-PROBES program will have studied, for each major discipline, almost all the steps in the total testing process. Although only one benchmark has been listed in Table 7-3 for each study, in fact a number of benchmarks have been derived from each of the 76 studies conducted. In addition to QAS-QA committee members shown in Table 7-3, others who have developed a number of Q-PROBES studies include Raouf Nakhleh, MD; Gordon Gephardt, MD; Fred Meier, MD; Andrew Saladino, MD; Jane Dale, MD; and David Novis, MD.

One of the original features of Q-PROBES studies was that suggestions for improved performance could be tested depending on a number of performance variables or enablers described in each study. Table 7-4

One of the original features of Q-PROBES studies was that suggestions for improved performance could be tested depending on a number of performance variables or enablers described in each study. Table 7-4

Selected Q-PROBES Benchmarks						
Step	Study	Participants	Sample Size	Median	Benchmarks	Lead Author
Order right test	Viral Hepatitis Serology Test Utilization	625	15,011 anti-HBC tests	23.0%	Anti-HBC (IgM) tests with neither AST and ALT ordered	R.B. Schiffman <sup>68</sup>
Patient prepared	Therapeutic Drug Monitoring Timing	666	18,769 specimens with toxic levels	24.4%	Digoxin specimen inappropriately collected within <6 hour of last dose	S.J. Steindel <sup>61</sup>
Accurate orders	Order Accuracy	577	224,431 measurements	1.8%	Tests ordered and order not received in laboratory	P.N. Valenstein <sup>62</sup>
Patient identified	Wristband Errors	204	451, 436 patients	6.5%	Patients not banded	S.J. Renner <sup>63</sup>
Specimen collected	Outpatient Phlebotomy	630	29,700 outpatients	6.0 minutes	For phlebotomy completion	P.J. Howanitz <sup>64</sup>
Specimen rejected	Hematology Specimen Acceptability	703	35,325 specimens	0.38%	CBC's improperly collected and rejected	B. Jones <sup>65</sup>
Accurately measured	Surgical Pathology Frozen Section	297	79,647 frozen sections	1.7%	Discordant diagnosis rate	G.G. Hoffman <sup>66</sup>
Results timely	Surgical Pathology Complex Specimen TAT*	489	14,298 specimens	1.0 days	Median TAT*	R. J. Zarbo <sup>67</sup>
Physician action	Post-Analytical QA: Hypercalcemia	555	5,837 results	85.0%	Proportion of abnormal results documented by physicians	G.S. Cembrowski (unpublished)
Physician action correct	Autopsy Contributions in Quality Assurance	248	2,479 autopsies	40.0%	Major unexpected findings contributing to death	P.B. Baker <sup>68</sup>
	Laboratory Quality Assurance Program	580	9,860 indicators used	40 hours per month	Time to complete QA	P. Bachner <sup>69</sup>

\* TAT=Turnaround time

Table 7-3.

illustrates enablers from the Q-PROBES study *Bedside Glucose Monitoring* that were associated with improved accuracy.<sup>70</sup> In this study, 35 different characteristics were evaluated for their effect on accuracy of bedside glucose measurements, and 11 were found to improve accuracy significantly. The table also indicates the value of a performance standard against which participants were compared. In this study, the standard of  $\pm 10$  percent of the reference (laboratory) value was established by the American Diabetes Association. As in this glucose monitoring study, each Q-PROBES study conducted to date has provided a number of enablers to assist participants in their improvement efforts.

**Q-PROBES Achievements** In 1990, the QAS-QC Committee sponsored the 17th CAP Conference, *Quality Assurance in Pathology and Laboratory Medicine*.<sup>71</sup> In attendance were approximately 300 individuals who established consensus on the value and direction of quality improvement programs for pathology and laboratory medicine. This conference was the first CAP consensus conference that was open to the public, and was widely attended by those interested in quality improvement in medicine.

During the brief history of the Q-PROBES program, a number of achievements have established its value for medicine in general, as well as for departments of pathology and laboratory medicine in particular. These achievements include the large number of benchmarks established from 76 studies completed to date; the exceedingly large data bases for each study; CAP publications of definitive information on health care topics for which almost no information previously existed; the publication of 37 scientific manuscripts in the peer-reviewed literature; presentation of almost 40 abstracts at scientific meetings; and more than 100 invited discussions on Q-PROBES presented at local, national, and international meetings.<sup>72</sup>

<b>Bedside Glucose Monitoring (BGM) Enablers Associated with Increased Accuracy<sup>70</sup></b>		
<b><u>Variable</u></b>	<b><u>Median Accuracy (%) for the Compared Group at ( 10% value</u></b>	<b><u>p value</u></b>
Laboratory personnel vs registered nurse responsible for BGM program	67 vs 49	0.0007
Laboratory personnel responsible for performing BGM test	65 vs 53	0.01
Nursing personnel not responsible for performing BGM test	63 vs 57	0.04
Laboratory personnel performs training	64 vs 50	0.02
Lecture used in training program	63 vs 45	0.01
Repeated training/performance reviewed for BGM operators	63 vs 41	0.0002
Regular BGM clinical laboratory correlations	63 vs 50	0.02
Routinely compare BGM results (laboratory glucose proficiency)	62 vs 50	0.04
Participate in external proficiency testing for BGM	63 vs 50	0.03
Laboratorian vs registered nurse collected BGM study results	67 vs 51	0.03

*Table 7-4.*

Other honors include a 1991 invitation to address a national audience at Juran Institute about Q-PROBES; recognition from the non-profit Healthcare Forum as one of six outstanding benchmarking programs for medicine;<sup>73</sup> and the frequency with which Q-PROBES studies or benchmarks are cited in the peer-reviewed literature. It is clear that the CAP's Q-PROBES program is recognized worldwide as a leading quality improvement program, and has made major contributions to improved care of patients.

**Conclusions** The CAP's QAS Committees have made important contributions to the field of pathology and laboratory medicine, and their quality assurance programs have become the standard by which all other laboratory QC and QA programs are measured. Many significant changes in practice patterns for QC and QA, and in other aspects of the practice of pathology, have resulted from the scientific contributions of these programs. We believe that these committees and the programs they oversee will continue to be in the forefront of scientific leadership for the future, as they evolve in response to change and as they lead changes in pathology and laboratory medicine.

## Notes

1. McWhorter CA. President's report to the House of Delegates. Atlanta 1970. *Pathologist*. 1970 Oct: 340-345.
2. Haven GT. QAS: 100,000 Files and 13 years ago. *Pathologist*. 1984 Feb:79-81,125.
3. Marquardt VC, Hutchens T. *Pathologist* queries Hutchens on Quality Assurance Service. *Pathologist*. 1970 Nov:375-380.
4. Lawson NS, Haven GT. The role of regional quality control programs in the practice of laboratory medicine in the United States. *Am J Clin Pathol*. 1976;66:268-275.
5. Rosenbaum JM. Regional quality control programs. In: Werner M, ed. *Handbook of Clinical Chemistry*, Vol. I. Boca Raton, Fla: CRC Press; 1982:433-438.
6. Blumenfeld CM. QAS: The group program of the California Society of Pathologists. *Pathologist*. 1971 Aug:260-268.
7. Copeland BE, Rosenbaum JM. Organization, planning, and results of the Massachusetts Society of Pathologists regional quality control program. *Am J Clin Pathol*. 1972;57:676-688.
8. DiSilvio TV, Sax SM, Moses TD, Berman HJ, Drowart WV. Day to day precision in clinical chemistry laboratories. *Pa Med*. 1978 Mar; 81:33-37.
9. Eilers RJ. Special projects for QEP: QAS microbiology, hematology and coagulation programs announced. *Pathologist*. 1973 Jan:6-8.
10. Wertz RK. The QAS coagulation program: contributions to standardization. *Pathologist*. 1974 Jan:27-29.
11. Keitges PW. The Quality Assurance Service hematology program. *Pathologist*. 1974 Feb:59-61.
12. Wertz RK. QAS Notes: platelet counting: precision and quality control. *Pathologist*. 1976 Sep:338-339,387.
13. Haven GT. QAS Notes: the QAS radioligand program. *Pathologist*. 1976 Jun:217-218.
14. Lohff MR. QAS Notes: QAS and therapeutic drug monitoring. *Pathologist*. 1978 Oct:610-611.
15. Marquardt VC. Quality control system for antibiotic susceptibility testing. *Pathologist*. 1973 Nov:428-432.
16. Haven GT. Outline for quality control decisions. *Pathologist*. 1974 Sep:373-378.
17. Knowles RC, Moore TD. Quality control of agar diffusion susceptibility tests: data from the Quality Assurance Service microbiology program of the College of American Pathologists. *Am J Clin Pathol*. 1980;74:581-585.
18. Ross JW, Fraser MD. The effect of analyte and analyte concentration upon precision estimates in clinical chemistry. *Am J Clin Pathol*. 1976;66:193-205.

19. Haven GT, Lawson NS. A national ligand assay internal quality control program: one year's experience. *Pathologist*. 1977 Jun;334-337.
20. Lawson NS, Haven GT. Regional quality control programs ("quality assurance programs") goals and achievements. In: Henry JB, Giegel JL, eds. *Quality Control in Laboratory Medicine: Transactions of the First InterAmerican Symposium*. New York, NY: Masson Publishing USA, Inc.; 1977:173-178.
21. Lawson NS, Ross JW. Long term precision for selected clinical chemistry analytes, as determined by data from regional quality control programs. In: Elevitch FR, ed. *Analytical Goals in Clinical Chemistry: CAP Conference/1976*. Skokie, Ill: College of American Pathologists; 1977:83-89.
22. Lawson NS, Haven GT, Moore TD. Long-term stability of enzymes, total protein, and inorganic analytes in lyophilized quality control serum. *Am J Clin Pathol*. 1977;68:117-129.
23. Ross JW, Fraser MD. Analytical clinical chemistry precision: state of the art for fourteen analytes. *Am J Clin Pathol*. 1977;68:130-141.
24. Lawson NS, Haven GT, Moore TD. Long-term stability of glucose in lyophilized quality control serum: a study utilizing data from the Quality Assurance Service (QAS) program of the College of American Pathologists. *Am J Clin Pathol*. 1978;70:523-531.
25. Gilbert RD, Rosenbaum JM. Accuracy in interlaboratory quality control programs. *Am J Clin Pathol*. 1979;72:260-264.
26. Ross JW, Fraser MD. Analytical clinical laboratory precision: state of the art for twenty-nine analytes. *Am J Clin Pathol*. 1979;72:265-273.
27. Haven GT, Lawson NS, Moore TD. Stability of mean values of organic analytes in lyophilized quality control serum. *Am J Clin Pathol*. 1979; 72:274-284.
28. DiSilvio TV. An examination of statistical strategies for evaluation of stability of lyophilized quality control serum under actual conditions of use. *Clin Chem*. 1979;25:1086.
29. Ross JW, Fraser MD, Moore TD. Analytic clinical laboratory precision: state of the art for thirty-one analytes. *Am J Clin Pathol*. 1980;74:521-530.
30. Lohff MR. Preliminary observations on the Quality Assurance Service therapeutic drug monitoring program. *Am J Clin Pathol*. 1980;74:542-545.
31. Lawson NS, Haven GT, Ross JW. Regional quality assurance for the 1980's, current status and future directions. *Am J Clin Pathol*. 1980;74:552-559.
32. Platt R, Batsakis JG. Intralaboratory analytic precision as estimated from two distinct programs from the College of American Pathologists. *Am J Clin Pathol*. 1981;76:578-580.
33. Lawson NS, Haven GT, DiSilvio TV, Gilmore BF. Stability of sodium and potassium in lyophilized quality control serum: a study of data from the Quality Assurance Service program of the College of American Pathologists. *Am J Clin Pathol*. 1981;76:581-589.

34. Knowles RC, Gilmore BF. Quality control of agar diffusion susceptibility tests: data from the Quality Assurance Service microbiology program of the College of American Pathologists. *Am J Clin Pathol.* 1981;76:590-596.
35. Ross JW, Fraser MD. Clinical laboratory precision: the state of the art and medical usefulness based internal quality control. *Am J Clin Pathol.* 1982;78:578-586.
36. Lawson NS, Haven GT, DiSilvio TV, Gilmore BF. Glucose stability in lyophilized chemistry quality control serum: a study of data from the Quality Assurance Service (QAS) program of the College of American Pathologists. *Am J Clin Pathol.* 1982;78:597-606.
37. Lawson NS, Haven GT, Williams GW. Analyte stability in clinical chemistry quality control materials. *CRC Crit Rev Clin Lab Sci.* 1982;17:1-50.
38. Lohff MR, DiSilvio TV, Ross JW, Lawson NS, Gilmore BF. Analytic clinical laboratory precision: state of the art for selected enzymes. *Am J Clin Pathol.* 1982; 78:634-643.
39. DiSilvio TV, Lawson NS, Haven GT, Gilmore BF. Stability of mean assay values of magnesium and iron in lyophilized quality control serum: a study based on data from the Quality Assurance Service (QAS) of the College of American Pathologists. *Am J Clin Pathol.* 1983;80:563-569.
40. Howanitz PJ, Howanitz JH, Lamberson HV, Tiersten D, Lansky H. Analytical biases with liquid quality control material. *Am J Clin Pathol.* 1983;80:643-647.
41. Knowles RC, Gilmore BF. Quality control of agar diffusion susceptibility tests: data from the Quality Assurance Service microbiology program of the College of American Pathologists. *Am J Clin Pathol.* 1983;80:603-608.
42. Rosenbaum JM. Accuracy in clinical laboratories participating in regional quality control programs. *Arch Pathol Lab Med.* 1985;109:485-495.
43. Kafka MT. Internal quality control, proficiency testing, and the clinical relevance of laboratory testing. *Arch Pathol Lab Med.* 1988;112:449-453.
44. Lawson NS, Gilmore BF, Tholen DW. Multiprogram characterization of laboratory bias, precision, and total error. *Arch Pathol Lab Med.* 1988;112:454-461.
45. Barnett RN, chairperson, et al. *Internal Quality Control Testing: Principles and Definitions.* Villanova, Pa: National Committee for Clinical Laboratory Standards; 1991. NCCLS document C24-A.
46. Lawson NS, Ross JW, Long T. "Shared pools" bring new dimension to QC. *CAP TODAY.* 1991 Apr:51-52.
47. Lawson NS, Cembrowski GS. Labs winners in crosslink scheme. *CAP TODAY.* 1991 Oct:20-24.
48. Arkin C. Advances in coagulation: shared pools: a boost for laboratory quality control. *CAP TODAY.* 1994 Jun:18-19.
49. Arkin C. Man v. beast: comparing human and bovine QC materials. *CAP TODAY.* 1994 Oct:49-51.

50. Lawson PL, Lawson NS, Ross JW. The stability of survey-assigned assay values when surveyed control materials are used in a daily interlaboratory quality control program. *Arch Pathol Lab Med.* 1995;119:312-333.
51. Ross JW, Lawson NS. Analytic goals, concentration relationships, and the state of the art for clinical laboratory precision. *Arch Pathol Lab Med.* 1995;119:495-513.
52. Tetrault GA. QC in the clinical lab: 6 questions for the pathologist. *CAP TODAY.* 1995 Apr:60-61.
53. Lawson NS, Williams TL, Ross JW. QAS and Surveys programs at heart of innovative concept. *CAP TODAY.* 1995 Apr:53-55.
54. Westgard JO, Bawa N, Ross JW, Lawson NS. Laboratory precision performance: state of the art versus operating specifications that assure the analytical quality required by Clinical Laboratory Improvement Amendments proficiency testing. *Arch Pathol Lab Med.* 1996;120:621-625.
55. Howanitz PJ, ed. *Quality Assurance in Physician Office, Bedside, and Home Testing: CAP Conference/1986.* Skokie, Ill: College of American Pathologists; 1986.
56. Howanitz PJ, Howanitz JH. Quality control for the clinical laboratory. *Clin Lab Med.* 1983;3:541-552.
57. O'Leary DS. The Joint Commission's "Agenda for Change." *J Med Assoc Ga.* 1987;76:503-507.
58. Clinical Laboratory Improvement Amendments of 1988: final rule. *Federal Register.* 1992 Feb 28; 55:7002-7186.
59. Howanitz PJ. Quality assurance measurements in departments of pathology and laboratory medicine. *Arch Pathol Lab Med.* 1990;114:1131-1135.
60. Schiffman RB, Meier FA. Viral hepatitis serology test utilization: data analysis and critique. Q-PROBES 93-01. Northfield, Ill: College of American Pathologists;1994.
61. Howanitz PJ, Steindel SJ. Digoxin therapeutic drug monitoring practices: a College of American Pathologists Q-PROBES study of 666 institutions and 18,679 toxic levels. *Arch Pathol Lab Med.* 1993;117:684-690.
62. Valenstein PN, Howanitz PJ. Ordering accuracy: a College of American Pathologists Q-PROBES study of 577 institutions. *Arch Pathol Lab Med.* 1995;119:117-122.
63. Renner SW, Howanitz PJ, Bachner P. Wristband identification error reporting in 712 hospitals: a College of American Pathologists Q-PROBES study of quality issues in transfusion practice. *Arch Pathol Lab Med.* 1993;117:573-577.
64. Howanitz PJ, Cembrowski GS, Bachner P. Laboratory phlebotomy: College of American Pathologists Q-PROBES study of patient satisfaction and complications in 23,783 patients. *Arch Pathol Lab Med.* 1991;115:867-872.
65. Jones BA, Meier F, Howanitz PJ. Complete blood count specimen acceptability: a College of American Pathologists Q-PROBES study of 703 laboratories. *Arch Pathol Lab Med.* 1995;119:203-208.

66. Zarbo RJ, Hoffman GG, Howanitz PJ. Interinstitutional comparison of frozen-section consultation: a College of American Pathologists Q-PROBES study of 79,647 consultations in 297 North American institutions. *Arch Pathol Lab Med.* 1991;115:1187-1194.
67. Zarbo RJ, Gephardt G, Howanitz PJ. Intralaboratory timeliness of surgical pathology reports: results of two College of American Pathologists Q-PROBES studies of biopsies and complex specimens. *Arch Pathol Lab Med.* 1996;120:234-244.
68. Baker PB, Saladino AJ. Autopsy contributions in quality assurance: data analysis and critique. Q-PROBES 93-06. Northfield, Ill: College of American Pathologists;1994.
69. Bachner P, Howanitz PJ, Lent RW. Quality improvement practices in clinical and anatomic pathology services: a College of American Pathologists Q-PROBES study of the program characteristics and performance in 580 institutions. *Am J Clin Pathol.* 1994;102:567-571.
70. Jones BA, Bachner P, Howanitz PJ. Bedside glucose monitoring: a College of American Pathologists Q-PROBES study of the program characteristics and performance in 605 institutions. *Arch Pathol Lab Med.* 1993;177:1080-1087.
71. Bachner P, McLendon WW, eds. College of American Pathologists Conference XVII on quality assurance in pathology and laboratory medicine. *Arch Pathol Lab Med.* 1990;114:1112-1177.
72. Schifman RB, Howanitz PJ, Zarbo RJ. Q-PROBES: a College of American Pathologists benchmarking program for quality management in pathology and laboratory medicine. *Adv Pathol.* 1996;9:83-120.
73. Sassenick SM, ed. Benchmarking: tales from the front. *Healthcare Forum J.* 1993 Jan/Feb;36:37-52.

## Chapter Eight

# Anatomic and Consultative Pathology Practice

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Throughout its history, the College of American Pathologists has made enormous contributions to the improvement of clinical laboratory practice through its Standards, Surveys, Laboratory Accreditation, and Quality Control/Quality Assurance programs, discussed in detail in previous chapters. The degree of improvement achieved through such efforts has been well documented through statistical analysis of the massive amounts of data generated in these College programs.

No less significant, however, have been CAP programs designed to enhance the pathologist's expertise in areas of practice where the exercise of judgment is critical to patient care, such as the performance of autopsies, surgical pathology, and cytopathology, as well as consultative areas of clinical pathology. Documentation of improvement presents more of a challenge in these areas, however; while clinical pathology deals largely with numerical values, anatomic pathology generally has as its end point a diagnosis depending on the experience and cognitive judgment of the pathologist. Such reasoning processes do not lend themselves to the same types of statistical evaluation as do voluminous aggregations of numerical data. Nonetheless, from its beginning, the College has not been hesitant to confront the subtler challenges involved in assessing the exercise of expert judgment.

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*Autopsy* Pathologists are unique among physicians in their knowledge and understanding of the anatomic manifestations of disease, gained historically by anatomic dissection in the performance of autopsies. Most of the well-recognized pathologists of the 19th century, such as Rudolph Virchow and Karl Rokitansky, were anatomic pathologists, as were many of their most visible 20th-century colleagues, including William Boyd and Ludvig Hektoen (both among the CAP's earliest honorary fellows). So, for that matter, were virtually all of the founders of the College of American Pathologists. It is perhaps surprising, therefore, how little mention of the autopsy is made in the earliest records of the College, and how unfocused its earliest autopsy-related activities were, even though an Autopsy Committee had been appointed by January 1949. This committee's first recorded project was to provide advice to the writer of a popular article on the autopsy that appeared in a July 1949 issue of *Collier's* magazine.<sup>1</sup>

In 1959, the College spearheaded the publication of a 10-page document, *Suggested Guide for Procedures and Ethics Relating to Autopsies*, co-published with the American Medical Association (AMA), American Hospital

Association, Catholic Hospital Association, National Funeral Directors Association, and the National Select Morticians. Its preamble contains the following statement which indicates the importance that the College attached to the autopsy: "The usual purpose of the autopsy is to secure all of the facts that can be obtained by examination of the dead body which bear on the diseases, injuries or other abnormalities that affected the person during his lifetime. The high standards of American medicine are and will continue to be dependent to a large degree on the frequency and care with which autopsies are performed."

Possibly some of the College's early complacency in this realm can be traced to the fact that in the early 1940s, just before the founding of the CAP, the national average autopsy rate for patients dying in hospitals was approximately 50 percent. In some institutions the procedure was almost routine. In the 1950s, an autopsy rate of 20-25 percent was required for accreditation of hospitals and resident training programs. In 1966, the College's Ad Hoc Committee to Study the Autopsy was empowered by the Board of Governors to approach the Joint Commission on Accreditation of Hospitals (JCAH) with a suggestion that the JCAH autopsy percentage requirement be dropped, in favor of a standard which would stress that the quality of autopsies and their systematic use in monitoring the quality of medical practice were more important than a simple quantitative requirement. In the early 1970s, the JCAH did drop its defined percentage requirement. However, the College's suggested emphasis on autopsy quality appears to have been disregarded in the meantime; the new JCAH requirement simply substituted a permissive "appropriate" autopsy percentage, and hospital autopsy rates plummeted. Among other issues adding to the decline was the failure of the Medicare program to recognize autopsy as a medical procedure that benefited a Medicare recipient. According to the National Center for Health Statistics, the autopsy rate had dropped to 14 percent in 1982; a survey by the CAP Committee on Anatomic Pathology confirmed percentages of 15.0 percent in 1983 and 13.2 percent in 1984. One of the authors reports, from personal knowledge, 1996 rates of 5 percent and 15 percent in two major teaching hospitals.

As the frequency of autopsies declined, the College began to stress the importance of the autopsy as a quality assurance measure for all of medicine. Educational activities were undertaken to improve the performance of autopsies by pathologists and to educate the public about their importance. Government agencies and insurance companies were also approached to secure funding to support this important activity to monitor and improve medical care.

As part of this effort, guidelines were developed by the College for the post-mortem diagnosis of several diseases caused by environmental or industrial factors. In 1975, criteria were formulated for the diagnosis of pneumoconiosis and black lung disease, a common cause of death and disability in coal miners. A study of the relationship of asbestos and pleural plaques was funded and undertaken by the College in the early 1980s.

The establishment of a National Autopsy Data Bank (NADB) was first approved by the Board of Governors in 1977. It was hoped that this would become the most comprehensive repository of diagnostic data in the United States, and would serve as a resource for a wide range of scientific and research projects. Improving the quality of mortality statistics was another major goal. Because of the perceived national importance of the NADB, additional funding from the National Center for Health Statistics was sought in 1979, but not achieved.

Under the NADB project, autopsy diagnoses from cases contributed by participating pathologists were to be encoded by the College using the *Systematized Nomenclature of Medicine* (SNOMED). Efforts to bring the project to fruition continued until 1987, but eventually failed due to the inconsistent terminology used by pathologists, making SNOMED coding impossible. Noble in its original intent, the main legacy of the NADB

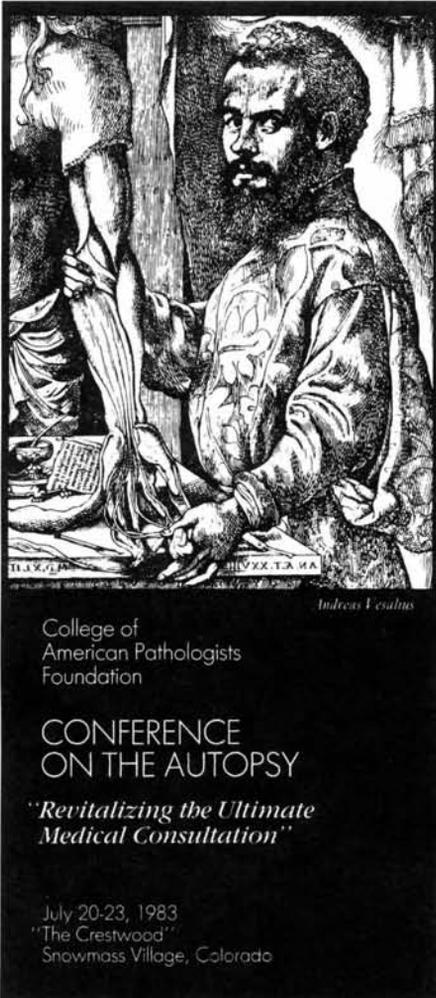


Fig 8-1. Brochure for 1983 CAP Foundation Conference on the autopsy.

was to clarify the need for improvement in the diagnostic reporting of autopsy findings and for a standardized death certificate in the various states; the latter did in fact occur in some states.

In the early 1980s, College leaders recognized that CAP efforts to gain general acceptance of the medical value of the autopsy had been largely unsuccessful up to that point. Nonetheless, the professional medical literature still gave solid support for the importance of the autopsy in areas such as clinical quality control, diagnostic accuracy, and reliability of death certificates.<sup>2-4</sup> Against this background, the CAP Foundation decided to devote the second of its new series of national invitational conferences to the autopsy, dubbing autopsy “the ultimate medical consultation”<sup>5</sup> (Fig 8-1). The College, meanwhile, made overtures to enlist the cooperation of the National Academy of Sciences (NAS) and the National Institutes of Health (NIH) in restoring the autopsy to its appropriate role in medical practice.

In 1984, a presentation was made to the NAS Institute of Medicine by the US National Committee of the International Council of Societies of Pathology (on which the College was represented), arguing that a national autopsy policy was essential if the United States was to maintain its preeminent world position in medical research. The Institute of Medicine (IOM) agreed with the merits of the proposal, and estimated that a budget of \$460,000 was necessary to develop such a policy. The College was asked to solicit funds for the project, since IOM funds were not available; the concept died when foundations approached to provide funding declined to do so.

A concomitant proposal to the National Institutes of Health was based on the NIH's preeminent role as the major source of funding for health care research, and in particular, through the National Cancer Institute (NCI), as a sponsor of numerous experimental protocols for the treatment of cancer. The CAP, in concert with the American Society of Clinical Pathologists (ASCP), argued from the premise that critical information on the efficacy and complications of experimental treatments was lost if autopsies were not performed on patients who died while participating in such studies, and proposed that a minimum autopsy rate be required for NCI funding of experimental treatment protocols. This proposal was initially well received, but in the end suffered the same fate as the NAS proposal.

In contrast to the declining prestige of the autopsy in health care circles, public interest in medical subjects rose dramatically in the last quarter of the 20th century, as the lay press reported the newest scientific discoveries even before the medical journals in which they were introduced reached the physicians for whom they were intended. This public interest extended even to information about individuals and their medical situations. In 1987, a Massachusetts newspaper sought access to the autopsy reports of three state hospital patients who had died under allegedly suspicious circumstances, arguing that the reports were subject to the disclosure requirements of the state's public records act. Eventually, the case reached the Appeals Court

of Massachusetts, and the College filed an *amicus curiae* brief supporting the contention of the state's chief medical examiner that autopsy is a medical procedure, and that autopsy findings deserved the same privacy protections as other patient medical data. Reversing a previous county court decision, the Appeals Court blocked access by the newspaper to the findings, declaring that an autopsy was indeed a medical procedure and that such records should not be publicly available.

In the 1990s, the Autopsy Committee turned its attention to the preparation of guidelines for the performance of autopsies and other publications on related topics. The products of this effort include the manual *Autopsy Performance and Reporting* and a videotape entitled *Safety Precautions for the High-Risk Autopsy*, both released in 1990; *Introduction to Autopsy Technique* and the *Medical Cause of Death Manual* in 1994; and a 1996 update of the *CAP Handbook for Post-mortem Examination of Unidentified Remains*, first published in 1986. CAP Conference XXIX, held in May 1995, was entitled *Restructuring Autopsy Practice for Health Care Reform*,<sup>6</sup> and a new brochure for lay readers, *Autopsy: Aiding the Living by Understanding Death*, was published in late 1996.

The recent trend toward formal published practice guidelines for various areas of medicine (discussed more fully in a later section of this chapter) has also been reflected in the Autopsy Committee's output; to date, guidelines on autopsy performance, autopsy reporting, and autopsy procedures for the brain, spinal cord, and neuromuscular system have been published in *Archives of Pathology & Laboratory Medicine*<sup>7-9</sup> and as separately available reprints.

**Forensic Pathology** In its efforts to promote the autopsy, the College did not neglect the forensic branch of the science. The first CAP Committee on Forensic Pathology was appointed in 1952, only five years after the College's founding.<sup>10</sup> The new committee listed its "most pressing problems" as the development of standards for state medical-examiner legislation, the establishment of a certificate in forensic pathology under the American Board of Pathology (a goal achieved in 1958), and improvement of forensic pathology training in undergraduate medical school curricula.

When the National Registry of Forensic Pathology was formed in 1958, the Board of Governors appropriated funds for its support. In November 1960 the CAP Board endorsed a resolution from the newly-formed Assembly, "recommending the establishment of an active teaching division in Forensic Pathology...in all medical schools of the United States." A fellowship in forensic pathology was also funded by the College at the Armed Forces Institute of Pathology, a position initially filled by Philip J.G. Quigley, MD in 1960. Dr. Quigley, still an active member of the College at this writing, was apparently the only recipient of this fellowship, and no further reference to it can be found in CAP records.

By 1970, under the leadership of Russell S. Fisher, MD, then chair of the Forensic Pathology Committee, an effort was underway to secure outside support for enhanced residency and post-graduate training in forensic pathology. This initiative came to fruition in 1972 with grants from the US Justice Department Law Enforcement Assistance Administration and from the National Institute of Criminal Justice. The former grant enabled the College to fund a number of forensic pathology fellowships for pathology residents for several years during the mid-70s; the latter supported a multi-year series of training seminars for practicing pathologists throughout the country. This program was continued through the late 70s with College support following the expiration of the federal grant, and was also expanded to include seminars focusing on the needs of non-pathologist and non-physician coroners and medical examiners.

As has often been the case, the interest of an individual member served as the stimulus for the development of a specific College program in forensic pathology. William J. Reals, MD, president of the College in

1971–1973, held an active reserve commission in the United States Air Force, eventually attaining the rank of Brigadier General, and was frequently involved in the investigation of military aircraft accidents. Largely through his efforts, a standard form for reporting autopsies of aircraft accident victims was formulated and approved in 1965. The College also published Reals's manual *Medical Investigation of Aviation Accidents* in 1968, followed by a revised and expanded version, *Aerospace Pathology*, in 1973. At this writing the College's list of current publications includes the *Handbook of Forensic Pathology*, first released in 1989.

**Surgical Pathology** Most early educational programs in surgical pathology used slides prepared by the individual or institution presenting the program. Surgical pathology slide seminars were presented by most of the existing pathology societies in the years preceding the formation of the College. Examples are the ASCP Anatomic Pathology slide seminars, begun in 1934, and those of the International Academy of Pathology (now the United States and Canadian Academy of Pathology). The early regional educational programs of the College also followed such formats. In addition, organizations such as the Armed Forces Institute of Pathology and the National Cancer Institute distributed slides of tumors to pathologists in the late 1940s and early 1950s, efforts that were supported by the College as well.

A major force behind surgical pathology activity in the College has been the Cancer Committee, established in the mid-1960s and chaired initially by past College President David A. Wood, MD, and later by Robert V.P. Hutter, MD. The founding of this committee appears to have been an outgrowth of a long-standing tradition of CAP representation on the Cancer Committees of the American College of Physicians and the American College of Surgeons. In 1971, the American College of Radiology (ACR) initiated a Patterns of Care Study under its Radiation Therapy Oncology Group (RTOG), and invited Dr. Hutter as a representative of the CAP Cancer Committee to meet with that group. Thus began a long and productive relationship with the ACR.

In 1978, this working relationship was formalized by the creation of a joint ACR/CAP Patterns of Care Steering Committee on Cancer in Pathology Practice. One of its purposes was to advise the ACR Patterns of Care project; it also began to develop guidelines for the minimum amount of data to be recorded by pathologists when examining specimens of breast and urinary bladder tumors and Hodgkin's disease. Three task forces, one devoted to each type of lesion, were impaneled for this project, each composed of pathologists from small and large community hospitals, university settings, and private office practice. Plans called for other pathologists to be surveyed by questionnaire to determine the acceptability of the proposed criteria in practice; practitioners in other clinical disciplines were also to be consulted about the guidelines prior to publication.

In 1981, a slightly different structure emerged with a new "Committee on the Pathologist as a Consultant in Cancer Patient Management," established as a sub-committee of the CAP Cancer Committee. Encompassing the previous task forces but functioning independently of the RTOG, this group was responsible for producing guidelines, later called practice protocols, to provide appropriate diagnostic consultation for selecting patient therapy, estimating prognosis, and evaluating outcomes. The specimen reporting guidelines for cancer of the breast and urinary tract and for Hodgkin's disease were approved by the CAP Board of Governors in August 1985, and published in the February 1986 issue of *Pathologist*.<sup>11</sup> A comprehensive new series of protocols was subsequently initiated under the guidance of Donald E. Henson, MD, with the first publications on colorectal carcinoma and prostate cancer appearing in the *Archives of Pathology & Laboratory Medicine* in February 1994 and August 1994 respectively.<sup>12-13</sup> This series will include 39 tumor sites when completed. At this writing, three additional protocols have been published during 1995 and 1996;<sup>14-16</sup> eight others are being prepared for publication; and the remaining 26 have been developed and await appropriate

committee review, Board approval, and publication. These protocols are useful for ensuring the quality and completeness of pathologic examinations for diagnostic and therapeutic guidance.

**Cytopathology** There is perhaps no area of pathology in which the College has played a more central role in the development of a discipline than cytology. Less than 18 months had passed since the CAP's founding when the first discussion of cytology appears in College records. The first official policy statement regarding cytology was not issued by the College until 1950, although concerns expressed by other organizations about this discipline had been addressed in previous discussions by the Board of Governors.

In 1948, the American Cancer Society (ACS) questioned the wisdom of accepting cytologic diagnoses without confirmatory histologic study. The ACS also condemned the diagnosis of smears by technicians without adequate supervision from physicians. A statement made in the same year by the scientific director of the American Registry of Pathology was prescient in anticipating some of the problems in cytologic diagnosis that plague this aspect of pathology to the present: "The Papanicolaou technique, for example, valuable as it is under proper conditions, may be the prelude to tragedy. We all know how difficult it is at times to determine malignancy from a satisfactory biopsy. How much more difficult, then, to base a decision as to necessity for a major operation on the appearance of a few isolated cells, especially if the person conducting the examination is less than expert."<sup>17</sup>

As the potential benefits of gynecological cytologic examinations for women were recognized, several state health departments began to offer free services, and other central cytology centers were established, raising several concerns on the CAP Board. The first College policy statement on cytology, adopted in early 1950, emphasized that it was essential for clinicians requiring cytologic diagnostic services to have access to consultation with the cytopathologist; and therefore, that "mail order" cytology diagnosis and inadequate supervision of technologists were both unacceptably dangerous.

The American Registry of Pathology's Registry of Cytologic Diagnosis and an Intersociety Cytology Council were both supported by the College in the early 1950s. A CAP Committee on Exfoliative Cytology was formed in August 1954, and in another policy statement in 1956, the Board urged pathologists to provide cytology and confirmatory pathology services to indigent patients *pro bono*.

Also in 1956, the Board of Governors urged the ASCP Board of Registry to establish certification of cytotechnologists, and suggested that the American Board of Pathology (ABP) establish subspecialty certification in cytology for pathologists. In October 1956, the ACS, which had been "accrediting" cytology training by providing funding for students at certain facilities, urged the College and/or the AMA to assume responsibility for formal accreditation of training programs in conjunction with the ABP. The CAP Board agreed to assume this responsibility on an interim basis.

During 1957, the CAP Committee on Exfoliative Cytology developed standards and a suggested curriculum for schools of cytotechnology, as well as criteria for certification of cytotechnologists. Students applying for entry to such schools were to have completed at least two years of college. They were then to complete six months of training in an approved school followed by six months of supervised experience to be eligible for the certification examination. In late 1957, the College provisionally approved 25 training programs. The "Essentials for Schools of Cytotechnology," including a provision that the director be a pathologist with at least three years of cytology experience, were approved in 1958. The ASCP Board of Schools assumed responsibility for the accreditation of schools on January 1, 1961.

The College also undertook to educate physicians about the benefits of cytology. Late in 1958, a brochure presenting guidelines for the use of cytology was sent to every physician in the United States, as well as to

medical students. It was also included as an insert in the *Bulletin* of the ACS, as well as being distributed in Canada. The total cost to the College for this project was \$29,000.

David A. Wood, MD, a former president of the College, in 1960 decried the hesitancy of pathologists to embrace cytology, and voiced concern about the many gynecologists without cytology training who were hiring technicians to screen slides in their own offices. The demand for services was outstripping the ability to screen smears. Approximately 3,000,000 women were screened in 1960, and a College survey indicated that pathologists had screened 5,100,000 cases in 1961. The ACS had set a goal of screening 25,000,000 women by 1962.

The passage of the Clinical Laboratories Improvement Act of 1967 (CLIA-67) marked the entry of the federal government into the regulation of cytology practice. In 1972, the program of the Centers for Disease Control (CDC) to implement cytology proficiency testing, as mandated by CLIA-67, drew objections from the College. Among the areas of concern were the adequacy and uniformity of slides for such testing; the CLIA requirement for "on-site" testing; and the required rescreening of 10 percent of normal cervical cytology smears, which the College considered to rest on questionable scientific grounds. A January 1976 CAP policy statement stressed that cytology examination was an intrinsically collaborative activity, yielding a diagnostic result that combined the expertise of the cytotechnologist and the pathologist in a laboratory; that the practice of rescreening 10 percent of normal smears could generate a false sense of security or accuracy; that rescreening could serve to evaluate part of the technical process, but its use and extent should be at the discretion of the pathologist; that the major role of the pathologist should be for review of "non-normal" cases and quality assessment; and that it was of paramount importance that cytology diagnostic information be carefully correlated with clinical and biopsy data.

In December 1977, the CAP Board affirmed the "Standards of Quality Control in Cytopathology" previously adopted by the House of Delegates. It is noteworthy that these standards incorporated procedures which are still valid twenty years later. Among these were principles concerning the qualifications and continuing education of professional personnel; assessment of continued competence by an annual review of the diagnostic patterns within the laboratory and in comparison to peer laboratories; and review of previous cytology smears for correlation of findings. Also addressed were histologic confirmation of abnormal results, and the importance of making certain that patients received clinical consultation on atypical findings; criteria for a pathologist's review of slides; and recommendations on how to handle inadequately prepared slides.

Late in 1987 a two-article series by Walt Bogdanich in the *Wall Street Journal* changed the public's perception of cytology quality and presented new challenges to the College. The articles detailed serious errors in cytologic diagnoses, primarily in so-called "Pap mills," citing lack of adequate supervision of overworked cytotechnologists and their frequent practice of screening slides in their homes, or elsewhere outside a laboratory environment. This and other critical media coverage, coupled with Congressional hearings leading to the passage of the Clinical Laboratories Improvement Amendments of 1988 (CLIA-88), resulted in a number of College initiatives related to cytology.

The *Wall Street Journal* series shook the confidence of American women in the accuracy of their cytology diagnoses. Fearing that this negative publicity would cause women to forego Pap smears, with a resultant increase in the number of women developing invasive cervical carcinoma, the College quickly initiated a public relations program early in 1988, stressing the importance of regular examinations. A brochure on cytology, providing guidance in the selection of a quality laboratory, was compiled and promoted through public service announcements, which included a toll-free telephone number.

An expanded policy statement on quality control in cytology was also issued by the College in 1988. The importance of an adequate smear was stressed, as was the need for pathologists to consult with the attending physician for clinical information and correlation. Also included was the need for an adequate number of well-trained cytotechnologists, and review of previous smears in high-risk patients.

The statement also endorsed the principle that laboratory personnel participate in an interlaboratory review program, a tacit acknowledgment that the proficiency testing in cytology mandated in CLIA-88 would indeed occur. Earlier in 1988, the CAP Board of Governors had approved the conversion of the cytology portion of the Performance Improvement Program (discussed below) into an inter-laboratory comparison program, to become known as PAP. The Bethesda System for Pap reporting was subsequently endorsed, as was a recommendation that women have an annual Pap smear (although other organizations were recommending a three-year interval for such examinations after three negative studies). The 1990s also witnessed more stringent inspection of cytology departments by the CAP Commission on Laboratory Accreditation; in addition, a 1996 CAP Conference, with nearly 400 participants, was devoted to quality and liability concerns connected with the Pap smear.<sup>18</sup>

**Practice Guidelines** The policies and publications of the College, referred to in this and other chapters of this history, all constitute guidelines for the practice of pathology. The original impetus for their formulation has been to improve medical practice for the benefit of patients, and can be traced back as far as the policy on surgical pathology examinations and reports adopted by the CAP Board of Governors in 1955 (see pages 139–140). In the mid-1980s, however, attempts by the federal government and other third-party payers to curtail health care expenditures became another driving force behind practice guidelines. The Tax Equity and Fiscal Responsibility Act (TEFRA) of 1983 established Diagnosis Related Groups (DRGs) that provided one lump sum payment to a hospital, based on average cost for all services needed to care for a Medicare beneficiary with a specific diagnosis, rather than reimbursement based on the actual cost of procedures performed for a particular patient. In this environment, the emphasis in the laboratory shifted to the selection of the fewest but most essential examinations to properly care for a patient. Early in 1986, the College published *Effective Laboratory Testing*, listing the most appropriate laboratory examinations for each of the 25 most common DRGs, which together accounted for 80 percent of admissions to hospitals.

In the early 1980s, the National Blue Cross/Blue Shield plans, in conjunction with the American College of Physicians, began the development of medical necessity guidelines, published under the title *Common Diagnostic Tests: Use and Interpretation*.<sup>19</sup> Written almost entirely by internists, ignoring the input of pathologists and the College, they included not only recommendations for clinical laboratory tests, but also proposed guidelines for examination of surgical specimens, several of which were misleading or incorrect. The College voiced strong opposition to these guidelines, and William B. Zeiler, MD, president of the College in 1987–1989, convened a consensus conference in the spring of 1989 in response to their publication. A major goal was to put forward the principle that when clinical guidelines were compiled which involved the practice of other specialists, those specialists should be consulted and involved in their development.

The federal Agency for Health Policy and Research was established in 1988 with a mandate to develop practice guidelines to be published in the *Federal Register*. Fearing the development of rigid guidelines without adequate medical input, the AMA organized a multi-specialty Forum and Partnership on Practice Parameters in 1989. The Forum was to be an umbrella policy-making body with a limited number of societies, including the College, as members; the Partnership was open to any medical society wishing to participate in guideline development. The term “parameter” was chosen over “protocol” and “guideline” in the hope of preserving some degree of professional discretion for the physician treating the patient, rather than implying a single required diagnostic and/or treatment regimen.

Subsequently, the Committee on Practice Guidelines was formed in the College under the leadership of Guy Glenn, MD, a member of the Board of Governors. This Committee was to: a) review guidelines produced by other organizations for possible endorsement or rejection; b) offer the College's assistance to other organizations as they developed guidelines to ensure proper pathology input; and c) develop parameters to guide pathology practice for use by CAP members, or to be incorporated into guidelines produced by other entities.

The committee established a mechanism to assure that any guideline published by the College would have been appropriately reviewed by pathologists in the various committees, the House of Delegates, and the Board of Governors. Several practice parameters have been produced by the College, covering topics including hemochromatosis, the use of fresh frozen plasma, and laboratory panel testing for screening asymptomatic adults.<sup>20-22</sup>

*Assessing the Art of Judgment* In contrast to the relatively objective numerical outputs characterizing much of clinical laboratory practice, the endpoint of anatomic pathology diagnosis involves the "subjective" judgment of the pathologist, and is less amenable to quantification and statistical analysis of accuracy. "Judgment, like art and taste, is an integrated complex of facets which may or may not be definable, and are often not even recognized or understood."<sup>23</sup>

The College's approach to assessing the judgment and diagnostic accuracy of pathologists in anatomic pathology can best be described as cautious. In 1950 the CAP Board had discouraged the National Advisory Cancer Council from conducting a national survey on the accuracy of histologic diagnosis, on the unexplained grounds that "the time was inopportune" for such a survey. In 1969, however, the Standards Committee reported to the House of Delegates that it had reconsidered previous decisions not to develop programs to evaluate pathologists' accuracy in histology and cytology, stating "...it is evident that proficiency testing in these areas must be developed by the appropriate professional society..." The Board gave approval to the concept in August 1969, and a Standards Committee sub-committee on Histopathology and Cytology first met in March 1970 to commence work on these projects. Since that time, this committee and its successors, including the present Surgical Pathology and Cytopathology Committees, have carried on a noteworthy effort to document the state of the art of anatomic and cytopathologic diagnosis.

The original sub-committee on Histopathology and Cytology consisted of Herbert Derman, MD, chair; Donald W. Penner, MD; Leopold G. Koss, MD; James D. Barger, MD; Robert W. Morrissey, MD; and Martin Hicklin, MD. This committee determined that its charge was to seek and test a means to evaluate proficiency in histopathologic and cytologic diagnosis, and that any evaluation method should reflect the laboratory's actual performance in patient care.

The first significant challenge in this effort was the scarcity of previous models upon which to draw. From 1957 through 1962, the New York State Association of Public Health Laboratories had conducted cytology testing by distributing "unknown" slide sets from cervix, sputum, and effusions.<sup>24</sup> Either Dr. Koss or Thomas Simon, MD, both cancer specialists from the Memorial Hospital for Cancer and Allied Diseases in New York City, would then discuss the cases and provide the "correct" diagnoses at regional meetings. In 1968, the Board of Education of the College of Pathologists of Australia began a survey program in which participants received slides and brief clinical summaries of a series of cases; the "correct" interpretations, with a discussion of each case and a tabulation of pathologists' responses, were then returned to the participants.<sup>25</sup> While both of these schemes had considerable educational value, their disadvantages included a lack of standard nomenclature, the absence of any mechanism to assess the effect of diagnostic performance on patient care,

and the fact that the “correctness” of responses was judged only against that of the individual selecting the cases.

The initial concept of the CAP committee was to select panels, each consisting of three expert histopathologists, to deal with breast tumors, endometrial lesions, lymphoma, and cytopathology. Participants were to submit slides from their patient files for comparison of their diagnoses with those of the experts. It was also contemplated that the experts would prepare slides of cases from their practices to send to the participants for diagnosis.

However, because of concern about the possible difficulty of finding experts with sufficient time to evaluate these slides, and particularly about establishing standards to measure satisfactory performance, the subcommittee turned to W.J. Youden, PhD, a renowned statistician from the National Bureau of Standards who had previously consulted with the CAP Standards Committee on evaluation of Surveys. It was Dr. Youden who had first pointed out that truth is more closely approximated by the mean of many different analyses than by the analyses of a few reference laboratories. The committee was also favorably impressed by his published statement that “It seems a more simple and a more scientific approach to insist that the precision has to be measured under conditions that correspond to those that operate when the procedure is used in regular work...” rather than under optimal conditions.<sup>26</sup> Dr. Youden advised that instead of panels of experts, the entire pool of contributed diagnoses should be used as the criterion against which to judge individual performance—in effect, that all the contributors of cases should be used to check each other’s work.

To Dr. Youden’s recommendation was added a concept of statistical modeling based on concurrences among peers, proposed by B.L. Parnell, chief of the Biometry Branch of the Armed Forces Institute of Pathology. Drawing on this background, the committee began a pilot project known as Histopathology I. Each of 50 volunteer pathologists, divided into five groups of 10 each, was asked to submit 10 duplicate slides (with reports rendered anonymous) of each of the first breast lesion, lymph node biopsy, epithelial skin tumor, abnormal liver, and endometrial lesion accessioned after July 1, 1970. The slides, in sets of 50, were then circulated to the pathologists in each group for diagnosis using an appropriate *Systematized Nomenclature of Pathology* (SNOP) code. This procedure allowed each volunteer’s original diagnosis to be evaluated alongside his/her diagnoses of the cases submitted as unknowns.

Important lessons were learned from the pilot project, which guided further development. Consensus was more easily achieved in breast lesions and skin tumors, where few diagnostic terms were in use, than in liver, lymph node and endometrium cases, where differences in nomenclature abounded. One participating pathologist, at least, was less than enamored of the effort, observing in a letter to Dr. Barger that “To me, a pathologist who makes diagnoses on 10 liver slides without clinical data is demonstrating rapport with the Almighty, not proficiency in histopathologic diagnosis.”

Nonetheless, the committee was able to formulate four fundamental criteria to guide any possible proficiency testing program in the art of diagnostic judgment: 1) It should evaluate routine diagnostic performance by using slides and diagnoses from actual patient files; 2) A common nomenclature should be used; 3) Performance must be measured against an objectively derived diagnosis as the standard, avoiding arbitrary diagnoses and passing grades, as well as all appearances of “gamesmanship”; 4) The program must be economically and logistically feasible. These criteria remain as valid today as when they were developed.

A successor project, Histopathology II, was designed to determine if interlaboratory comparison of performance in anatomic pathology was possible, and whether peer diagnosis was comparable to that of recognized experts (Olympians) in the field. Five hundred laboratories volunteered to participate in Histopathology II. One hundred laboratories were randomly selected and asked to submit slides from 10

**Histopathology II:  
Peer Performance on Benign and Malignant Cases**

Peer Status	Criterion		Peer Majority Diagnosis	
	Olympian Diagnosis Proportion	%	Proportion	%
Submitter	973/994	97.9	975/989	98.6
Participant	9681/9940	97.4	9690/9890	97.7

Table 8-1.

consecutive breast cases accessioned after a certain date. The 1,000 slides were divided into 10 groups of 100 slides each, which were then reviewed by the laboratories in a group as well as by two experts. If there was disagreement between the two experts, a third expert was called on to review the case. The impressive correlation between peer consensus and Olympian diagnoses is illustrated in Table 8-1; in sum, the performance of the average pathologist in diagnosis of breast lesions was equal to that of the experts.

The format of this study suffered from slowness; slides, diagnoses, and critiques were all sent by what today is known as "snail mail," and participants found that the educational benefits were diluted by the long intervals between their examination of slides and receipt of the diagnoses. However, the procedural pattern set in Histopathology II continued until 1984, with studies in prostate, cervical cytology, and effusion cytology added to the breast studies.

In 1984, the Histopathology and Cytology Committee shifted from the previous model to one that chiefly emphasized education, rather than after-the-fact performance



**Benign?  
Malignant?  
Specific Diagnosis?**

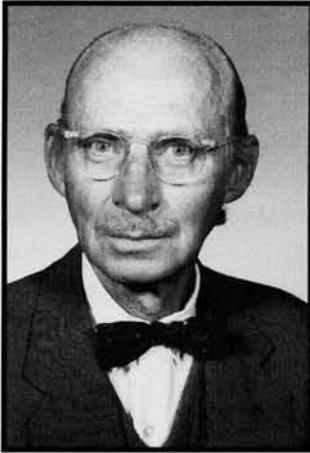


**Compare YOUR diagnoses with PEER diagnoses and with EXPERT diagnoses by participating in the College of American Pathologists' totally new Performance Improvement Program in Diagnostic Surgical Pathology and Cytopathology**



**College of American Pathologists**  
7400 N. Skokie Boulevard  
Skokie, Illinois 60077  
312-677-3500

Fig 8-2. Brochure announcing the Performance Improvement Program (PIP) in Diagnostic Surgical Pathology and Cytopathology, 1984.



*Fig 8-3. Donald W. Penner, MD (b. 1918), whose efforts were crucial in launching PIP.*

evaluation. From the massive number of cases which had been collected up to that time, some 1,500 were selected in which there had been sufficient disagreement on diagnoses that an educational effort focusing on those particular types of lesions was deemed appropriate. These cases were used to launch a new Performance Improvement Program (PIP) in Diagnostic Surgical Pathology and Cytopathology, inaugurated with 200 founding laboratories in its first year (Fig 8-2).

Under PIP, sets of slides representing 60 cases annually were circulated to participants, who returned them to the College after their review, as well as submitting 16 new cases a year from their own files. Experts on the subject prepared critiques and Kodachrome slides on these cases which were sent to and retained by the participants as soon as they had returned their diagnoses to the College. Educational programs based on these cases were also presented at the spring and fall meetings of the College, and today remain among the most well attended of all those offered. A large part of the success of this phase of the program is due to the efforts of Dr. Penner, who spent essentially an entire summer reviewing slides for possible PIP use, and to whom a major debt of gratitude is owed (Fig 8-3).

In 1989, the program underwent still another metamorphosis. The committee members began to select cases in which sufficient material had been furnished to allow slides to be retained by the participants following their examination. Pertinent histories and a set of questions to be considered were included with each of the 40 slides in the annual series. Following the participants' review, a critique giving the diagnosis, pertinent histologic findings, differential diagnoses, and other information was sent as follow-up.

While this format has proven exceptionally popular, it has some limitations. The practical limit in numbers is the requirement for some 30 to 40 tissue blocks from a single case to prepare about 2,000 slides. This skews the case mix in favor of larger specimens, and effectively excludes small biopsy material from the program. The committee attempts to ensure that each slide is of high quality and contains diagnostic features typical of the case. However, it is interesting to note that even when a slide is judged less than optimal, there is great likelihood of a correct diagnosis being made by the pathologist, probably indicating that the program duplicates "real life" practice to a large degree.

The year 1988 was a milestone for the cytology portion of the Performance Improvement Program. The Surgical Pathology and Cytopathology Committee began assembling gynecologic smears contributed by members' laboratories for what would become known as the PAP program. The 15 members of the committee met on three occasions to screen some 2,000 slides for a pilot program serving 207 laboratories in 1989. In 1990, the Cytopathology Committee became free-standing when the College made a commitment to expand PAP to accommodate all members who wished to participate in the program. The history of the Cytopathology Committee from 1990 to the present provides an incredible demonstration of the devotion and dedication of individual pathologists and cytotechnologists to improving the practice of cytology without concern for personal gain or aggrandizement.

The committee continued to meet during 1990–1991 to screen additional slides. The CAP Board's commitment to guarantee enrollment in PAP to any laboratory submitting case material brought a massive influx of slides to the committee. In response, the committee held longer and more frequent meetings, and invited

guest reviewers to participate in slide screening sessions. These reviewers included pathologists and cytotechnologists whose laboratories had submitted many high-quality slides to the PAP program, as well as others recommended by committee members. A full-time cytotechnologist was also added to the CAP headquarters staff in 1995.

During 1996, 25 committee members and guests met seven times to review more than 10,000 slides, bringing the total number of slides in the program to nearly 35,000. Thanks to this extraordinary effort, the Board's commitment of guaranteed PAP enrollment for all contributors was met. As of January 1, 1996, enrollment in PAP or an equivalent program became a requirement of the College's Laboratory Accreditation Program. At this writing the Cytopathology Committee is developing a similar program for non-gynecologic cytology, having now screened some 5,000 slides.

**Conclusion** Throughout its history, the College's efforts to achieve demonstrable objective improvement in clinical laboratory performance have been paralleled by comparable efforts in the various areas of anatomic pathology—a realm in which the assessment of performance can seem especially treacherous and “subjective.” By treading cautiously but confidently on such difficult ground, the College has convincingly demonstrated the breadth and depth of its commitment to the continuing pursuit of excellence. Dr. Penner described in 1983 the College's pursuit of excellence in assessing the art of judgment: “A quantum leap will be required to get from where we are now to where the Committee believes it will be a decade from now. The magnitude of this task is frightening until we remind ourselves that it will be achieved one step at a time with the willing help of many, for the College has an enviable record of commitment to the betterment of pathology.”<sup>27</sup> The quantum leap was made!

## Notes

1. Ewing MB. Autopsy. *Collier's*, 1949 Jul 23:30,40.
2. Scottolini AG, Weinstein SR. The autopsy in clinical quality control. *JAMA*. 1983;250:1192.
3. Goldman L, Sayson R, Robbins S, Cohn LH, Bettman M, Weisberg M. The value of the autopsy in three medical eras. *N Engl J Med*. 1983;308:1000-1005.
4. Gobbato F, Vecchiet F, Barbierato D, Melato M, Manconi R. Inaccuracy of death certificate diagnoses in malignancy: an analysis of 1405 autopsied cases. *Human Path*. 1982;13:1036-1038.
5. Bowman HE, Williams MJ, King DW, et al. College of American Pathologists Foundation conference on the autopsy: revitalizing the ultimate medical consultation. *Arch Pathol Lab Med*. 1984;108:437-512.
6. Hutchins GM, McLendon WW, eds. College of American Pathologists Conference XXIX on restructuring autopsy practice for health care reform. *Arch Pathol Lab Med*. 1996;120:733-781.
7. Hutchins GM, CAP Autopsy Committee. Practice guidelines for autopsy pathology: autopsy performance. *Arch Pathol Lab Med*. 1994;118:19-25.
8. Hutchins GM, CAP Autopsy Committee. Practice guidelines for autopsy pathology: autopsy reporting. *Arch Pathol Lab Med*. 1995;119:123-130.

9. Powers JM, CAP Autopsy Committee. Practice guidelines for autopsy pathology: autopsy procedures for brain, spinal cord, and neuromuscular system. *Arch Pathol Lab Med.* 1995;119:777-783.
10. Larson CP. History of the CAP Forensic Pathology Committee. *Pathologist.* 1976;30:23-25.
11. Guidelines for data to be included in consultation reports on breast cancer, bladder cancer, and Hodgkin's disease. *Pathologist.* 1986;40:18-23.
12. Henson DE, Hutter RVP, Sobin LH, Bowman HE. Protocol for the examination of specimens removed from patients with colorectal carcinoma. *Arch Pathol Lab Med.* 1994;118:122-125.
13. Henson DE, Hutter RVP, Farrow G. Practice protocol for the examination of specimens removed from patients with carcinoma of the prostate gland. *Arch Pathol Lab Med.* 1994;118:779-783.
14. Nash G, Hutter RVP, Henson DE. Practice protocol for the examination of specimens from patients with lung cancer. *Arch Pathol Lab Med.* 1995;119:695-700.
15. Scully RE, Henson DE, Nielsen ML, Ruby SG. Practice protocol for the examination of specimens removed from patients with ovarian tumors. *Arch Pathol Lab Med.* 1995;119:1012-1022.
16. Hammond EH, Henson DE. Practice protocol for the examination of specimens removed from patients with carcinoma of the urinary bladder, ureter, renal pelvis, and urethra. *Arch Pathol Lab Med.* 1996;120:1103-1110.
17. CAP Secretary's Newsletter. 1948 Jun;2:6.
18. Austin RM, McLendon WW, eds. College of American Pathologists Conference XXX on quality and liability issues with the Papanicolaou smear. *Arch Pathol Lab Med.* 1997;121:227-342.
19. Sox HC, ed. *Common Diagnostic Tests: Use and Interpretation.* 1st ed. Philadelphia, Pa.: American College of Physicians; 1987.
20. Witte DL, Crosby WH, Edwards CQ, Fairbanks VF, Mitros FA. Hereditary hemochromatosis. *Clinica Chimica Acta.* 1996;245:139-200.
21. Fresh-Frozen Plasma, Cryoprecipitate, and Platelets Administration Practice Guidelines Development Task Force of the College of American Pathologists. Practice parameter for the use of fresh-frozen plasma, cryoprecipitate, and platelets. *JAMA.* 1994;271:777-781.
22. Glenn GC, CAP Laboratory Testing Strategy Task Force. Practice parameter on laboratory panel testing for screening and case finding in asymptomatic adults. *Arch Pathol Lab Med.* 1996;120:929-943.
23. Derman H, Chandler FW, Hicklin MD, Penner DW. Anatomic Pathology. In: Inhorn SL, ed. *Quality Assurance Practices for Health Laboratories.* Washington, DC: American Public Health Association;1978:390.
24. Derman H. Analysis of the Association's five-year cytology program. *Proceedings of the New York State Association of Public Health Laboratories.* 1961;41:12-14.

25. Reports of Surveys. Sydney, Australia: College of Pathologists of Australia;1969, 1970, and 1971.
26. Youden WJ. *Statistical Techniques for Collaborative Tests*. Washington, DC: Association of Official Analytical Chemists;1969:26.
27. Penner DW, Bradford S, Hyman MP, Koss LG, Soule EH, Derman H. Taking a quantum leap in histopathology and cytopathology. *Pathologist*. 1983;37:777-779.

## Chapter Nine

# Ethics and Professional Relations

Loyd R. Wagner, MD

The purposes for which the College of American Pathologists was founded were reflected in the organization's initial constitution, adopted at the December 1946 meeting in Chicago, Illinois, which marked the birth of the College. Among them was that of "foster[ing] the highest standards in...the practice of Pathology." At the organizational meeting of the Board of Governors in January 1947, several committees mandated in the original constitution and bylaws were appointed, including an Ethics Committee. The initial members of this committee were three Governors—F. William Sunderman, MD as chair, Ward H. Cook, MD, and Everett L. Bishop, MD.

*The Code of Ethics* Virtually every professional society at that time had an ethical code to guide its members, and the College was not to be an exception. During the early months of 1947, the committee drafted a Code of Ethics, which was discussed at length by the Board of Governors at its meeting of May 18, 1947. Approved in concept, the Code was referred back to the committee for revision of its details, which took place during the summer of 1947.<sup>1</sup> The Code was then reviewed by the Chief Justice of the Supreme Court of Pennsylvania, a friend of Dr. Sunderman. Submitted to the College's membership at the first general meeting of October 27, 1947, the Code was approved unanimously and published in the November 1947 *Secretary's Newsletter*. By the early part of 1948, copies of the Code of Ethics suitable for framing were sent, along with Certificates of Membership, to each member of the College (Fig 9-1).

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copies of the Code of Ethics  
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The preamble to the Code of Ethics called for members of the College to adhere to the "Principles of Medical Ethics" of the American Medical Association (AMA).<sup>2</sup> Then followed eight "Canons" that set forth rules of conduct to assure cooperation with colleagues for the benefit of the sick and injured. These canons dealt with courteous relations between pathologists; required reporting of laboratory and pathology results to physicians instead of patients; and prohibited fee-splitting with referring physicians, as well as competition on the basis of fees. One canon prohibited acceptance of a salaried position with a "for-profit" institution; others dealt with laboratories operated by non-physicians, and forbade the acceptance by a CAP member of a position with any entity that did not abide by the Code of Ethics of the College.

## Original CAP code of ethics

*I affirm my adherence to the "Principles of Ethics" of the American Medical Association and my determination to practice the profession of medicine and the specialty of pathology in accord with them. That my services may be of the greatest benefit to the sick and injured, and to that end, to ensure the fullest measure of cooperation with my colleagues, I also agree to adhere to the following canons of professional ethics:*

*I shall not solicit, knowingly permit others to solicit in my behalf, nor shall I accept a position which is occupied by another pathologist without first consulting with that pathologist.*

*I shall not issue a report on preparations or material from another pathologist's laboratory or from the institution which he serves, without immediately making every reasonable effort to inform that pathologist of the results of my examination.*

*I shall not either directly or by means of any subterfuge divide fees from laboratory services with referring physicians.*

*I shall not compete for laboratory services on the basis of fees.*

*I shall not issue reports to patients except when requested to do so by the patient's attending physician.*

*I shall not participate, directly or by means of any subterfuge, in an arrangement whereby an individual not regularly licensed to practice medicine is encouraged to operate a clinical or pathological laboratory.*

*I shall not accept a position with a fixed stipend in any hospital, clinic, or sanitarium which is owned and operated for profit by an individual, partnership, or corporation; however, I may be affiliated with such an organization as a private physician practicing my specialty and receiving fees for service.*

*I shall not accept a position in any hospital or other medical organization which does not conform to such relationships between the institution and the pathologist as may be approved by this College.*

Responsibility for monitoring compliance with the Code of Ethics was assigned to the Ethics Committee. In 1948, an additional Committee on Hospital and Institutional Relations (H & I R) was established to deal with members' relationships with hospitals, other laboratories, and other pathologists; this committee focused largely on contractual details. But because the College's ethical canons were inevitably reflected in the contracts of pathologists, it was only natural that there would be frequent overlap and confusion between the roles of the two committees. Neither of the two nor the Board of Governors, however, suffered from a lack of issues in this arena. The minutes of each entity, as well as many of the early publications of the College, are replete with details of alleged ethical breaches and contractual problems.

The earliest effort by the CAP to widen support for one of the canons in the Code of Ethics is recorded in the December 1947 *Secretary's Newsletter*. A resolution had been passed by the CAP Board in May of that year, requesting the AMA to alter its "Essentials of a Registered Hospital" by including a

Fig 9-1. The original CAP Code of Ethics, adopted October 27, 1948.

statement that "It shall not be the policy of the hospital to make a profit from the Department of Pathology."<sup>3</sup> At the AMA's January 1948 meeting, a resolution to this effect was introduced, along with another recommending that the AMA "Council on Medical Education and Hospitals refuse approval for training of residents and interns [in] any hospital exploiting professional medical service."<sup>4</sup> Both were ultimately referred to a special committee of the AMA Board of Trustees, charged to meet with representatives of the hospital community in an effort to resolve issues concerning the corporate practice of medicine by hospitals and their alleged exploitation of hospital-based physicians.

**Compensation Issues** During the late 1940s and early 1950s, the College became directly involved with a number of issues regarding how, and how much, a pathologist should be paid. Early in 1949, the College accepted an invitation to make an official inspection of the 22 New York City municipal hospitals, in response to concerns about understaffing of pathology departments and low salaries paid to pathologists.<sup>5</sup>

This matter continued to absorb a goodly portion of the College's attention through the next several years, ending without resolution in late 1951 when the city of New York declared it had no funds with which to raise salaries.

The policy of the College in regard to pathologists' compensation during the 1940s and 1950s was clearly to oppose the acceptance of a fixed salary. The CAP's efforts were directed at relating compensation more directly to the pathologist's professional activities and the volume of laboratory services rendered. In the case of pathologists practicing in hospitals, the College promoted direct billing of patients for pathology services, as well as percentage contracts, under which the pathologist's compensation consisted of a specified percentage of the laboratory's total revenues. The percentage contract concept apparently gained support from an unexpected outside source as well.

According to past CAP President and Historian Frank C. Coleman, MD, a major impetus for incentive-based compensation came from the Catholic Hospital Association (CHA).<sup>6</sup> Concerned about a public perception that the quality of care in Catholic hospitals was inferior to that in non-Catholic institutions, the president of the CHA convened a committee to study ways to improve the public image of Catholic hospitals. This study suggested that improvement of the pathology and radiology services was the first step in elevating the level of care in hospitals, and that an incentive compensation arrangement would attract the best-qualified professionals in these areas. To this end, percentage contracts were recommended by the CHA, although acceptance by member hospitals was slow.

The College's efforts to alter compensation arrangements with hospitals were hampered by provisions in most health insurance contracts. Payments for pathology and clinical laboratory services were usually included in hospital service contracts, rather than in contracts for physicians' services. The College was only partially successful in achieving changes in insurance contract language to include pathology services as physicians' services.

During this period, the College actively promoted the concept that states should require pathologists to be licensed physicians, and should recognize pathology as the practice of medicine. Many states still allowed pathologists to practice without medical licensure, and this state of affairs caused problems for the CAP Membership Committee, as licensure was required for CAP membership. In June 1952, the Board of Governors adopted a definition of pathology to guide those in the various states who were seeking enactment of this legislative requirement. This definition read, in part "...the practice of human pathology is that specialty in...medicine which may contribute to the diagnosis, treatment, observation and understanding of the progress of disease...by means of information obtained by morphologic, microscopic, chemical, microbiologic, serologic or any other type of laboratory examination...."<sup>7</sup> Attorneys-General in several states, such as New York, assisted the College's efforts by declaring officially that pathology was the practice of medicine.

Meanwhile, the Ethics Committee received and investigated numerous complaints about unethical conduct. In general, the committee concerned itself with individual issues rather than focusing on broad policy matters; most of the complaints involved contractual difficulties between pathologists and hospitals. In several instances, members of the Ethics Committee consulted directly with the members involved and their hospital administrations to resolve disputes. As of the end of 1949, 25 cases were under review by the committee, many of them involving pathologists who had accepted salaried positions. Confusion as to how to handle the salary issue was apparent, however. For example, there was disagreement on the definition of a "for-profit" institution, since under the language in the Code of Ethics, it was only in such institutions that members were forbidden to accept salaried positions.

There is evidence that the College attempted to control other aspects of individual pathologists' behavior as well. For example, in June 1959 the Board of Governors referred to the Ethics Committee, as an ethical violation, the case of a member who testified in court against the use of Drunkometers because substances other than ethanol could decolorize potassium permanganate, which was used in these devices. The disposition of this case is not recorded.

In 1952, the Ethics Committee and the Hospital and Institutional Relations Committee presented a joint proposal to the Board of Governors to produce a brochure to guide residents and young pathologists in contract negotiations. Approved by the Board, the proposal led to the publication in 1954 of the first CAP *Manual of Contractual and Ethical Relations*. This first edition contained a detailed exposition of the Code of Ethics; addressed terms to be covered in a written contract; and described four methods of compensation. These included lease of the department; independent contractor status; a percentage arrangement; and finally a salary, but only if it represented the total profit from the laboratory. The *Manual* has been revised several times since 1954, and every effort has been made to avoid antitrust problems that may have been associated with earlier versions. The current version available to members of the College is the *Professional Relations Manual, 10th edition* (1992).

The Board of Governors and other committee members were not always unanimous on issues of ethics and contracts. In early 1952, a conference was proposed at Columbia University on hospital/pathologist relations and the role of university departments in the private practice of pathology. Some CAP Board members expressed concern that it could be detrimental to the profession for pathologists to participate in a meeting which also included hospital administrators and other non-pathologists. A motion was made to bar the officers of the College and other members from attending the conference. The Board eventually voted to discourage attendance by members, although a significant minority including David A. Wood, MD, president of the College, defended the right of any pathologist to attend, feeling that the Board's action infringed upon the Constitutional right to assembly, and had possible antitrust implications.

Contracts and ethics, though they loomed large, were not the only professional relations concerns of the College during this period. In response to widespread allegations of unnecessary surgery, the American College of Surgeons in 1953 proposed the establishment of tissue committees in hospitals to monitor surgical quality. The College voiced several objections to the proposal: It did not believe that tissue diagnosis was the only measure of surgical quality, and maintained that other clinicians as well as pathologists should be involved in such evaluations. The College also objected to the hospital-based pathologist being placed in a "policeman's" role when, as was generally the case, she or he was named to chair the committee.<sup>8</sup> Tissue committees became a fact of life, however, when the Joint Commission on Accreditation of Hospitals included them in its requirements for an accredited hospital.

*The Iowa Hospital Association Case* In the mid-1950s, the College became involved in a case which had broad implications for compensation of pathologists, their contractual arrangements, and the corporate practice of medicine. This case arose from a Blue Cross/Blue Shield contract that denied benefits for anesthesia to employees of a Waterloo, Iowa, packing company unless the anesthesiologist was a hospital employee. The Iowa Medical Society immediately recognized the implications of such provisions for other hospital-based specialists, particularly radiologists and pathologists. The Iowa Attorney General, responding to a request from the Iowa Board of Medical Examiners, ruled in 1954 that pathology and radiology were the practice of medicine, and that neither for-profit nor non-profit hospitals could provide these services themselves since to do so would constitute the illegal corporate practice of medicine.

IN THE DISTRICT COURT OF THE STATE OF IOWA, IN AND FOR POLK COUNTY, MAY TERM, 1955.

IOWA HOSPITAL ASSOCIATION, et al.,	)	
	)	
Plaintiffs,	)	
	)	
vs.	)	
	)	Equity No. 63095
IOWA STATE BOARD OF MEDICAL EXAMINERS, et al.,	)	
	)	Transcript of Evidence.
Defendants,	)	
	)	
IOWA STATE MEDICAL SOCIETY, a Corporation,	)	
	)	
Intervenor.	)	
	)	
.....		
<b>A P P E A R A N C E S:</b>		
HERRICK, LANGDON & SIDNEY, by A. A. Herrick & Herschel Langdon,		
		for the plaintiffs,
LEHMANN, HURLBURT, BLANCHARD & CLESS, by Phillip Cless & John A. Blanchard,		
		for the defendants and intervenor.
Case called for trial at 9:15 a. m., May 19, 1955,		
a regular day of said Term, before the Honorable C. Edwin Moore, Judge.		
Warren E. Beach William C. Stanton Official Shorthand Reporters 415 Court House Des Moines, Ia.		

Fig 9-2. Opening page of court transcript from the Iowa Hospital Association lawsuit, May 1955.

The Iowa Hospital Association (IHA), disagreeing with this ruling, attempted in various ways to isolate the three specialties from the rest of medicine and from each other; pathologists were particularly targeted by IHA efforts to circumvent the ruling. One of these efforts involved separate reimbursements for the professional and technical components of pathology services. When this tactic failed, the IHA and 28 Iowa hospitals filed suit in January 1955 against the Attorney General, the Iowa Association of Pathologists, the Secretary of the Iowa Board of Medical Examiners, and Frank C. Coleman, MD, then president of the Iowa Association of Pathologists (later to be president of the College in 1960–1961). The suit sought to restrain pathologists and the Board of Medical Examiners from abiding by the Attorney General’s ruling (Fig 9-2).

The Iowa pathology community called for financial support from the College in defending against the suit, but the issue proved extremely controversial among the Board of Governors and no CAP funds were committed. The Board did, however, authorize the filing of an *amicus curiae* brief,

and later in the year funds from a voluntary solicitation of pathologists were also supplied. The decision of the court, handed down late in 1955, supported the position that all of pathology was the practice of medicine and that corporations in Iowa could not practice medicine. The significance of this decision for the recognition of pathology as the practice of medicine cannot be overstated.

In February 1957, the Hospital and Institutional Relations Committee suggested the establishment of a surgical pathology evaluation service to investigate complaints of incompetence lodged against pathologists. The proposal was carefully scrutinized and discussed at the Board level, particularly with regard to its organizational structure and reporting mechanisms; it was then referred back to the committee for more study.<sup>9</sup> No further action on the proposal is recorded, and throughout the ensuing years the College has avoided establishing any programs which would involve it in evaluating the competency of individual pathologists.

However, during the 1950s, numerous advisory statements concerning business practices were issued. The College took positions favoring *pro bono* performance of laboratory examinations for hospital employees, and direct billing of hospital patients or insurance carriers for pathology services. It opposed fee-splitting with referring physicians, the use of patient revenue for research, and acceptance of tissues directly from lay practitioners and osteopaths. In the early 1960s, the solicitation of physicians for laboratory referrals by national laboratories, ownership of laboratories by non-physicians, and advertising were all officially condemned by the College.

*The CAP Antitrust Case* Late in 1965, the US Justice Department opened an investigation of possible antitrust violations by the College and issued a subpoena for documents relating to the enforcement of the Code of Ethics. In July 1966, a formal antitrust action was filed in the federal district court in Chicago, alleging violations of the Sherman Antitrust Act. The complaint was amended in February 1967.

The College was the only defendant in the suit. However, various unspecified groups, firms, corporations, organizations and individuals, including all members and Fellows of the College, were named as co-conspirators. The complaint alleged that the College had violated the antitrust laws by (a) attempting to ensure that all laboratories be owned by and operated solely for the profit of pathologists; (b) forbidding pathologist-owned laboratories to compete on the basis of price in the sale of services; and (c) attempting to force all non-pathologist-owned and -operated laboratories out of business. The complaint also alleged that, acting through the College, pathologists had attempted to monopolize laboratory services by (a) agreeing to refuse employment or affiliation with any non-pathologist-owned laboratory; (b) refusing salaried positions unless all laboratory profits went solely to the pathologist; and (c) fixing prices for laboratory services. The alleged antitrust violations were said to have raised costs for clinical pathology services and thereby harmed patients.

The first response of the Board of Governors to the suit was to mobilize a legal defense team. In July 1966, the Board also imposed a \$50 per member assessment for a legal defense fund, and requested added voluntary contributions. Canadian pathologists were exempted from the assessment, which most other members reportedly paid.

The discovery phase of the Justice Department investigation continued through 1967 and most of 1968. Voluminous files were produced at the request of the government, including all records of the Ethics Committee dating back to 1950; depositions were also taken from College officers and others. At the December 1968 meeting of the Board, legal counsel was authorized to meet with the Justice Department regarding a possible settlement of the case.

Meetings between representatives of the College and the Justice Department continued through the next several months, and a special meeting of the Board was set for April 26, 1969, to discuss a draft of a proposed consent decree. At that meeting, settlement on the basis of the draft proposal was authorized by the Board, with the proviso that no announcement would be made to the general membership of the College until the document had been signed. A meeting of the Assembly, which all CAP members were invited to attend, was also scheduled to take place in Chicago on July 26, 1969.

Word of the settlement leaked, however, and a number of protests were lodged with the Board, including one from the Florida Association of Pathologists. Still, by the time the July Assembly meeting convened, most members were under the impression that it had been called to discuss whether or not the case should be settled. When the president, Oscar B. Hunter Jr., MD, announced that the consent decree had been finalized approximately two weeks earlier on July 15, 1969, a good deal of controversy was generated. Dr. Coleman characterized the result as “a disaster.”<sup>10</sup> That assessment may not have been universally shared, but it is clear that some members felt they had not been allowed to participate in the settlement process to the degree that they wished to be.

In August 1969, as one step in implementing the consent decree, the Board voted to suspend Canons 4, 6, 7, and 8 of the Code of Ethics until such time as they could be revised to meet the concerns of the Justice Department.<sup>11</sup> This task was entrusted to a special committee, which instead recommended that the Code be

abolished entirely and replaced by a simple declaration that CAP members are bound by the *Principles of Medical Ethics* of the AMA, leaving matters of individual physician ethics in the hands of local medical societies. This course of action was affirmed by the general membership of the College at the Spring Meeting of February 1970.

The signing of the consent decree did not end the controversy on the Board or among the members over the wisdom of doing so. In a 1986 interview, Dr. Coleman estimated that half of the College's membership (himself included) opposed the decree. In June 1970, the Texas Society of Pathologists repudiated the agreement, passing a resolution severing all ties with the College—an action that prompted a further inquiry from the Justice Department. Some members believe to this day that the consent decree should not have been signed, despite the slim chance of a successful defense against the Justice Department suit, projected legal costs estimated to run well over \$1,000,000, and the threat of severe financial penalties to the College and its members if the effort failed.

It is important to understand the exact provisions of the consent decree and what they do and do not mean for the College and its members. The consent decree contains no admission by the College that any of the allegations in the complaint were true. The College and its members are “enjoined and restrained” from any and all of the following actions:

- 1) Restricting in any manner any person from owning or operating a laboratory, referring specimens to any laboratory, performing services for any person, or associating with any laboratory.
- 2) Preventing any person from accepting advertising or exhibiting at any meeting.
- 3) Boycotting any laboratory.
- 4) Limiting any compensation arrangement.
- 5) Fixing fees in any manner.

The agreement further required the College to amend its bylaws within six months to eliminate any clause inconsistent with the above provisions.

Equally important are the actions which the consent decree specifically *permits*. The College may adopt lawful, reasonable, and non-discriminatory standards for the operation or accreditation of laboratories, provided that programs administering such standards are open to all laboratories. Sanctions may be imposed against College members found to be deficient in moral character or professional competence, or guilty of professional misconduct. Finally, the College may require its members to report laboratory and pathology results only to physicians or others permitted by law to receive such results.

In addition to amending the bylaws, other actions were needed to comply with the consent decree. In February 1970, the Ethics Committee was disbanded and replaced with a Committee on Professional Relations. The Hospital and Institutional Relations Committee was also faced with the task of revising the *Manual of Physician and Hospital Relations*. Previous references to the CAP Code of Ethics were removed from the manual, and examples of several types of acceptable contracts were included without promoting any one paradigm. A disclaimer had already been inserted in the 1967 *Manual*, in response to the passage of Medicare in 1965, to the effect that the alternative contracts presented therein were not in conflict with CAP policy.

The importance of providing guidance for CAP members in professional relations and contractual matters was not diminished after issuance of the consent decree. In fact, the significance of these issues grew in the post-Medicare era, as the College sought to assist members in an increasingly complex regulatory and economic environment. During the Congressional debate connected with the passage of Medicare in 1965, the College was heavily involved in questions about introducing a professional/technical split in pathology billing, and whether pathologists should be paid for clinical pathology services under Medicare Part A (hospital services), Part B (physician services), or a separate Part C. The focus of professional relations activities regarding Medicare compensation rapidly shifted to the College's National Legislative Committee, and to the Washington office of the College, opened early in 1970.

Exactly how payment for clinical laboratory services was to be made remained unclear when Medicare went into effect in 1965, and practices around the country varied. Some pathologists were allowed to bill and were paid for their services under Part B. In 1975, Senator Herman Talmadge of Georgia introduced a bill that would have effectively banned percentage, lease, and direct billing contracts for hospital-based physicians. It would have mandated fee-for-service payments for directly provided services as agreed by the hospital, and compensation on a salaried basis for supervisory activities. In response to the contractual provisions in the Talmadge bill, the CAP Board in 1976 affirmed as College policy that any type of contract should be allowed as long as it did not entail exploitation of the patient, the institution, or the pathologist.

Ultimately the Talmadge bill was defeated, thanks in large part to the efforts of a broadly representative task force impeded by the CAP and ASCP. In 1980, however, the Health Care Financing Administration (HCFA) published regulations that also prohibited payments under Part B of Medicare for services of pathologists in directing laboratories unless the pathologist personally performed a procedure or reviewed its results. These regulations were struck down by the federal district court in Little Rock, Arkansas, as the result of litigation initiated by the College. (These topics are treated in greater detail in Chapter 10.)

*Professional Relations and Compensation in the 80s and 90s* Not long after this victory, the Tax Equity and Fiscal Responsibility Act (TEFRA) of 1983 was passed by Congress. TEFRA instituted Diagnosis Related Groups (DRGs) governing payment for hospital services to Medicare beneficiaries; payment for clinical laboratory services was included in the DRG rates. With TEFRA, many of the proposals in the failed Talmadge bill had in fact been enacted into law.

Following the publication of TEFRA regulations on March 2, 1983, the CAP determined to seek an injunction preventing their implementation. While the College eventually lost this suit, several favorable modifications in HCFA's approach to payment for clinical pathology services were made. However, pathologists had to adapt to a system which mandated payment for supervision of the clinical laboratory from Part A of Medicare, and limited payment under Part B to services that met specific regulatory criteria. (This lawsuit is also covered in more detail in Chapter 10.)

The enactment of TEFRA, the imposition by the government of a clinical laboratory fee schedule, proposals for competitive bidding for lab services, and the development and use of a Resource Based Relative Value Schedule (RBRVS) for pathology services all had a negative impact on payment to pathologists under Medicare. In addition, methods of payment set for Medicare patients were sometimes adopted by private insurance companies for other patients as well. Although DRGs were intended to include payment by hospitals to pathologists for clinical laboratory supervision, a number of hospitals refused to compensate pathologists for these activities. These hospitals began to demand that the pathologist supervise the clinical laboratory without payment in exchange for the right to practice and to bill for anatomic pathology in that institution.

The preservation of clinical pathology as a specialty became a major goal of the College in the mid- to late 1980s. Negotiations with the HCFA in the late 1980s and early 1990s were successful in establishing a limited list of clinical pathology tests for which payment was to be allowed under Part B of Medicare for the pathologist's interpretation. The benefits were hardly noticeable, however, as other assaults continued on professional component billing as a viable compensation option for pathologists. Some third party payers were not content with simply denying payment to pathologists for the professional component of clinical laboratory services; they further sought to prevent pathologists from billing patients for those services. Notable among these was the Central States Pension Fund, which provides health benefits for workers associated with the Teamsters Union and is regulated under the federal Employee Retirement Income Security Act (ERISA).

In June 1992, Central States filed suit against Pathology Laboratories of Arkansas in federal district court in Chicago, alleging that the Pension Fund was not required to pay for the pathologist's professional component charge unless a direct, "hands-on" service was performed. The suit further alleged that Central States beneficiaries could not be required to pay pathologists directly for such charges, and that the defendant pathologists should be required to repay all amounts that Central States had previously paid for professional component charges. Pathology Laboratories of Arkansas filed a counterclaim against Central States over these issues and claimed the company had defamed them by telling patients that they had provided no services. Meanwhile, Central States filed approximately 50 similar suits against other pathology groups. Because of the potential adverse impact of this litigation on all of pathology, the College committed funds and other legal support to assist the defendant pathologists in this case.

The trial judge declared on June 30, 1994, that Central States indeed had discretion to deny payments for professional component services, that Central States could seek to enjoin pathologists from billing patients for such services, and that it could seek to recover past payments. Briefs were subsequently filed addressing (a) whether the court should enter an injunction barring Pathology Laboratories of Arkansas from billing patients and (b) whether Central States was entitled to recoup payments previously made for clinical pathology services. A different trial judge ruled after a trial on April 17, 1995, that although Central States did not have to pay a professional component for clinical pathology services, the ERISA law did not prevent Pathology Laboratories of Arkansas from billing patients for the professional component. The court also ruled that Central States was not entitled to restitution of payments previously made to the pathology group.

Central States appealed this ruling on June 26, 1995. On December 1, 1995, the United States Court of Appeals for the Seventh Circuit ruled in favor of Pathology Laboratories of Arkansas. The decision established that pathologists who direct laboratories (a) provide "supervisory services of value to all patients, and interpretation services of value to some" and (b) are entitled to be paid for those services. This was the first time such a position was upheld in an appellate court, and the decision had beneficial implications for all of pathology.

The appellate court decision against Central States did not halt the Fund's assault on professional component billing, however. Letters to pathologists from Central States indicated that it would provide legal defense for any of its beneficiaries who were subjected to collection proceedings for non-payment of pathologists' charges for clinical pathology. At this writing, other challenges to pathology compensation are also being countered by the College. The most significant is a class action lawsuit against two pathology groups in Peoria, Illinois, alleging that professional component charges are fraudulent, and seeking repayment of all such charges to all patients for several previous years. The College is supporting the defense of these two

groups, since the results would be devastating for pathologists if the plaintiffs' position prevails. Indeed, if the Peoria pathologists lose, it can be anticipated that similar litigation will be brought against numerous other pathology groups around the country that have used professional component billing. [Ed. note: This case was decided in the defendant pathologists' favor on April 14, 1997.]

The history of the College in the area of ethics and professional relations demonstrates its ongoing commitment to the establishment of pathology as the practice of medicine, and to the improvement of pathology services to patients by ensuring the economic viability of the profession. While early efforts in this area ran afoul of the antitrust laws and resulted in a consent decree with the US Department of Justice, the courts have also provided support for some pathology positions in recent years. Thoughtful action by the College and guidance to pathologists in professional relations are essential if the College and its members are to continue their "Pursuit of Excellence" for the benefit of patients and the public.

## Notes

1. Sunderman FW. Oral history interview, 1985 Apr 13.
2. *Principles of Medical Ethics*. Chicago, Ill.: American Medical Association;1937.
3. CAP Board of Governors Minutes, 1947 May 18:4. Hereafter referred to as "Minutes."
4. CAP *Secretary's Newsletter*, 1948 Jan:2.
5. Minutes, 1949 Jan 16:1.
6. Coleman FC. Oral history interview, 1986 Jun 23.
7. Minutes, 1952 Jun 7:2.
8. Minutes, 1953 May 30:29.
9. Minutes, 1957 Feb 17:109-115.
10. Coleman FC. Oral history interview, 1986 Jun 23.
11. Minutes, 1969 Aug 22:2.

## Chapter Ten

# Legislation and Regulation

Jerald R. Schenken, MD  
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From its beginnings, the College of American Pathologists has had as one major focus the socioeconomic standing of the profession. Indeed, one of the three original objects of the College, as stated in its Constitution, includes “improvement of the economic aspects of the practice of Pathology.” As years have passed, factors including local and national legislation, medicolegal issues, and third-party reimbursement have begun to have increasingly negative effects on both the economics of the profession and its ability to provide quality pathology services to patients. Thus, it was to be expected that the College would become progressively more involved in these areas.

*Legislative and Regulatory Committees* The original CAP Legislative Committee was definitively established by the Board of Governors in February 1952, following the passage of a somewhat ambiguous motion at its June 1951 meeting that “a suggestion be made to the President” to assemble such a committee.<sup>1</sup> The first chair of the committee was Francis C. (Frank) Coleman, MD, an exceptionally versatile leader of the CAP, later to become its president in 1960–1961. By the testimony of those who worked with him—including the senior author—Dr. Coleman was especially gifted at dealing productively both with the personalities of dedicated but individualistic professionals and with the vagaries of legislative and bureaucratic processes. He was succeeded in turn by Oscar B. Hunter Jr., MD (1956–1961) and Robert S. Haukohl, MD (1961–1964).

*The College's efforts on  
the legislative and  
regulatory fronts  
remain on the cutting edge  
as the CAP enters its second  
half-century of service to patients  
and the profession.*



The Legislative Committee was originally charged with the task of gathering information relevant to legislative affairs and disseminating it to state pathology societies for their use in political interaction with state legislatures and health departments. It may be difficult to appreciate this scenario after 30 years of federal dominance in the socioeconomic affairs of medicine in general and pathology in particular. However, in those days, the states were the principal arenas of legislative and regulatory action affecting the health professions. (This may well become the case again, as a trend toward deregulation and federal block grants to cover a variety of health care programs seems to be gaining momentum throughout the nation.)

The names and functions of CAP bodies charged with legislative and regulatory affairs have changed over the years due to the changing milieu in which the College has existed, as well as to changes in the overall organization of the CAP itself. In 1964, the Legislative Committee was divided into separate national and state committees, which existed in one form or another until 1973. The change appears to have been made in response to the impending enactment of the Medicare Law in 1965, and this decision proved over time to be very well-considered.

Early in 1973, these committees were replaced by a single Committee on Legislation and Related Affairs, reporting to a more broadly charged Council on Government Affairs that also oversaw the College's Committee on Forensic Pathology and other CAP activities in the legislative and regulatory realms. The name of this body was changed in 1975 to Council on Government Relations and Liaison. This modification was in response to changing conditions within the federal bureaucracy and the larger arena of organized medicine; the term "liaison" reflects the College's increasing recognition of the crucial importance of close coordination with other organizations—notably the major umbrella medical organization, the American Medical Association (AMA)—given the status of pathology as a small and relatively inconspicuous specialty. Under the purview of this council, separate national and state committees came into being once again, chaired respectively by the senior author and by Phillips Gausewitz, MD. In 1978 these committees were again replaced by a single body, the Legislative and Regulatory Activities Committee.

In 1981, as part of a comprehensive overhaul of the CAP's volunteer structure, the council became a commission, again overseeing separate national and state legislative committees. In 1983, this commission evolved into the Council on Government and Professional Affairs, chaired initially by Donald A. Senhauser, MD. At its establishment this council oversaw Commissions on Government Relations, Professional Relations, and Public Relations, with Committees on Professional Relations and Third Party Reimbursement reporting to the Professional Relations commission. By 1986, this structure had devolved into a single level including three committees: Government Affairs, Professional Affairs, and Reimbursement. In 1994, the latter two bodies were replaced by a single Committee on Professional and Economic Affairs, and an ancillary State Advisory Committee was added.

*State Legislative and Regulatory Activities* The earliest reported activity of significance undertaken by the Legislative Committee was to evaluate trends in state regulation of laboratories. In 1949, before the committee's establishment, the Board of Governors had already gone on record in opposition to state licensing of medical technologists. In 1953, in response to the committee's initiatives in this area, it took a position against similar licensing of medical laboratories. In the same year, the Board also opposed the enactment of legal requirements for laboratory performance—even a requirement that all tissues removed at surgery be submitted for pathological examination, a principle that the College now supports.

There is no clear record of the reasons for the Governors' opposition to these several proposals. At this period, however, one of the College's highest priorities was to advance the seemingly basic principle that the practice of pathology is indeed the practice of medicine. This concept had been affirmed by the AMA only a decade earlier, and not yet been definitively embraced by the legal establishment. In this environment, any proposals that would have involved licensing laboratories rather than individual practitioners, formalizing the professional standing of non-MD laboratory personnel, or in any way circumscribing the pathologist's professional judgment, tended to be viewed as threats to the still-tenuous recognition of the professional status and autonomy of MD physicians practicing the specialty of pathology. This interpretation would seem to be supported by a slightly later Board resolution on the same subject, passed in May 1961, which stated that "Governmental certification or licensure of any segment of medical practice by non-medical personnel results in division of responsibility in the care of the patient, and is not in the public interest...."

Additionally, the Board's positions would be consistent with the long-standing principle that the best way to assure quality laboratory performance was through voluntary means. It is significant that, while both legislative and regulatory controls on many aspects of laboratory medicine have been in place for years, the backbone or "gold standard" of laboratory inspection and accreditation has come to be the CAP's voluntary program.

One of the pivotal episodes in the early organizational life of the CAP was a contention originally arising in 1955 in Waterloo, Iowa, and known for years in College circles simply as “the Iowa Controversy.” This episode is recounted in greater detail in Chapter 9 (see pages 114–115). In brief, it arose from a Blue Cross/Blue Shield group contract that provided for payment of anesthesiology benefits for insured patients only if the service was rendered by hospital employees. Both the Iowa Medical Society and the AMA speedily recognized the implications of such a provision for other hospital-based physicians, principally pathologists and radiologists. Eventually a lawsuit was filed by the Iowa Hospital Association against several defendants, including the Iowa Association of Pathologists and its then president, Dr. Frank Coleman. The court’s decision, later affirmed by the state Supreme Court, vindicated the position of the medical profession; it held in essence that pathology was indeed a branch of medicine and, as such, could not legally be practiced by corporations, including hospitals. This principle was later enacted into law by the state’s legislature. This case served as a clear demonstration that teamwork and the support of professional organizations offered the best protection against such threats to the integrity of the profession. The lessons of Iowa were remembered and relived often in the coming decades.

During the mid-1960s, the CAP state legislative keyman program, now known as the Key Contact Program, was established at the initiative of the State Legislative Subcommittee. Initially this program was designed to identify and equip pathologists in the several states to work with state legislatures and agencies to articulate the concerns of the pathology community. The role of this program began to decline as health care-related legislative activity began to center more and more on Washington, DC. However, the program was revived with a major infusion of budgetary and staff resources in the early 1980s, and its focus was shifted to the federal level. Today the Key Contact Program involves more than 400 pathologists in communication with key legislators and government administrators.

While the main focus of CAP legislative and regulatory activities gradually moved to the federal level beginning in the 1960s, involvement at the state level continued as well. Over the years, the CAP has been involved in a number of lawsuits on behalf of its members and state pathology societies—whether as an actual party to the action, or as a source of financial and/or legal support. The first recorded action of this type took place in 1964, when the CAP voted to provide any assistance short of financial aid to four Portland, Oregon, pathologists who were named as defendants in a suit filed by United Medical Laboratories, at that time the country’s largest independent medical laboratory. Similar actions during the 1980s include providing financial assistance to the Florida Medical Association in its efforts to gain tort reform legislation in that state (1984); to the California Society of Pathologists, to oppose the proposed repeal of a rule requiring that a hospital clinical laboratory be directed by a pathologist (1986); and to the Tennessee Society of Pathologists to preserve Medicare reimbursement for clinical consultations by pathologists (1989). In the 1990s the College has backed legal efforts in a number of states to preserve professional component billing for clinical pathology.

***Federal Legislative and Regulatory Efforts*** The CAP’s long history of involvement in the federal legislative and regulatory realms begins in the early 1950s with its decision to assist the Armed Forces Institute of Pathology (AFIP—formerly the Army Medical Museum) in obtaining adequate funding and other legislative support from the Congress. Over the years, the CAP has consistently supported the AFIP, often with testimony before Congressional committees, and with generally successful outcomes. One former director of the AFIP, Major General Joe M. Blumberg, MC, US Army, later headed the CAP’s Laboratory Inspection and Accreditation program for 10 years, from 1969 through 1978.

Perhaps the most memorable initiative related to AFIP was a cooperative effort by the presidents of the CAP and the American Society of Clinical Pathologists (ASCP), in concert with other professional societies, to

assist the Institute by establishing a quasi-governmental organization which could accept private funding on behalf of AFIP and assist with its goals and missions. In 1973, a strategy was developed to obtain a federal charter for such purposes. Arthur Silverstein, MD, who had completed his military service with AFIP, was at that time holding a fellowship in the office of Senator Edward Kennedy. Silverstein enlisted the help of Senators Kennedy and Sam Nunn to obtain the passage of a 1976 bill which designated the American Registry of Pathology (ARP) as a 501(c)(3) Foundation empowered to accept research grants and contracts, and to carry on publication and education programs.

Under this new mandate, the *Atlas of Tumor Pathology*, Series II was published by ARP in 28 fascicles from 1976 through 1991. (Series I had been published beginning in 1950 by the National Research Council of the National Academy of Sciences.) At this writing, sales of fascicles from the current *Atlas of Tumor Pathology*, Series III have increased to more than 50,000 copies annually, and the *Atlas* has also been published in CD-ROM format. During the same period, the Registry has greatly expanded its offerings of educational courses, and its involvement in grant-funded research and consultations with civilian institutions. Currently, the listing of courses offered by ARP runs to nearly 50 discrete topics. The ARP's educational offerings have continued to increase in quality and variety, with a number of lectureships, symposia, and seminars including annual offerings at the joint meetings of the CAP and ASCP. Indeed, the CAP's investment in laying the foundation for this enterprise has paid notable dividends.<sup>2</sup>

Without doubt, the pre-eminent arena of cooperation and contention between the College and the federal government has been the Medicare program of federal health insurance for senior citizens, first enacted into law in 1965. This program and its evolving impact on the CAP are described in a separate section (see page 127).

Another major chapter in the College's relations with Washington also opened in 1965 with the initiation of an antitrust investigation by the US Department of Justice, in response to allegedly anticompetitive provisions in the College's Code of Ethics. This investigation and the ensuing litigation are treated in detail in Chapter 9. The matter came to a close with a June 14, 1969, consent decree. Although it proved controversial among the College's membership, the consent decree probably represented the most desirable solution for the College, given the high cost of a court defense, the slim probability of success, and the relatively small impact it has had on College activities. In this connection, it is important to note that the consent decree explicitly permitted the continuation of the laboratory improvement programs that the CAP has so successfully operated before and since.

Following the 1965 enactment of Medicare, the government moved to define its relationships with the laboratories that would provide services to Medicare beneficiaries, by developing "Conditions of Coverage of Services of Independent Laboratories." Congressional hearings convened for this purpose also proved to be the impetus for what would eventually become the Clinical Laboratories Improvement Act of 1967 (CLIA-67), principally authored by Senator Jacob Javits (R-NY). At these hearings, representatives of several federal and state agencies including the Centers for Disease Control (CDC) depicted a crisis in quality in America's clinical laboratories.

The first shot appears to have been fired on February 11, 1966, in testimony by a representative of the US Public Health Service, stating that "premature death, extended hospital stay, unnecessary suffering, and loss of productivity as well as tremendous economic losses are consequences of inaccurate laboratory results. It is conservatively estimated that at least 430 million tests are performed annually with an approximate error rate of 25 percent. At an average cost of \$4 per test, this represents a waste of some \$430 million annually

to the nation in payments for erroneous laboratory diagnostic results. The cost in human life and suffering is beyond monetary measurement.”<sup>3</sup>

A CAP committee appointed to research the charges and develop a response determined that (1) the data cited were not current, and in some cases as much as 20 years old; (2) that the figures cited in the debate were based on statistically unjustified extrapolation from extremely small and unrepresentative samples; and (3) that current data painted a vastly different picture.<sup>4</sup> The CAP forcefully described its programs for laboratory inspection and accreditation, laboratory standards, and quality assurance. It specifically objected to the proposed exemption of physician office laboratories from the “Conditions of Coverage,” which nonetheless included the laboratories of other physicians—notably pathologists—who were the most qualified to direct laboratories. When passed, CLIA-67 ultimately did include specific licensure requirements and other standards for laboratories engaged in interstate commerce. However, it also provided that laboratories could be certified by other national accrediting bodies if the programs of these bodies were officially recognized as “equivalent” by the Secretary of Health, Education and Welfare (HEW). To qualify for such recognition, an accreditation program’s requirements had to be found to be “equal to or more stringent than” the requirements of the CLIA regulations. The CAP was quickly granted equivalency, to the benefit of its members and their patients.

In subsequent years, numerous efforts were made to expand the scope of CLIA-67. The proposed Clinical Laboratories Improvement Act of 1975, also introduced by Senator Javits, would have effectively eliminated the equivalency provision, which by then had proven eminently workable in practice. In September 1975, the CAP’s forceful testimony on this issue was presented to the Health Subcommittee of the Senate Finance Committee by a team headed by President Robert C. Horn, MD.<sup>5</sup> The CAP was successful in restoring the equivalency provision to the bill as reported to the full Senate. (Passed by the Senate, the bill failed to reach a vote in the House, effectively leaving the status quo in place.)

Additional issues pertaining to the scope, nature, and goals of proficiency testing were debated over the next few years in connection with proposed revisions of CLIA in 1976, 1977, and 1979; the College’s positions were generally accepted. However, proposals for unannounced on-site proficiency testing—originating in the CLIA-67 debate and strenuously opposed at that time by the CAP as unproven, ineffective, and probably counterproductive—arose again in 1979.<sup>6</sup> This provision was eliminated from the most recent version of CLIA passed by the full Congress in 1988, but continues to surface periodically to this day.

The concept of political action committees (PACs) was an outgrowth of the Congress’s response to reports of financial abuses in the 1972 Presidential campaign. Under the reforms that followed, candidates were required to disclose the identities of donors and the amounts of their donations; personal contributions were limited, and provision was made for groups (PACs) to be formed to allow pooling of their members’ fiscal assets for political support. The first recorded mention of a College PAC was in April 1978, when the Board of Governors voted that the CAP would not form a PAC of its own, and that College members would be urged instead to support state political action committees and AMPAC, the American Medical Association PAC. This action was taken on the recommendations of the State Legislative Committee and the Council on Government Relations, but the reasons underlying the decision are otherwise unrecorded.

In 1984, as an alternative to a College PAC, the College began its Government Interface program. Still ongoing at this writing, the Interface program brings pathologists to Washington for structured meetings with their members of Congress and Administration officials. Over the course of the program, more than 500 pathologists have participated in these meetings. However, by the early 1990s many medical specialty



Fig 10-1. Brochure announcing the formation of PathPAC, the CAP Political Action Committee, 1992.

societies had active government affairs programs and had created PACs. The importance of grassroots contact had increased, as had competition for the attention of members of Congress. In addition, health policy had moved to the center stage of Congressional and public policy activity, and Congress had changed its internal guidelines to forbid the acceptance of honoraria by its members. This development in turn made it more difficult for members of Congress to attend meetings such as those represented by the Interface program.

In view of these changed circumstances, in August 1992 the CAP Board reconsidered and approved the formation of a College PAC (Fig 10-1). PathPAC provides another means for establishing and maintaining Congressional contact. The effort has remained small by comparison with other PACs and other CAP programs, with participation thus far by about 10 percent of the membership. Nonetheless, PathPAC has been deemed by most observers to be successful.

In the late 1980s, “scandalous” medical laboratory inadequacies were again in the public eye, thanks in large part to a two-part article by Walt Bogdanich in the *Wall Street Journal* late in 1987, detailing widespread deficiencies in diagnostic cytology and in physician’s office laboratories. The outcome of this round of public and legislative scrutiny was the Clinical Laboratories Improvement Amendments of 1988 (CLIA-88), which went beyond CLIA-67 in regulating virtually all medical laboratories, not just those engaged in interstate commerce. It is worth noting, in passing, that neither the *Wall Street Journal* articles nor any of the subsequent Congressional testimony revealed that the CLIA-67 regulations already applied to cytology, and that all cited instances of unsatisfactory performance were already subject to existing federal regulations—which unfortunately had never been implemented by CDC.

In response to the advent of CLIA-88, the CAP worked closely with the AMA and other sectors of organized medicine to develop a classification of laboratory tests based on relative complexity that could address the relevant quality issues, yet permit physician office-based laboratory service without unduly burdensome regulation. In excess of 60,000 comments were received by the US Health Care Financing Administration (HCFA) concerning the proposed implementing regulations for CLIA-88. These regulations required over two more years of successive development and modification. Among the revisions made with CAP input during this process were daily limits on screening workloads, and prohibitions on off-site screening and per-test compensation, often referred to as “piece-work.”<sup>7</sup> The CAP’s involvement in the interface between Congress and the federal agencies on issues raised by CLIA was probably its most complex and time-consuming, requiring close cooperation between the Council on Government and Professional Affairs and all other sectors of the College.

*The CAP and Medicare* The story of Medicare represents a turbulent and yet quite productive era in the history of the CAP. Among other benefits, the Medicare debate served to cement the College's cooperative relationship with the AMA, which would contribute to other CAP successes over subsequent decades.

The saga of Medicare really dates back to 1935 and the passage of the Social Security Act, which included assistance for state public health programs, but no provisions for general medical care.<sup>8</sup> During the next 30 years, a number of legislative proposals for various forms of federal health insurance for the aged were introduced, but none was actually enacted until the 1960 Kerr-Mills Bill, sponsored by Robert S. Kerr (D-OK) and Wilbur Mills (D-AR), which provided medical vendor payments to states that operated public assistance programs. The Kerr-Mills legislation was implemented slowly and inconsistently, and did not significantly retard the impetus toward more comprehensive federal medical insurance financed through Social Security.

The 89th Congress opened the health debate in 1965 with HR-1 and S-1, "Health Insurance for the Aged." The emotional climate was still tense in the aftermath of the November 1963 assassination of President John F. Kennedy, a strong advocate of national health insurance. This circumstance tended to make detailed debate on technical issues more difficult than it might otherwise have been. HR-1 and S-1 both included pathologists' services as hospital services rather than physician services, leading to strong objections from both the CAP and the AMA. It was at this time that the CAP Board voted to hire the College's first Washington lobbyist, Victor Knox, on a short-term contract basis. Mr. Knox, a former member of the House Ways and Means Committee, subsequently facilitated a meeting between the CAP and then-Assistant HEW Secretary Wilbur Cohen, which proved informative but not helpful to the CAP's efforts. Chairman Wilbur Mills of the House Ways and Means Committee, concerned about the costs of the proposed bills, introduced as HR-6675 a modified version which provided for a mandatory hospital insurance plan (Part A) and a supplemental voluntary plan (Part B) to cover "1) Physicians' services; 2) Services and supplies furnished as an incident to a physician's professional service; 3) Diagnostic X-ray tests, diagnostic laboratory tests, and other diagnostic tests." The implicit distinction between "physician services" and "laboratory tests" would cause more than a decade of confusion and conflict pitting the CAP against the federal agencies involved with Medicare.

The Mills bill passed the house; but in the Senate, more than 500 amendments were introduced, including one proposed by Senator Paul Douglas (D-IL) that would have placed pathologists' services under Part A (hospital services). Medicare was eventually passed by the Senate without the Douglas amendment. The House/Senate conference committee charged with reconciling the two versions of the bill then came under heavy pressure to include it, but due to the opposition of Chairman Mills and the efforts of the CAP and AMA, it was also omitted from the final legislation.

Significantly, however, the Douglas amendment debate gave rise to the concept of a "professional-technical split" for purposes of Medicare payments to hospital-based physicians, with Part B paying professional (physician) costs, and Part A paying technical (hospital) costs. It was clear to the CAP that the responsibilities of pathologists were not so easily separated into two components as were those of some other hospital-based specialists. Up to this point, the College had advocated the leasing of hospital laboratories to pathologists as the only viable method for reimbursing pathologists as physicians entirely under Part B. But after careful consideration, the CAP decided to accept the alternative of split payments as well, concluding that this was necessary in order to avert an even more objectionable outcome, the incorporation of pathology services entirely under Part A. This strategy succeeded at the time, but set the stage for another decade of wrangling with the federal bureaucracy over appropriate professional component charges for pathologists under Part B.<sup>9</sup>

Medicare was finally enacted as Public Law 89-97, signed by President Johnson on July 30, 1965. On September 11 and 12 of that year about 300 pathologists gathered in Chicago for a two-day workshop on Medicare sponsored by the College, including material on the program's application to pathology in general, its impact on contractual relations with hospitals, and a report from a CAP advisory committee appointed to work with the AMA and the HEW to draw up implementing regulations for the program. This workshop was repeated at the annual joint meeting of the CAP and ASCP in October; the presentations were then published in large part in the *CAP Bulletin's* first special issue, "Medicare and Pathology," in November 1965.

The CAP was represented on two of the major technical advisory committees established by HEW to develop the necessary regulations to implement Medicare. One of these committees was charged with reviewing the proposed *Conditions for Participation of Independent Laboratories*; the other was one impaneled to refine a set of eight principles for Medicare participation by medical specialists, drafted initially by HEW staff. One principle defined a professional service as one which was distinctly identifiable, "requiring performance by a physician in person"—a standard which was to prove rich in potential for future controversy. Another principle provided that if hospital-based physicians bore the operating costs of a hospital department, they could bill totally under Part B, with Medicare Carriers (Part B) and Intermediaries (Part A) then "reconciling" or allocating costs between the two Parts. This interpretation permitted a leased-laboratory operation, but this option was not actually used by many pathologists in the following years. One problem leasing raised was that of possible adverse tax consequences to not-for-profit hospitals from leasing to a for-profit entity, such as a pathology laboratory. In response to this concern, the CAP Board in 1966 endorsed a recommendation from Idaho pathologist John Broz, MD, to substitute the term "mutual working agreement" for "lease." With this change in place, the groundwork was laid for pathologists' participation in Medicare; but this was far from the only problem that had to be solved.

The issue of an identifiable personal service in clinical pathology testing was more difficult. The AMA and CAP vigorously attacked the division of pathology services into professional and technical components when linked to an arbitrary "identifiable services" requirement. In their final version, the Medicare regulations did permit professional component billing for most if not all services provided by, or under the direction of, the pathologist, even if such billing represented simply a uniform percentage of laboratory charges. For reference in calculating such billings, a revised version of the CAP's relative value schedule (RVS) was released in August 1965. But the turmoil continued. In 1967 a bill was introduced in Congress to separate pathologists and radiologists from other physicians and to treat them differently under a new Medicare "Part C." Again, vigorous opposition by the CAP and the AMA helped prevent this proposal from being adopted; but controversy over the professional-component billing option—by now utilized by large numbers of pathologists—continued to ferment until the introduction of the Medicare and Medicaid Administrative and Reimbursement Reform Act (S-3205) by Senator Herman Talmadge (D-GA) early in 1975.

The Talmadge legislation provided that a procedure must (a) be of such nature as to *require* personal performance by a physician, and (b) be in fact performed by a physician, in order to qualify for reimbursement. This provision would have eliminated much of the professional component billing for clinical pathology services that was then permissible under Medicare. In an attempt to moderate or delete these restrictions, CAP and AMA representatives held several meetings with the Senator and his staff, but little progress was made. In June 1975, the CAP Board of Governors appointed a comprehensive 26-member task force with representatives from a broad range of pathology interests, co-chaired by Dr. Coleman and past ASCP President Vernie Stembridge, MD, to develop a response to S-3205. With the help of several consultants, the task force prepared a strong case supporting clinical pathology as the practice of medicine, and therefore appropriate for Part B reimbursement. Several Georgia pathologists met with Senator Talmadge and his staff at the

College's request; the Senator was also invited to speak at the 1976 CAP Spring Meeting to share his views and engage in dialogue with the College leadership. These measures also failed to produce any substantial change in the Senator's understanding of professional component billing. The arena then shifted to the Senate Finance Committee hearings on the bill.

The task force was instrumental in the preparation of the College's testimony, presented to the Finance Committee on July 29, 1976. By that time, Dr. Coleman had stepped down as task force chair. In his report to the Board, Dr. Coleman noted that "the CAP testified in opposition as did the AMA. Many irrelevant or peripheral issues were introduced during the hearings...including [excessive] pathologists' incomes and attempts to relate surging Medicare expenditures...to...pathologists' incomes." Nor was public media coverage of the hearings always illuminating. One *Washington Post* article spoke of a jet plane supposedly owned and used by the senior author for some of the 300-mile trips necessary to cover his far-flung rural Nebraska practice; the "jet" in question was actually a chartered single-engine Cessna®. Nonetheless, the efforts of the CAP and its allies were largely successful and this portion of the Talmadge bill was defeated, both in 1976 and on its reintroduction the following year (Fig 10-2).



**Fig 10-2.** CAP representatives testify before the US Senate Finance Committee on the Talmadge Medicare and Medicaid Administrative and Reimbursement Reform Act in 1976. Left to right: Jerald R. Schenken, MD; Dennis B. Dorsey, MD; Gen. Joe M. Blumberg, MC, USA Ret.



**Fig 10-3.** Jack R. Bierig, JD, of the Chicago firm of Sidley & Austin, represented the CAP in its successful 1980 Arkansas litigation against the United States Health Care Financing Administration (HCFA), and remains the College's general counsel at this writing.

Meanwhile, however, HCFA had drafted regulations that also prohibited payments under Part B of Medicare for services of pathologists in directing laboratories unless the pathologist personally performed a procedure or reviewed its results. In late 1978, HCFA staff in Region 3, headquartered in Philadelphia, began denying payment for professional component billing for most clinical laboratory services. Lengthy negotiations ensued between CAP representatives and HCFA; late in 1979 the CAP Board voted to seek a legal remedy if HCFA published the proposed regulations.<sup>10</sup> The regulations were in fact published in the *Federal Register* on March 11, 1980, re-imposing substantially the same requirement for "identifiable and personal" services

that had previously been embodied in the Talmadge bill and rejected by the Senate. At this juncture, the CAP Board retained the law firm of Sidley & Austin of Chicago to represent the College in litigation, with Jack R. Bierig, JD, as chief counsel (Fig 10-3).

On May 28, 1980 the CAP—together with the Arkansas Society of Pathologists and two individual Arkansas pathologists—filed suit in United States district court in Arkansas to challenge the HCFA notice. The CAP claimed that HCFA had exceeded its authority; had violated the clear intent of the Medicare Act, as well as its own regulations against interfering with contractual arrangements; and had acted without proper and timely notice. The government strongly resisted this position and also argued that the court lacked jurisdiction to resolve the controversy. Presiding Judge Richard Arnold relied heavily on the articulate testimony of Dean Tom Bruce of the College of Medicine of the University of Arkansas, concerning the benefit of pathologists' services to patients. On June 5, Judge Arnold issued a ruling stating, in part, that clinical pathology procedures "whether or not the pathologist sees the patient and whether or not he or she looks through the microscope, are, and the Court finds as a fact that they are, professional services performed for the benefit of the patients, as that phrase is used in the Medicare Act." The court went on to grant an injunction in favor of the plaintiffs, barring implementation of the March 11 regulations and enjoining HCFA from denying payment under Part B to those who had previously been paid in that manner. The CAP had carried the day.

It was expected that the Department would appeal, and it did. Meanwhile, the issue was taken up by Congress, and a provision restricting Part B payment for the professional component of clinical pathology services for Medicare patients was enacted as part of the Tax Equity and Fiscal Responsibility Act of 1983 (TEFRA). The CAP had instituted a massive effort to oppose this provision. However, insurmountable difficulties existed—not the least of which was that the proposal was included in a comprehensive budget reconciliation package, rather than in a specific bill with traditional hearings, witnesses, and similar opportunities for input. The budget reconciliation process required that each change be "scored" for its fiscal impact, and that any spending increases be offset by savings elsewhere.

At the time, few in the profession thoroughly understood the mechanics of the budget reconciliation process, and the objectionable provision was enacted despite the College's efforts. The government soon issued regulations implementing the new statute on professional component billing for clinical pathology services for Medicare patients. The proposed regulations were quite restrictive. In essence, they precluded payment under Part B for any clinical pathology services unless those services were (a) "performed by a physician in personal administration of test devices, isotopes, or other materials to an individual patient" or (b) met a very narrow definition of "consultative pathology services." This definition mandated that the services in question "must (1) be requested by the patient's attending physician; (2) relate to a test result that lies outside the normal range established by the laboratory; (3) result in a written narrative report for inclusion in the patient's medical record; and (4) require the exercise of medical judgment by the consultant physician." The proposed regulations thus appeared to eliminate payment under part B for several clinical pathology procedures in which the pathologist had traditionally been personally involved. These included blood banking, hematology, and various electrophoreses. Detailed comments filed by the College on the proposed regulations explained that they had exceeded the scope of the governing statute and were, in certain particulars, directly contrary to it. Nonetheless, the regulations were adopted.

In the circumstances, the College Board of Governors met in emergency session on March 6, 1983, and once again determined to go to court. Since 1980, the jurisdictional issues surrounding challenges to Medicare regulations had only grown worse. Indeed, the only court that had established a favorable precedent on the jurisdictional issue was the federal court in the District of Columbia. Accordingly, a suit was brought in

Washington, DC, challenging the TEFRA regulations. In essence, the complaint alleged that the regulations had gone beyond the intent of Congress as manifested in the TEFRA provision that governed payment for professional component services under Part B of Medicare.

Ultimately, the Court of Appeals upheld the TEFRA regulations. However, in many ways, the litigation was successful. Specifically, in defending the proposed regulations from the criticisms leveled by the College, the Department of Health and Human Services made a number of important concessions which significantly moderated their scope. For example, the Department acknowledged that blood banking and certain hematology services should be treated as directly performed physician services for Medicare payment purposes. It also recognized that the concept of “outside the normal range” was difficult if not impossible to apply to procedures that require pathologist involvement but do not yield numeric results. Consequently, the Department agreed to continue payment under Part B for certain laboratory procedures in which pathologist involvement was deemed to be necessary—even if the results turned out to be “normal.”

The impact of the TEFRA regulations on individual pathologists varied substantially, depending on the geographic regions in which they practiced and the varying prevalence of professional component billing in the different regions. Understandable frustration over the consequent reductions in Part B payment for clinical pathology services stimulated the formation of new organizations of pathologists purporting to offer more effective lobbying than the CAP. Dr. Coleman had observed many years earlier that about 90 percent of effective political action consisted in “keeping your own troops in the boat” and only about 10 percent in actually fighting the “enemy.” Although the establishment of these alternative organizations demonstrated that it is not always easy to “keep the troops in the boat,” the College has over the years remained the most effective advocate on pathology issues on the national legislative front.

In an effort to re-focus the profession’s efforts concerning legislative and regulatory matters, CAP President Herbert Derman, MD, established a Joint Pathology Task Force to attempt to unite established organizations such as the CAP with the other smaller organizations that had appeared on the scene in the wake of TEFRA. This group met from 1983 through 1985 and was largely successful. As part of its deliberations, the Task Force developed proposed language relating to the types of tests that were of such nature as to require personal performance and/or interpretation by a pathologist, and should therefore be required to be so performed and/or interpreted for Medicare reimbursement purposes. HCFA later accepted most of this language when developing its revised regulations.<sup>11</sup> However, changes in the budget and regulatory environment would soon lead to government interest in formulating fee schedules for clinical pathology services in certain circumstances. This development again required action on the part of the CAP.

The first record of CAP interest in the issue of fee schedules dates from 1959, when the Board of Governors considered the concept of a CAP relative value schedule (RVS). An RVS is distinct from a fee schedule in that it attempts only to differentiate procedures in terms of their “relative value”—i.e., relative complexity and cost—leaving the actual setting of fees to individual practitioners. Nonetheless, the discussion of the issue at that time reflected deep differences of opinion among pathologists as to the purpose of such schedules and the potential for their misuse; consequently, the matter was not pursued. In the early 1960s, however—partly in response to a similar initiative by the California Medical Association—the CAP did prepare several editions of its own RVS, only to be forced by the 1969 antitrust consent decree to discontinue the practice.

However, in the evolving regulatory environment of the mid-1980s, Congress began to consider a more comprehensive, government-developed RVS for all of medicine, as an alternative to the possible implementation of a diagnosis-related group (DRG) payment system for physicians. HCFA had contracted with

William Hsiao, PhD, of Harvard University to develop a relative value schedule based on resources expended in a procedure—as distinct from a traditional, market-based schedule. The College, under the leadership of Paul A. Raslavicus, MD, devoted thousands of hours to consulting, advising, and critiquing successive versions of the proposed resource-based relative value schedule (RB-RVS). As a result, the original schedule for pathology, which in the College's estimation was significantly flawed, was re-studied and revised, with results ultimately accepted by the AMA and by Medicare and many insurers. Two contentious issues remained: The comparability of the scales between specialties, and the conversion factor used in conjunction with the schedule to calculate actual payments. Neither has yet been resolved to all parties' satisfaction, and the latter remains a designated priority for CAP activity during the 105th Congress.



*Fig 10-4. Alfred S. Ercolano, the first director of the CAP Washington office, served in that capacity from 1970 to 1991.*

*CAP Legislative Affairs Staffing* Throughout the 1950s, the College's legislative program depended on volunteer work by individual members engaging in political action at the state level—which, as already noted, was at that time the primary locus of legislative activity affecting health care. However, during the debates leading up to the passage of Medicare in 1965, the need for full time professional support for the CAP's legislative activities became clear. In June 1965, coincident with the short-term hiring of Medicare lobbyist Victor Knox, H. David Moore was employed as director of professional and legislative relations. The CAP subsequently hired Kenneth Roberts, a former member of Congress, as its first regular lobbyist in the spring of 1967. By May 1969, the Board recognized the need for a CAP Washington office. Later that fall, space was acquired near the Washington office of the AMA. In June 1970, Alfred S. Ercolano, formerly executive director of the American Nursing Home Association, was appointed as the first full time director of the new office (Fig 10-4). Ercolano's legislative expertise—in addition to his gregarious nature and talents as a host—result in such a congenial “fit” between himself and the College that he remained at his post for 21 years, until his retirement in 1991. The College's successes during that period in connection with CLIA, Medicare, TEFRA, and other federal issues owed much to Ercolano's careful selection and preparation of

CAP members for testimony before Congressional committees and government agencies.<sup>12</sup> Ercolano's successor, Jayne Hart Chambers, now presides over a Washington staff of 20 with special expertise in such areas as lobbying, policy analysis, political development, state legislative affairs, practice management, and communications.

As mentioned earlier, one of the topics that is receiving special attention from the College's Division of Government and Professional Affairs at this writing is the vexing question of conversion factors used in calculating Medicare payments to pathologists. Other legislative issues on the College's agenda for the 105th Congress include opposition to competitive bidding for clinical laboratory diagnostic services under Medicare; preservation of patients' right to choose their caregivers; sound methodologies for payment of practice expense costs; medical liability reform; appropriate debate on the development of quality assurance and patient protection in genetic testing; and advocating the use of the College's *Systematized Nomenclature of Medicine* (SNOMED) in patient records systems designed to enhance portability of health insurance coverage. This listing of concerns confirms that the College's efforts on the legislative and regulatory fronts remain on the cutting edge as the CAP enters its second half-century of service to patients and the profession.

## Notes

1. CAP Board of Governors Minutes, 1951 Jun 9-11:7.
2. King DW. *A Brief History of the American Registry of Pathology*. Washington, DC: American Registry of Pathology. 1996.
3. Copeland BE, Bernhard WC, Derman H, et al. Clinical Laboratory Performance in the U.S. *CAP Bulletin*. 1968;22:39-45.
4. Copeland BE et al. *CAP Bulletin*. 1968;22:39-45.
5. *CAP Bulletin*. 1975;29:367-386.
6. Coleman FC. A brief look at the sociopolitical and economic history of pathology in the United States. *Journal of the Florida Medical Association*. 1980;67:89-96.
7. Bachner P, Hamlin WB. Federal regulation of clinical laboratories and the CLIA amendments of 1988. *Clinics in Laboratory Medicine*. 1993;13:739-752,987-994.
8. Coleman FC. The legislative history of Medicare. *Pathologist* 35;1981:97-99,156-159.
9. Coleman FC. The coming of Medicare—a turbulent time for pathology. *Pathologist* 35;1981:216-219,272-276,332-336.
10. CAP Board of Governors Minutes, 1979 Nov 27:16-17.
11. Lambird PA (Task Force member). Personal communication, 1997 Jan.
12. Ercolano AS. Oral history interview. 1987 Oct 27.

## Chapter Eleven

# Inter-Organizational Relationships

Loyd R. Wagner, MD

In its efforts to promote pathology and pathologists, and to elevate standards of pathology practice for the benefit of patients, the College of American Pathologists interacts with many professional societies and other organizations. Some of these relationships have developed as the natural result of common interests with other physician groups, and have existed since the early years of the College. Others have resulted from the convergence of common interests in laboratory medicine; some of these interactions have been short-term, while others have persisted to the present. Regardless of their duration, these relationships have provided mutual benefits to the College and its members, to the other organizations and their members, and to the general public. The most important of them are discussed in this chapter.

*American Society of Clinical Pathologists* Among the intersociety relationships of longest duration is that which exists between the College and the American Society of Clinical Pathologists (ASCP). As recounted in Chapter 1, the College's founding is traceable in large part to ASCP efforts to improve the socio-economic status of the profession during the 1940s. A number of ASCP members were active participants in the formation of the College and were supportive of its goals and mission. Mutual support between the ASCP and CAP continues to the present, fostered by the membership and active involvement of many pathologists in both organizations. The substantial overlap in membership, coupled with joint national meetings and other factors, does sometimes blur the distinction between the two societies; but in fact each plays a complementary role in serving the needs of pathologists, other laboratory professionals, and the public.

*Through its cooperative efforts  
with other organizations,  
the College has consistently  
demonstrated its commitment  
to the improvement  
of pathology and medical care  
for the general public.*



The primary focus of the ASCP has always been the education of laboratorians. One of the stated goals in the original constitution of the College of American Pathologists was also education, to be achieved chiefly through presentation of scientific educational programs by the Regional Committees. Recognizing that the scientific educational role of the two societies could become a point of controversy, the CAP and ASCP formed a joint committee in the fall of 1947 to recommend ways to promote cooperation between the two societies and prevent overlap of their respective functions. In the fall of 1948, agreement was reached that the ASCP would be responsible for the publication of a pathology journal, the planning and presentation of national scientific meetings and seminars, and the Registry of Medical Technologists. The CAP would be responsible for regional scientific education, a Placement Bureau, and socio-economic issues.

As leadership changes occur in any organization, however, understanding of and adherence to previous agreements tend to vary. In October 1956, a proposal for regional scientific educational programs sponsored by the ASCP led to a re-examination of the role of each society. As a result, the governing bodies of CAP and ASCP began a regular exchange of minutes of the meetings of the respective Boards, to ensure that the needs of pathology and pathologists were met without undue conflict. In 1964, agreement was reached that the president of each society would attend the Board meetings of the other, a practice that continues to the present. Over the ensuing years, a number of additional joint committees have continued to delineate the societies' respective roles and address related issues in a collegial manner. The role of each organization in presenting scientific educational programs has been an ongoing concern. Over time, an understanding has evolved that the ASCP will concentrate on in-depth and repetitive workshops and seminars for both pathologists and technologists, both at national meetings and regionally. The CAP's educational focus will be on scientific issues identified through its laboratory improvement programs, rapidly emerging medical issues, laboratory management, and legislative and regulatory matters.



*Fig 11-1. Program from Fall 1972 joint meeting of College of American Pathologists and American Society of Clinical Pathologists, marking the societies' 25th and 50th anniversaries, respectively.*

During the first decade or so after the founding of the College, the Advisory Council of the ASCP played a quasi-official role in fulfilling the goals of the CAP. The Councilors served as the "grass-roots" contacts for the transmission of information between the Board of Governors of the College and individual pathologists. Issues identified through this mechanism were discussed at meetings of the Council and then reported to the CAP Board, in a fashion similar to the current operation of the CAP House of Delegates. However, the Council itself also dealt with issues of ethics and socio-economic matters. Questions soon were raised about possible conflicts of interest and the effectiveness of this arrangement, inasmuch as a number of ASCP Councilors were not members of the CAP. Concerns about these issues were among the factors that led to the formation of the CAP Assembly in 1957.

National meetings of the CAP and ASCP have long been held jointly, at first annually and then, since 1963, semi-annually (Fig 11-1). In the early years, program contents and meeting logistics frequently consumed the greater part of the agendas of the CAP Board of Governors and its joint meetings with the ASCP Board of Directors. These sometimes protracted discussions recorded in verbatim transcripts of Board minutes provide, at least in retrospect, moments of humor. An example is the June 1959 meeting of the College Executive Committee, when the annual joint banquet was discussed. Sponsorship had been rotated between the two organizations, and the sagging attendance for the event demonstrated that enthusiasm for it was less than overwhelming. As an alternative to a banquet, a boxing and wrestling smoker was suggested; beer would be supplied by a major brewer, and CAP awards would be presented at ringside. This proposal led A. Reynolds Crane, MD, a Governor of the College, to comment that "the concept of a smoker as part of a scientific assembly makes my old Philadelphia bones blush and blanch!" The smoker concept was never brought to a vote.

Levity, however, was not always the outcome of the discussions regarding meeting space, meeting locations, and program scheduling conflicts. Rancorous debate over these issues led the governing bodies of the two societies to resolve in 1971 to discontinue joint meetings; but the conflict was resolved prior to its being presented to the membership. There have been other discussions of separate meetings over the ensuing years, but joint meetings continue, and they are largely perceived as promoting ongoing harmonious relations between the ASCP and the CAP.

*American Medical Association* The founders of the College of American Pathologists were pathologists who understood that they were physicians first, and pathologists second. Many were active in the American Medical Association, and served as representatives of their state societies in the AMA House of Delegates. A natural result of this involvement was the scheduling of a number of early meetings of the College in conjunction with annual meetings of the AMA.

However, the view that pathology was the practice of medicine was not universally shared by others in the medical community. In 1921, the AMA House of Delegates had declared that clinical laboratory determinations were not the practice of medicine. Led by Alfred S. Giordano, MD, then secretary-treasurer of the ASCP, pathologists in the AMA House of Delegates were successful in 1943 in having this policy statement rescinded. Not until 1955, however, was it clear that the resulting concept of pathology as the practice of medicine also extended to microbiology. In that year, efforts to establish a separate American Board of Microbiology (which presumably would have certified PhD microbiologists in addition to MDs) came to an end when the AMA House of Delegates voted against establishing a formal relationship between the proposed new Board and the Advisory Board for Medical Specialties. Since that time, the AMA has generally supported efforts to maintain the integrity of pathology as a specialty of medicine. For example, the AMA has adopted policies urging that patient specimens should be referred only to laboratories directed by physicians, and that payment for services of radiologists, pathologists, and anesthesiologists should be made from medical service insurance contracts instead of from those for hospital services.



**Fig 11-2.** CAP Fellow Richard E. Palmer, MD (1919-1986), elected president of the American Medical Association in 1975.

As early as 1950, the Board of Governors became concerned with coordinating the efforts of pathologists and increasing their effectiveness in the AMA. In 1964, the first pathology caucus at an AMA meeting was hosted by the College, to present the CAP viewpoint on the many resolutions and reports before the AMA House of Delegates. This caucus continues to the present. As a component specialty society in the AMA federation, the CAP now has two seats in the House of Delegates and has representation on the AMA Pathology Section Council. Members of the College have served on the Board of Trustees and the various Councils of the AMA, with several serving as chairs of councils. Richard E. Palmer, MD, a CAP Fellow from Virginia, was elected president of the AMA in 1975 (Fig 11- 2).

In 1958, and for 10 years thereafter, the College co-sponsored with the AMA a model laboratory at AMA national meetings. Urinalysis and simple hematology examinations were conducted for the attendees, with testing later expanded to include simple blood chemistries as well. The performance of Pap smears was considered but abandoned because "there were too few women [in attendance],

facilities were poor, and adequate screening was not possible after the first day of the meeting.” (What factors would have changed after the first day was not made clear.) The laboratory project, which in the meantime had gained co-sponsorship by the ASCP, was discontinued in 1968, with insufficient space being cited as the main reason.

Since the passage of Medicare in 1965, the AMA and the College have worked closely together on numerous legislative and regulatory issues. These cooperative efforts have been greatly enhanced since the establishment of the CAP Washington, DC, office in 1970. Despite the Health Care Financing Administration’s adoption of the AMA’s *Current Procedural Terminology* (CPT) instead of the CAP’s *Systematized Nomenclature of Medicine* (SNOMED), the two organizations have worked closely on coding issues as they affect Medicare payments for pathology services. The AMA appoints a member of the College to the CPT editorial board. The College also participates in an AMA-led initiative to evaluate and update the Resource Based Relative Value System on which Medicare payments for physician services are based.

Other cooperative efforts with the AMA, notably the joint publication of *Archives of Pathology & Laboratory Medicine*, are discussed in Chapter 3.

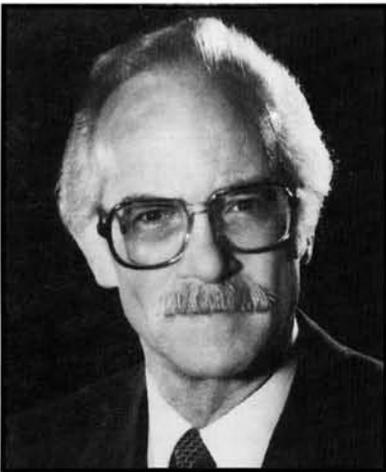


Fig 11-3. Robert V.P. Hutter, MD (b. 1929) played a key role in initiating ongoing cooperation between the CAP and the American College of Radiology, and later served as president of the American Cancer Society.

*American College of Radiology* The CAP’s ties to the American College of Radiology (ACR) date back to the very founding of the College, when the ACR’s committee structure was used as a model for that of the CAP (see page 5). At a CAP workshop on Medicare in the autumn of 1965, the ACR’s Professional Component Relative Value Schedule was used as a teaching tool. A more sustained and substantive cooperative relationship began in 1971, when the ACR initiated a Patterns of Care Study under its Radiation Therapy Oncology Group (RTOG), and invited Robert V.P. Hutter, MD, as a representative of the CAP Cancer Committee, to meet with that group (Fig 11-3). In 1978, the working relationship between the two Colleges was formalized by the creation of a joint ACR/CAP Patterns of Care Steering Committee on Cancer in Pathology Practice. One of the Committee’s purposes was to advise the ACR Patterns of Care project; it also began the process of developing practice guidelines for data recording by pathologists when examining tumor tissue specimens. This in turn laid the groundwork for a more comprehensive series of protocols being developed at this writing under the guidance of Donald E. Henson, MD, which will cover 39 tumor sites when completed; this project is described in greater detail in Chapter 8.

*American Association for Clinical Chemistry* The American Association for Clinical Chemistry (AACC) and the CAP have been partners in a number of joint ventures. The earliest formal contact between the two societies was the formation of a joint liaison committee in 1974, and in January 1976, the CAP Board approved the formation of an Intersociety Committee on Quality Assurance Programs, with initial representation from AACC, the American Association of Blood Banks, and the American Academy of Microbiology. A joint conference on blood alcohol testing was held in 1984; in 1986, a joint proficiency testing program for blood lead levels began. During the 1980s, the AACC also played an important role in development of the CAP Forensic Urine Drug Testing (FUDT) Accreditation program to ensure quality in

laboratory testing for drugs of abuse. Meetings of the officers of AACC and CAP have been held frequently to discuss laboratory issues of mutual interest.

*Joint Commission on Accreditation of Hospitals* In the past, most pathologists have practiced primarily in hospitals and have had responsibilities in both medical staff and administrative affairs. Since both the CAP and the Joint Commission on Accreditation of Hospitals (JCAH)—now the Joint Commission on Accreditation of Healthcare Organizations (JCAHO)—are concerned with the quality of pathology and laboratory services in hospitals, pathologists deal with both organizations in their practice. Thus for the CAP to meet the needs of its members, it was inevitable that a need for continuing dialogue with the JCAH/JCAHO would emerge.

The practice of formally inspecting and approving hospital facilities was actually initiated by the American College of Surgeons (ACS) in 1919, as the outgrowth of a concerted campaign for hospital standardization spearheaded by Ernest A. Codman, MD, and ACS Director John G. Bowman.<sup>1</sup> This program was continued by the ACS until the 1951 founding of the JCAH, which included representation from the American Medical Association, American Hospital Association, ACS, and American College of Physicians.

Late in 1951, a perception that an undue number of normal tissues were being removed by surgeons led the ACS to propose the formation of tissue committees in hospitals. For reasons which are not recorded, the term “tissue committee” was judged to be inappropriate by the CAP Board of Governors; the Board also objected to the omission of pathologists from the original ACS proposal for the composition of tissue committees. By May of 1953, the subject of “unnecessary” surgery and the removal of normal tissues had garnered sufficient public attention that the CAP Board anticipated it would be a significant subject of discussion at the upcoming meeting of the AMA House of Delegates in 1953. The Board determined that for the time being the College “should maintain an interested although basically neutral position” on the issue in general, and a posture of “complete aloofness” from the anticipated AMA debate, pending a fuller discussion of the subject by the Board.

In preparation for that discussion, a meeting took place on October 7, 1953, between a specially appointed College committee and representatives of the JCAH. This was the first recorded official contact between the two organizations. Among the issues discussed was that of specifying coverage in pathologists’ contracts with hospitals; the JCAH proposed that there should be a “full-time coverage” clause in such contracts, while the College took the position that pathologists should provide “adequate coverage.” Also on the agenda was the question of whether pathologists should chair tissue committees, a procedure opposed by the Board because it could place pathologists in an uncomfortable “watchdog” role over surgeons in their hospitals. The meeting also dealt with the issue of accountability for removal of normal tissues. The Board was quick to point out the incongruity of the pathologist being held accountable for something over which he or she had no control, and maintained that any penalty for excesses in this area should be assessed instead against a hospital’s surgical department.

Shortly after this interchange the JCAH made an attempt—or what was perceived as an attempt—to dictate how pathology should be practiced in hospitals, a turn of events that stimulated the CAP Board of Governors to issue what might be considered the first practice guideline for pathologists. In February 1955, information reached the Board that a JCAH surveyor had reported to a hospital in Alabama that the JCAH and the College had agreed that “normal” tissues would be evaluated by pathologists without charge. This erroneous report was immediately refuted by the Board, and a detailed discussion followed on which tissues required

microscopic examinations. In response, the Board adopted a policy on surgical pathology examinations and reports that included the following points:

- Every tissue removed surgically was to have at least a gross description.
- Performance of a microscopic examination was to be at the discretion of the pathologist.
- The number of blocks and the site from which taken was to be recorded for each tissue examined microscopically.
- Any special stains were to be listed and described in the report.
- The report was to indicate any diagnosis made on the basis of a gross or microscopic examination. The clinical implications of the diagnosis were to be recorded.
- Microscopic slides were to be retained in the department of pathology.<sup>2</sup>

In 1957 debate turned to the issue of accepting into hospital records the results of clinical laboratory examinations performed in laboratories other than the hospital laboratory. At that time the CAP Board adopted a policy that results could be accepted only from a laboratory run by a board-certified pathologist or another laboratory approved by the executive committee of the hospital medical staff. However, when in 1960 the JCAH approved acceptance of laboratory results from any government-licensed laboratory, the Board of Governors expressed its opposition to this change by rescinding the CAP policy of accepting results from laboratories approved by the staff executive committees.

Other proposals by the JCAH to regulate medical practice in hospitals also drew responses from the College. When the JCAH instituted a policy in 1963 that the pathologist must record the number of hours actually spent in the laboratory, the Board of Governors vigorously opposed the requirement. In 1964, the JCAH requisite for routine syphilis serology on all patients upon admission was opposed as being scientifically unsound and not cost-effective. The JCAH-specified autopsy percentage in accredited hospitals led to a statement from the College in 1966 that the quality of an autopsy was more important in improving medical care than a specification for a specific number of autopsies.

The institution of federal laboratory regulation in 1967 led to acceptance by the JCAH in 1968 of the CAP laboratory standards as their standards for laboratories in accredited hospitals. In the early 1970s, the College sought equivalency or “sub-deemed” status from the JCAH for the Inspection and Accreditation Program, in order to relieve CAP-accredited hospital laboratories of the necessity for a separate inspection by the JCAH. After the College offered virtually all of its services to inspect hospital laboratories, the JCAH recognized the CAP program by granting it sub-deemed status in August 1978 (although a formal contract defining this relationship was not signed until 1993).

The Laboratory Accreditation Standards of the College adopted by the JCAH in 1968 included a requirement that the hospital laboratory should be directed by a physician, preferably a pathologist. In 1984, the JCAH proposed deletion of this requirement. This revision was vigorously opposed by the College and was delayed for a number of years, but in 1991 the laboratory director standard of the Commission (now renamed the Joint Commission on Accreditation of Healthcare Organizations [JCAHO]) was changed to allow direction by non-physicians.

Today representatives of the JCAHO and the College meet on a regular basis to discuss operational issues relating to laboratory accreditation. In addition, a pathologist representing the College is a member of the JCAHO's Professional/Technical Advisory Committee.

*American Board of Pathology* The College's objective "to foster the highest standards in education, research, and the practice of Pathology" creates a strong commitment to the education of pathologists and assessment of their competency. The long association of the College's first president, Frank W. Hartman, MD, with the American Board of Pathology (ABP) did much to foster early and strong support of the ABP by the College. It appears that members of the Board of Governors met periodically with the Trustees of the ABP soon after the founding of the College, although the CAP did not become a sponsor of the ABP until 1959. At this time it began to participate formally in the nomination process for the ABP Board of Trustees by submitting a list of proposed members.

On occasion, concern about a possible negative impact on residency recruitment has caused the CAP Board of Governors to resist changes in residency requirements proposed by the ABP. The 1950 proposal to increase the training period to four years from the then-current three plus a year of practice raised fears that clinical and anatomic pathology might be split from each other, thus undermining the CAP position that pathology was a single, unified specialty. In 1982, a fifth clinical year was added to the ABP requirements for residency, with the support of the College; but concern about a possible decrease in the number of residents led the Board of Governors in 1991 to endorse a House of Delegates resolution asking the ABP to rescind this requirement—a request which the ABP did not honor.

On the other hand, the College has also been instrumental in increasing training requirements in residency programs when the need for added expertise in an area of pathology practice was identified. In 1953, the CAP Board concluded that current patterns of forensic pathology training were inadequate, and several years later the ABP responded by initiating a sub-specialty certification examination in this area of practice. In 1959, specific training in the use of radionuclides in clinical pathology was urged by the Board of Governors; added competency certification in radionuclides was then established by the ABP, and the ABP also co-sponsored the conjoint American Board of Nuclear Medicine in the early 1970s. The CAP also supported certification in cytopathology in 1987, and in laboratory management in 1992 (the latter proposal remains under consideration by the ABP at this writing). The CAP Board has also voiced its opposition to both the ABP and the American Board of Medical Specialties when proposals have surfaced for sub-specialty certificates or independent certifying boards in areas of practice which it has considered to fall within the purview of pathology.

The issue of whether pathologists should be periodically recertified by the American Board of Pathology was debated by that body for at least a quarter of a century. While recertification plans have been submitted by the ABP to the American Board of Medical Specialties on several occasions, no action was taken to implement any of these recommendations. In the late 1980s, however, the issue of assuring continued competency on the part of all physicians began to gain increased public attention, prompting the Board of Governors to consider the pros and cons of recertification. A CAP task force formulated recommendations for recertification by multiple pathways, including participation in continuing medical education, participation in the CAP Laboratory Accreditation Program, and a challenge examination tailored to the current practice expertise of the individual pathologist. The voluntary recertification program implemented by the ABP in 1996 is structured largely in line with the College's recommendations.

**National Pituitary Agency** In the 1950s research on pituitary dwarfism led to the treatment of patients having this disorder with pituitary extract, the only source of which was human pituitary glands collected from autopsied patients. In June 1963, the National Pituitary Agency was formed to promote and coordinate the collection of pituitary glands by pathologists around the country. The efforts of the College for the Agency were led by Manuel A. Bergnes, MD, a Pennsylvania pathologist and member of the College. By 1965, a reported 65,000 to 70,000 glands were being collected annually, sufficient to treat 650 to 700 children. This program continued into the 1980s, when legal issues arose concerning informed consent from next of kin authorizing collection of pituitary glands. Moreover, reports of possible transmission of Jakob-Creutzfeld disease by the extract were beginning to be made. By this time, laboratory synthesis of human growth hormone had obviated the need for collecting human pituitary glands, and the Agency's collection program was discontinued.

**Association of Pathology Chairs** Founded in 1967 as the American Association of Chairmen of Medical School Departments of Pathology, the 150-member Association of Pathology Chairs (APC) functions as an advocacy group and a center for exchange of information on matters relating to the administration of medical school pathology departments and to pathology teaching and resident training. It is especially with respect to the latter concern that the APC's mission coincides with that of the College, and the CAP supports this group particularly through its legislative and regulatory initiatives. The CAP also assists the APC in efforts to maintain adequate levels of government funding for pathology training provided through Medicare and other federal programs. Projections of workforce needs became a joint effort of the CAP, APC, and ASCP in 1995.

In addition, the CAP Residents, Young Physicians, and General Membership Committee includes a liaison member representing APC; CAP representatives are also appointed to the APC Graduate Medical Education Committee and to the CAP/ASCP/APC Conjoint Residency Program Directors (PRODs). This structure is intended to provide channels for input from program directors on issues relating to training programs, and to provide feedback on those programs from residents.

**Blood Banking** Unquestionably one of the greatest advances in the treatment of patients with massive trauma resulted from the extensive use of plasma and whole blood, where available, for the treatment of shock during World War II. The massive efforts mounted by the American Red Cross to collect blood and plasma moved that organization into a prominent position in the United States in the procurement of blood from voluntary donors. At the same time, blood banks were established or greatly expanded in hospitals, many of which became associated with the American Association of Blood Banks (AABB) and obtained their blood from both voluntary and paid donors.

In 1949, the American Medical Association undertook a survey of United States blood banks, an effort in which the College cooperated. By December of that year, 894 blood banks had been located and identified, a total thought to be only about half of those which actually existed. This modest inventory of facilities is the first recorded activity by the College to ensure adequate blood banking facilities and a safe blood supply for the nation. Concerning itself primarily with quality, the CAP remained aloof from the voluntary-versus-paid donor discussion, with its official policy favoring pluralism in blood procurement.

In 1952, the College joined with the AMA and the American Red Cross in efforts to better coordinate blood banking activities. From this effort emerged the concept of a national blood foundation which was realized as the Joint Blood Council, composed of the American Red Cross, the AABB, the ASCP, and the CAP. The Board of Governors believed that the Joint Blood Council should be an advisory and coordinating body only,

and should not itself operate any programs. The successor to the Joint Blood Council in 1975 was the American Blood Commission, charged with the integration of blood banking services and the development of a national blood policy.

The two organizations most involved in ensuring the quality of transfusion services have always been the College and the AABB. In 1970, the two bodies introduced a joint Survey for enzymology and instrumentation specifically tailored for blood banks, followed in 1972 by proficiency testing materials for hepatitis B surface antigen (HBsAg). A parentage testing Survey was introduced in 1989.

In 1974, a joint CAP/AABB liaison committee was formed to manage the Survey programs. It was also instructed to investigate the possibility of a joint blood bank inspection and accreditation program. While a true joint program has not yet resulted, there is close cooperation between the two associations in setting standards for blood banking and the contents of checklists for both CAP and AABB inspections. When institutions are accredited by both the CAP and the AABB, inspections are coordinated whenever possible in order to avoid duplicate effort. Possibilities for even closer cooperation are being pursued at this writing.

The legal resources of the College have also been brought to bear when litigation has threatened the ability of blood banking facilities to supply safe blood to patients. Late in the 1980s, a number of suits were filed which attempted to hold blood banks liable for the transmission of the human immunodeficiency virus (HIV) through transfusions, even though they had followed the screening procedures for the virus that were generally utilized at the time. In a 1991 Colorado lawsuit, *Quintana vs. United Blood Services*, the College filed an *amicus curiae* brief in support of the defendant blood bank. This brief took the position that blood banks which followed generally utilized procedures for HIV screening should not be found to have acted negligently. Nevertheless, the court held that a blood bank could be found negligent in those circumstances.

**Joint Proficiency Testing** On a number of occasions the College has joined with other medical societies to operate proficiency testing programs either for or in cooperation with those organizations. The earliest such program was begun with the American Society of Internal Medicine (ASIM) in 1970, when the ASIM endorsed the CAP proficiency testing program for physician office laboratories (PEP), and a formal agreement between the College, ASIM, and the California Society of Internal Medicine was signed. The College provided proficiency testing materials for the ASIM from 1986 through 1995. As noted in Chapter 5, similar proficiency testing programs have been operated with the American Academy of Family Physicians, the American Academy of Pediatrics, the American Osteopathic Association, and the American Society for Histocompatibility and Immunogenetics.

Proficiency testing in nuclear imaging by means of organ "phantoms" was pioneered by the College in the 1970s. The Society for Nuclear Medicine participated in this program in a liaison role beginning in 1971, with the American College of Nuclear Physicians (ACNP) following in a similar capacity starting in 1981. The ACNP assumed full responsibility for the nuclear phantom program in 1994. At the same time, the inspection and accreditation of nuclear imaging facilities was discontinued by the CAP, this function also being assumed by the ACNP.

**American Cancer Society** Most CAP relationships with other organizations are with other medical professional societies, or with associations directly connected with the laboratory medical community. When other organizations are engaged in activities which affect patient welfare, however, the CAP may become involved as well. This is pre-eminently the case with respect to the American Cancer Society (ACS), which performs a vital function in the education of the public about cancer treatment, prevention, and research.



*Fig 11-4. David A. Wood, MD (1904–1996) served as president of the College of American Pathologists in 1953–1955, and of the American Cancer Society in 1956–1957.*

As early as 1948, when the Papanicolaou smear for the detection of cervical cancer was in its infancy, the ACS expressed fears about the possible adverse consequences of relying on this technique without histologic tissue confirmation of diagnosis. The ACS urged that there be special training in cytology for both technical and professional personnel, a concept also endorsed by the College. To support education in this field, the ACS gave special training grants to a number of pathologists in the 1950s. The ACS has also supported a number of conferences on topics such as breast cancer.

A number of Fellows of the College have also been active in the ACS at the national level. Notable among them was David A. Wood, MD, third president of the College in 1953–1955. Following the completion of his term as president of the CAP, he was president of the ACS in 1956–1957, and was instrumental in setting goals for the ACS which complemented many of those of the College (Fig 11-4).

**Conclusion** Through its various cooperative efforts with other organizations, the College has consistently demonstrated its commitment to the improvement of pathology and laboratory services, as well as the improvement of all medical care for the general public. Via these relationships, the CAP's "Pursuit of Excellence" extends well beyond the confines of the College in order to benefit the patient, the pathologist, and the public.

## Notes

1. Davis L. *Fellowship of Surgeons: A History of the American College of Surgeons*. Chicago, Ill.: American College of Surgeons; 1960:172-174,204-211,220-222.
2. CAP Board of Governors Minutes, 1955 Feb 5:12-13.

## Appendix A

# CAP History Timeline

1922

- American Society of Clinical Pathologists (ASCP) established

1936

- American Board of Pathology (ABP) established

1943

- American Medical Association (AMA) recognizes pathology as the practice of medicine

1945

- ASCP Committee on Hospital and Public Relations (“Hartman Committee”) suggests formation of a separate “academy of pathology”

1946

- “Rump session” at June ASCP meeting sets December date for meeting to establish a college of pathology
- College of American Pathologists (CAP) formed at organizational meeting in Chicago, December 12 and 13

1947

- Organizational meeting of CAP Board of Governors, January 4 and 5
- Melbourne G. Westmoreland, MD, appointed as first Executive Secretary (January)
- First headquarters office opened at 203 North Wabash Ave., Chicago (May or earlier)
- *Secretary's Newsletter* begins publication (May)
- College incorporated in Illinois, May 14
- First general meeting on October 27 approves CAP Code of Ethics

1948

- Ludvig Hektoen, MD, named College's first honorary fellow

1949

- First chemistry Survey conducted
- CAP cooperates in American Medical Association blood bank survey

1950

- *Basic Requirements of a Department of Clinical Pathology in a Modern Hospital* published
- Policy statement on cytology adopted

1951

- First standard solutions offered

1952

- Board of Governors adopts definition of pathology
- Liaison committee established with Joint Commission on Accreditation of Hospitals (JCAH)
- First Legislative Committee established
- CAP forms Joint Blood Council with ASCP, American Red Cross, and American Association of Blood Banks

1953

- Arthur H. Dearing, MD, replaces Dr. Westmoreland as executive secretary
- CAP *Bulletin* supersedes *Secretary's Newsletter*
- College committees grouped under three councils (this procedure abandoned the following year)

1954

- CAP first offers group health and accident insurance for members
- First *Manual of Ethical and Contractual Relations* published

1955

- CAP Board no longer includes formal representation from other societies
- Officer and board nominations by petition permitted
- President's term shortened from three years to two years
- Office of president-elect established
- Iowa Hospital Association lawsuit legally establishes pathology as the practice of medicine
- Board adopts surgical pathology policy (ancestor of practice guidelines)

1956

- Headquarters office moves to Prudential Plaza, Chicago
- George Papanicolaou, MD, named an honorary fellow
- Regular exchange of Board minutes begun with ASCP

1957

- CAP Assembly established
- S.E. Gould, MD, becomes the first pathologist editor of the *Bulletin*
- Intersociety Committee on Pathology Information formed
- College begins accreditation of cytology training programs (turned over to ASCP in 1961)

**1958**

- First bacteriology Survey conducted
- National Registry of Forensic Pathology founded with CAP support
- College sends brochure on cytology to all United States physicians
- First model laboratory operated at regular American Medical Association meeting

**1959**

- Standards Laboratory established
- *Suggested Guide for Procedures and Ethics Relating to Autopsies* published
- CAP becomes a sponsor of American Board of Pathology

**1960**

- CAP sections introduced
- First group life insurance coverage offered to members
- Assembly passes resolution calling for feasibility study of laboratory accreditation program

**1961**

- Ad Hoc Committee on Laboratory Accreditation submits report to Board of Governors, recommending establishment of accreditation program
- First CAP relative value schedule (RVS) prepared

**1962**

- First CAP computer education program offered
- Board of Governors approves establishment of Inspection and Accreditation Program

**1963**

- Oliver J. Neibel, JD, replaces Dr. Dearing as executive director
- CAP Foundation established
- First comprehensive Surveys offered
- First resource committees established as subcommittees of Standards Committee
- First spring interim meeting held in New Orleans
- National Pituitary Agency formed

**1964**

- First edition of *Systematized Nomenclature of Pathology* (SNOP) published
- Standards Laboratory relocates to Cleveland, Ohio, and becomes CAP Certification Laboratory
- Product Evaluation Program instituted
- First laboratories accredited under Inspection and Accreditation Program
- National and state legislative subcommittees established
- Legislative keyman program initiated
- CAP and ASCP presidents begin attending both societies' Board meetings
- CAP hosts first pathology caucus at a regular meeting of American Medical Association

**1965**

- Headquarters office moves to Carbide and Carbon Building, 230 North Michigan Ave., Chicago
- First laboratory accreditation checklist compiled
- Federal Medicare legislation enacted
- First CAP legislative lobbyist hired

**1966**

- College contracts with Belfour & Stulen, Inc. of Traverse City, Michigan, for computer analysis of survey data
- First small hospital Survey offered
- United States Justice Department files antitrust complaint against College

**1967**

- Motto "Join Us in the Pursuit of Excellence" adopted
- First Surveys-validated reference materials (SVRMs) made available
- National Committee for Clinical Laboratory Standards founded
- Surveys participation becomes a requirement for Laboratory Accreditation Program
- Three states adopt Basic Survey for state-operated health agencies
- Clinical Laboratories Improvement Act of 1967 (CLIA-67) passed
- JCAH adopts CAP laboratory accreditation standards
- American Association of Chairmen of Medical School Departments of Pathology (now Association of Pathology Chairs) formed

1968

- Board adopts stylized flask logo
- “Member” status abolished
- Basic Survey accorded equivalency under CLIA-67 by United States Department of Health, Education and Welfare

1969

- Assembly becomes House of Delegates
- Title of *Bulletin* changed to *Pathologist*
- Office laboratory proficiency evaluation program first offered (becomes EXCEL® in 1980)
- First enzymology and instrumentation Surveys offered
- Inspection and Accreditation Program declared equivalent to CLIA-67 standards
- First regional laboratory inspection workshops offered
- College signs antitrust consent decree with Justice Department

1970

- Washington, DC office opens at 1775 K Street, NW
- Workload Recording Method inaugurated
- First supplement to *American Journal of Clinical Pathology* for publication of surveys-based scientific articles
- *AMA Principles of Medical Ethics* supersedes CAP Code of Ethics
- First joint Surveys offered with American Association of Blood Banks and American Society of Internal Medicine
- Histopathology/Cytopathology Subcommittee formed

1971

- College purchases Belfour & Stulen, Inc. computer services firm
- First toxicology and virology Surveys offered
- Quality Assurance Service (QAS) inaugurated
- CAP establishes liaison with American College of Radiology patterns of care study
- College begins proficiency testing in nuclear imaging (phased out in 1994)

1972

- Committees grouped under councils
- Election of secretary-treasurer transferred from Board to general membership
- House of Delegates speaker becomes ex-officio member of Board
- Howard E. Cartwright replaces Mr. Neibel as executive director
- Board authorizes conversion of SNOP to *Systematized Nomenclature of Medicine* (SNOMED®)
- *Inspection & Accreditation Newsletter* inaugurated

1973

- Laboratory accreditation cycle shortened from three years to two years

1974

- Headquarters office moves to 7400 Skokie Boulevard, Skokie, Ill.
- Liaison committee formed to oversee joint survey with American Association for Clinical Chemistry

1975

- First CAP Conference “Clinical Relevance in Microbiology” held at Aspen, Colo.
- First edition of SNOMED published
- First nuclear medicine survey offered
- CAP Fellow Richard E. Palmer, MD, elected president of American Medical Association
- American Blood Commission established

1976

- First interstate commissioner appointed for Inspection and Accreditation Program
- CAP efforts help to defeat bill proposed by Sen. Herman Talmadge to abolish Medicare coverage for professional component in laboratory testing

1977

- Sections abolished
- Board adopts “Standards of Quality Control in Cytopathology”

1978

- Washington, DC, office moves to shared quarters with ASCP at 1333 New Hampshire Ave., NW
- CAP establishes research fellowship at National Bureau of Standards
- Joint CAP/American College of Radiology Patterns of Care Steering Committee on Cancer in Pathology Practice established
- JCAH grants deeming authority for CAP Inspection and Accreditation Program

**1979**

- Inspection and Accreditation Program re-named Laboratory Accreditation Program (LAP)
- Continuing medical education (CME) credit approved for laboratory inspectors

**1980**

- Arkansas lawsuit filed by CAP prevents implementation of excessively restrictive Medicare reimbursement regulations proposed by Health Care Financing Administration (HCFA)

**1981**

- CAP/ASCP Washington, DC, office moves to AMA building, 1101 Vermont Ave., NW
- First CAP Foundation Conference held
- First CAP Reference Preparation for Serum Proteins available
- Digest of 1970–1980 Surveys data published as *Data ReCAP*

**1982**

- Dues abolished for first-year resident members
- Tax Equity and Fiscal Responsibility Amendments of 1982 (TEFRA) enacted, proposing severe new restrictions on Medicare payment for laboratory services

**1983**

- College purchases land in Northfield, Ill., as possible future headquarters site
- CAP lawsuit challenging TEFRA regulations results in significant modifications
- Joint Pathology Task Force established to coordinate the profession's response to TEFRA

**1984**

- Mail balloting instituted for CAP elections
- House of Delegates speaker granted voting privileges on CAP Board of Governors
- CAP begins joint publication of *Archives of Pathology & Laboratory Medicine* with American Medical Association
- College hires first full-time director of public services
- CAP *Archive of Standards* published
- First hormone receptor assay Survey offered
- Performance Improvement Program in Diagnostic Surgical Pathology and Cytopathology (PIP) established
- CAP Government Interface Program begun

**1985**

- Headquarters office moves to 5202 Old Orchard Road, Skokie, Ill.

**1986**

- Joint inspection of blood banks initiated by CAP and American Association of Blood Banks
- First cancer specimen reporting guidelines published in *Pathologist*
- *Effective Laboratory Testing* published

**1987**

- Resident representation added in House of Delegates
- Publication of *CAP TODAY* begun

**1988**

- *Archives of Pathology & Laboratory Medicine* begins publishing CAP Conference proceedings
- Clinical Laboratories Improvement Amendments of 1988 (CLIA-88) enacted
- Q-PROBES program initiated
- College mounts public information campaign on cytology in response to *Wall Street Journal* “Pap mill” exposé
- Revised policy statement on quality control in cytology adopted
- Residents Forum founded

**1989**

- New headquarters building opens at 325 Waukegan Road, Northfield, Ill., consolidating previous Skokie and Traverse City offices
- Resident members appointed to most CAP committees
- Lee VanBremen, PhD, replaces Mr. Cartwright as executive vice president
- Dues abolished for all Junior Members
- Accreditation program first offered for forensic urine drug testing (FUDT)
- Surveys/QAS shared pools program initiated
- Committee on Practice Guidelines formed

**1990**

- Performance Improvement Program in Cervicovaginal Pathology (PAP) inaugurated

**1991**

- Vice-presidency eliminated; president-elect becomes two-year office with automatic succession

**1992**

- Laboratory Management Index Program (LMIP®) replaces Workload Recording Method
- Forensic identity and parentage testing Survey initiated
- Athletic drug testing (ADT) and reproductive biology accreditation programs implemented
- Central States Pension Fund lawsuit in Arkansas upholds professional component billing
- PathPAC established

**1993**

- Washington, DC, office moves to 1350 I Street, NW
- College reaches formal agreement with Joint Commission on Accreditation of Healthcare Organizations (JCAHO) on equivalency of CAP laboratory inspection for JCAHO accreditation
- College-wide strategic plan adopted by Board of Governors

**1994**

- CAP achieves deeming authority for LAP under CLIA-88

**1995**

- CAP takes over publication of *Archives of Pathology & Laboratory Medicine*
- Surveys re-engineering project begins

**1996**

- Chair of Residents Forum becomes a voting member of the Board of Governors
- Information Services Strategic Plan adopted

## Appendix B

# Statistical Summary of CAP Growth

<u>Year</u>	<u>Members</u>	<u>Staff</u>	<u>Budget</u>
1946	357	2	\$25,000
1951	1,546	4	\$55,000
1956	2,359	6	\$103,000
1961	3,600	9	\$187,000
1966	4,660	29	\$452,000
1971	5,651	80*	\$2,939,000*
1976	6,738	127	\$7,602,000
1981	8,816	169	\$15,006,000
1986	10,090	178	\$22,600,000
1991	12,391	272	\$41,600,000
1996	15,234	350	\$69,400,000

\*These figures reflect 1971 acquisition of Belfour & Stulen, Inc. computer services firm.

Appendix C  
CAP Presidents



Frank W. Hartman, MD  
1947-1949

*FW Hartman*



Frederick H. Lamb, MD  
1950-1952

*F.H. Lamb*



David A. Wood, MD  
1953-1955

*David A. Wood*



W. A. D. Anderson, MD  
1956-1957

*W.A.D. Anderson*



Charles P. Larson, MD  
1958-1959

*Charles P. Larson*



Frank C. Coleman, MD  
1960-1961

*Frank C. Coleman MD*



Donald A. Nickerson, MD  
1961–1963

*Donald A. Nickerson*



Victor B. Buhler, MD  
1963–1965

*Victor B. Buhler, M.D.*



Ernest E. Simard, MD  
1965–1967

*Ernest E. Simard, M.D.*



Oscar B. Hunter, Jr., MD  
1967–1969

*Oscar B. Hunter, Jr.*



C. A. McWhorter, MD  
1969–1971

*C. A. McWhorter*



William J. Reals, MD  
1971–1973

*William J. Reals*



Robert C. Horn, Jr., MD  
1973-1975

*Robert C. Horn*



Dennis B. Dorsey, MD  
1975-1977

*Dennis B. Dorsey*



Tyra T. Hutchens, MD  
1977-1979

*Tyra T. Hutchens*



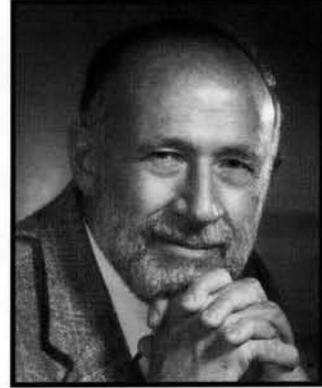
Lawrence J. McCormack, MD  
1979-1981

*Lawrence J. McCormack*



James D. Barger, MD  
1981-1983

*James D. Barger*



Herbert Derman, MD  
1983-1985

*Herbert Derman*



Robert L. Breckenridge, MD  
1985–1987

*R. L. Breckenridge*



William B. Zeiler, MD  
1987–1989

*William B. Zeiler*



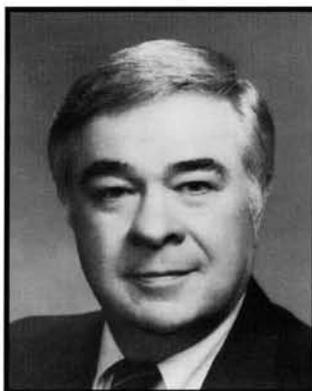
Loyd R. Wagner, MD  
1989–1991

*Loyd R. Wagner*



Donald A. Senhauser, MD  
1991–1993

*Donald A. Senhauser, MD*



Daniel L. Seckinger, MD  
1993–1995

*Daniel L. Seckinger*



Raymond C. Zastrow, MD  
1995–1997

*Raymond C. Zastrow*

## Appendix D

# Officers, Governors, Speakers, Vice-Speakers, and Residents' Forum Chairs

### Presidents-elect

†Charles P. Larson, MD — 1957  
†Frank C. Coleman, MD — 1959  
†Donald A. Nickerson, MD — 1961  
†Victor B. Buhler, MD — 1962-63  
Ernest E. Simard, MD — 1964-65  
†Oscar B. Hunter, Jr., MD — 1966-67  
†C. A. McWhorter, MD — 1968-69  
William J. Reals, MD — 1970-71  
†Robert C. Horn, MD — 1972-73  
Dennis B. Dorsey, MD — 1974-75  
Tyra T. Hutchens, MD — 1976-77  
Lawrence J. McCormack, MD — 1978-79  
James D. Barger, MD — 1980-81  
Herbert Derman, MD — 1982-83  
Robert L. Breckenridge, MD — 1984-85  
William B. Zeiler, MD — 1986-87  
Lloyd R. Wagner, MD — 1988-89  
Donald A. Senhauser, MD — 1990-91  
Daniel L. Seckinger, MD — 1991-93  
Raymond C. Zastrow, MD — 1993-95  
Thomas P. Wood, MD — 1995-1997

† Deceased

### Vice-presidents

†Granville A. Bennett, MD — 1947-49  
David A. Wood, MD — 1950-52  
†W. A. D. Anderson, MD — 1953-55  
†Charles P. Larson, MD — 1956-57  
†Frank C. Coleman, MD — 1958-59  
†Donald A. Nickerson, MD — 1960-61  
†Victor B. Buhler, MD — 1961-63  
†H. Russell Fisher, MD — 1963-65  
†Oscar B. Hunter Jr., MD — 1965-67  
†C. A. McWhorter, MD — 1967-69  
William J. Reals, MD — 1969-71  
†Robert C. Horn Jr., MD — 1971-73  
Dennis B. Dorsey, MD — 1973-75  
Tyra T. Hutchens, MD — 1975-77  
Lawrence J. McCormack, MD — 1977-79  
James D. Barger, MD — 1979-81  
Herbert Derman, MD — 1981-83  
Robert L. Breckenridge, MD — 1983-85  
William B. Zeiler, MD — 1985-87  
Lloyd R. Wagner, MD — 1987-89  
Donald A. Senhauser, MD — 1989-91  
[Vice-presidency was abolished in 1991]

### Secretary-Treasurers

†Tracy B. Mallory, MD – 1947-51  
 †Harry P. Smith, MD – 1951-53  
 †Donald H. Kaump, MD – 1954-55  
 †Donald A. Nickerson, MD – 1956-59  
 Ernest E. Simard, MD – 1959-64  
 William J. Reals, MD – 1964-69  
 †A. James French, MD – 1969-70  
 †Robert C. Horn Jr., MD – 1970-71  
 James D. Barger, MD – 1971-79  
 †Herbert Lansky, MD – 1979-85  
 Loyd R. Wagner, MD – 1985-87  
 †Robert W. Woods, MD – 1987-88  
 Raymond C. Zastrow, MD – 1988-93  
 Paul Raslavicus, MD – 1993-

### Governors

†Hollis N. Allen, MD – 1951-53  
 †W. A. D. Anderson, MD – 1950-55  
 James D. Barger, MD – 1966-71  
 William Beautyman, MD – 1974-80  
 †Granville A. Bennett, MD – 1947-52  
 †William G. Bernhard, MD – 1958-64  
 †Everett L. Bishop, MD – 1947  
 †Joe M. Blumberg, MG MC USA – 1965-71  
 †Charles M. Blumenfeld, MD – 1970-72  
 Harold E. Bowman, MD – 1979-85  
 F. Wells Brason, MD – 1965-71  
 Robert L. Breckenridge, MD – 1969-75  
 †Victor B. Buhler, MD – 1957-61  
 †John J. Clemmer, MD – 1954-56  
 †Frank C. Coleman, MD – 1954-59  
 †Ward H. Cook, MD – 1947-50  
 William R. Cowan, Col MC USAF – 1980-83  
 †A. Reynolds Crane, MD – 1955-60  
 Joseph A. Cunningham, MD – 1953-58  
 †Theodore J. Curphey, MD – 1947-53  
 †Israel Davidsohn, MD – 1956-58  
 †Elbert DeCoursey, MD – 1956-58  
 Herbert Derman, MD – 1971-80  
 Dennis B. Dorsey, MD – 1964-70  
 John K. Duckworth – 1987-1993  
 †Russell J. Eilers, MD – 1970-76  
 Cyrus C. Erickson, MD – 1954-56  
 †Maxwell J. Fein, MD – 1952-55  
 †H. Russell Fisher, MD – 1951-53, 1959-61

†A. James French, MD – 1964-70  
 Phillips L. Gausewitz, MD – 1972-75  
 †Roger K. Gilbert, MD – 1976-81  
 P. Ridgway Gilmer Jr., MD – 1985-91  
 Guy C. Glenn, MD – 1989-95  
 †John L. Goforth, MD – 1948-50  
 †S. E. Gould, MD – 1957-62  
 †Omer E. Hagebusch, MD – 1966-72  
 William B. Hamlin, MD – 1985-91  
 †Ralph M. Hartwell, MD – 1960-66  
 Edwin B. Herring, MD – 1981-84  
 †Arthur T. Hertig, MD – 1960-62  
 †George K. Higgins, MD – 1963-69  
 †Henry F. Hunt, MD – 1949-51  
 †Oscar B. Hunter Sr., MD – 1947-48  
 †Oscar B. Hunter Jr., MD – 1958-64  
 Tyra T. Hutchens, MD – 1968-74  
 F. Lamont Jennings, MD – 1975-81  
 †Leslie S. Jolliffe, MD – 1967-73  
 †Donald H. Kaump, MD – 1953-55  
 Pierre W. Keitges, MD – 1980-86  
 †James W. Kernohan, MD – 1954-56  
 Albert S. Koenig, MD – 1961-64  
 †Frederick H. Lamb, MD – 1947-50  
 Perry A. Lambird, MD – 1984-92  
 Robert D. Langdell, MD – 1977-83  
 †Charles P. Larson, MD – 1953-58  
 †Carl J. Lind Jr., MD – 1971-77  
 †Alexis E. Lubchenco, MD – 1960-66  
 Paul K. Lund, MD – 1960-66  
 †Thomas B. Magath, MD – 1947-49  
 †Tracy B. Mallory, MD – 1947-51  
 †George D. Maner, MD – 1956-58  
 †John H. Manwaring, MD – 1978-81  
 Frank Matthews, MD – 1977-84  
 Kenneth D. McClatchey, MD, DDS – 1986-92  
 Thomas H. McConnell III, MD – 1985-88  
 Lawrence J. McCormack, MD – 1972-77  
 †James B. McNaught, MD – 1947  
 †C. A. McWhorter, MD – 1964-67  
 William A. Meissner, MD – 1965-68  
 †J. J. Moore, MD – 1947-49  
 †Alan R. Moritz, MD – 1954-59  
 †Sanford A. Mullen, MD – 1966-69, 1970-73  
 †George H. Murphy, MD – 1977-80  
 John C. Neff, MD – 1987-90

†Donald A. Nickerson, MD – 1954-59  
 Richard M. Nunnally, MD – 1988-94  
 †Harold D. Palmer, MD – 1953-58  
 Donald W. Penner, MD – 1973-79  
 Edwin E. Pontius, MD – 1975-81  
 †Joseph E. Porter, MD – 1962-65  
 †Frank B. Queen, MD – 1948-50, 1958-60  
 †John R. Rainey Jr., MD – 1979-85  
 Arthur E. Rappoport, MD – 1962-68  
 Paul A. Raslavicus, MD – 1987-1993  
 Howard M. Rawnsley, MD – 1985-93  
 Harold E. Resinger, MD – 1973-79  
 Gale R. Richardson, MD – 1972-78  
 †Maurice N. Richter, MD – 1960-63  
 †John R. Schenken, MD – 1950-52  
 Jared N. Schwartz, MD, PhD – 1991-96  
 Daniel L. Seckinger, MD – 1984-90  
 Donald A. Senhauser, MD – 1980-86  
 †John F. Sheehan, MD – 1959-61  
 Ernest E. Simard, MD – 1959-64  
 Milton Simons, MD – 1979-85  
 Eleanor B. Sinton, MD – 1981-88  
 †Harry P. Smith, MD – 1947-53  
 Louis S. Smith, MD – 1958-60  
 †Douglas H. Sprunt, MD – 1949-51  
 †Gretchen V. Squires, MD – 1958-60  
 Jon V. Straumfjord Jr., MD – 1969-72  
 F. William Sunderman, MD – 1947-48  
 Robert G. Thomas, MD – 1986-92  
 Herbert S. Uemura, MD – 1981-87  
 †Martin J. Valaske, MD – 1972-79  
 Loyd R. Wagner, MD – 1983-85  
 †George Z. Williams, MD – 1962-65  
 Marjorie J. Williams, MD – 1971-77  
 H. L. Wollenweber, MD – 1951-53  
 †David A. Wood, MD – 1950-53  
 Kay H. Woodruff, MD – 1991-96  
 †Robert W. Woods, MD – 1983-87  
 Raymond C. Zastrow, MD – 1985-88  
 William B. Zeiler, MD – 1981-85

### Speakers of the Assembly and House of Delegates

†H. Russell Fisher, MD — 1957-59  
 †Russell S. Fisher, MD — 1959-61  
 William J. Reals, MD — 1961-64  
 †Robert C. Horn, Jr., MD — 1964-68  
 †Carl J. Lind, Jr., MD — 1968-71  
 Lawrence J. McCormack, MD — 1971-72  
 Edwin E. Pontius, MD — 1972-75  
 †Herbert Lansky, MD — 1975-79  
 Robert G. Thomas, MD — 1979-84  
 Richard M. Nunnally, MD — 1984-88  
 Emmett B. Reilly, MD — 1988-92  
 Thomas P. Wood, MD — 1992-96  
 Donald D. VanFossan, MD — 1996-

### Vice-speakers of the Assembly and House of Delegates

†Robert C. Horn, Jr., MD — 1962-64  
 James D. Barger, MD — 1964-66  
 Lawrence J. McCormack, MD — 1966-67  
 †Carl J. Lind, MD — 1967-68  
 Lawrence J. McCormack, MD — 1968-71  
 Edwin E. Pontius, MD — 1971-72  
 †Herbert Lansky, MD — 1972-75  
 Robert E. Perry, MD — 1975-76  
 Robert G. Thomas, MD — 1976-79  
 Herbert S. Uemura, MD — 1979-81  
 Loyd R. Wagner, MD — 1981-83  
 Richard M. Nunnally, MD — 1983-84  
 Raymond C. Zastrow, MD — 1984-85  
 Emmett B. Reilly, MD — 1985-88  
 Thomas P. Wood, MD — 1988-92  
 Donald D. VanFossan, MD — 1992-96  
 Joseph P. Leverone, MD — 1996-

### Chairs of the Residents' Forum

Cynthia L. Reid, MD — 1989-90  
 Stacey L. Garry, MD — 1990-91  
 Leslie G. Dodd, MD — 1991-92  
 Rebekah L. Wold, MD — 1992-93  
 Kimberly A. Collins, MD — 1993-94  
 William Becker, DO — 1994-95  
 Donna M. Skinker, MD — 1995-96  
 Mohammad Nasar Qureshi, MD, PhD — 1996-

† Deceased

*Appendix E*  
*Honorary Fellows*

	<u>Elected</u>
Robert E. Anderson, MD	1977
†William Boyd, MD	1955
†Thelma B. Dunn, MD	1963
†John F. Enders, MD	1961
George M. Hass, MD	1963
†Ludvig Hektoen, MD	1948
†Howard T. Karsner, MD	1961
U. Pentti Kokko, MD	1973
†Leonard W. Larson, MD	1961
†George Papanicolaou, MD	1956
†George H. Whipple, MD	1954

*Appendix F*  
*Chief Executive Officers*

†Melbourne G. Westmoreland, MD	1947–1953
†Arthur H. Dearing, MD	1953–1963
Oliver J. Neibel, JD	1963–1972
Howard E. Cartwright	1972–1989
Lee VanBremen, PhD	1989–present

† Deceased

## Appendix G

# CAP Awards and Their Recipients

### CAP/ASCP Distinguished Service Award

Established in 1965 and presented annually; given to a pathologist who belongs to both societies, in recognition of outstanding contributions to American pathology and to the two organizations.

†Harry P. Smith, MD – 1965  
†Israel Davidsohn, MD – 1966  
†John R. Schenken, MD – 1967  
†W. A. D. Anderson, MD, 1968  
†Lall G. Montgomery, MD – 1969  
†James Earle Ash, MD – 1970  
†John L. Goforth, MD – 1971  
†Arthur T. Hertig, MD – 1972  
†Frank W. Hartman, MD – 1973  
†Richard E. Palmer, MD – 1974  
†Thomas D. Kinney, MD – 1975  
William D. Dolan, MD – 1976  
†A. James French, MD – 1977  
†Frank C. Coleman, MD – 1978  
William A. Meissner, MD – 1979  
James J. Humes, MD – 1980  
Warren L. Bostick, MD – 1981  
William J. Reals, MD – 1982  
Jack M. Layton, MD – 1983  
Robert W. Coon, MD – 1984  
James D. Barger, MD – 1985  
Dennis B. Dorsey, MD – 1986  
Vernie A. Stembridge, MD – 1987  
F. William Sunderman, MD, PhD – 1988  
Frank B. Walker, MD – 1989  
Pierre W. Keitges, MD – 1990  
Murray R. Abell, MD – 1991  
Thomas F. Dutcher, MD – 1992  
Herbert Derman, MD – 1993  
George C. Hoffman, MD – 1994  
Howard M. Rawnsley, MD – 1995  
George D. Lundberg, MD – 1996

### CAP Pathologist of the Year Award

Established in 1955 and presented annually to a leader of the CAP for outstanding contributions to pathology and to the programs of the College, particularly during the preceding five years.

†Shields Warren, MD – 1955  
†Arthur Hawley Sanford, MD – 1956  
†James W. Kernohan, MD – 1957  
David A. Wood, MD – 1958  
†W. A. D. Anderson, MD – 1959  
†Israel Davidsohn, MD – 1960  
†John R. Schenken, MD – 1961  
F. William Sunderman, MD, PhD – 1962  
Bradley E. Copeland, MD – 1963  
†Alan R. Moritz, MD – 1964  
†Frank C. Coleman, MD – 1965  
†Victor B. Buhler, MD – 1966  
†Ralph M. Hartwell, MD – 1967  
Ernest E. Simard, MD – 1968  
Dennis B. Dorsey, MD – 1969  
†Oscar B. Hunter Jr., MD – 1970  
†Russell J. Eilers, MD – 1971  
†Joe M. Blumberg, MG MC USA – 1972  
†A. James French, MD – 1973  
William J. Reals, MD – 1974  
†C. A. McWhorter, MD – 1975  
†Robert C. Horn Jr., MD – 1976  
James D. Barger, MD – 1977  
Marjorie J. Williams, MD – 1978  
†Russell S. Fisher, MD – 1979  
Tyra T. Hutchens, MD – 1980  
Donald W. Penner, MD – 1981  
Lawrence J. McCormack, MD – 1982  
Jerald R. Schenken, MD – 1983  
Frank Matthews, MD – 1984  
George D. Lundberg, MD – 1985  
Herbert Derman, MD – 1986  
Milton Simons, MD – 1987

Robert L. Breckenridge, MD – 1988  
Thomas L. Gavan, MD – 1989  
William B. Zeiler, MD – 1990  
†John H. Rippey, MD – 1991  
Lloyd R. Wagner, MD – 1992  
William B. Hamlin, MD – 1993  
Donald A. Senhauser, MD – 1994  
Thomas D. Trainer, MD – 1995  
Daniel L. Seckinger, MD – 1996

### **Frank W. Hartman Memorial Award**

Established in 1977 to honor the College's first president; presented to a CAP member in recognition of outstanding service to a single CAP program or project, generally over a long period of time. Given not more often than annually.

†Robert S. Haukohl, MD – 1977  
†Martin J. Valaske, MD – 1978  
Roger A. Côté, MD – 1979  
†Roger K. Gilbert, MD – 1980  
Eleanor B. Sinton, MD – 1981  
John K. Duckworth, MD – 1982  
J. Scott Pennepacker, MD – 1984  
†Frank C. Coleman, MD – 1986  
Pierre W. Keitges, MD – 1987  
†John H. Rippey, MD – 1988  
†Israel Diamond, MD – 1990  
Beverly Balfour Kraemer, MD – 1991  
William B. Hamlin, MD – 1992  
Bernard L. Kasten, MD – 1993  
Henry Travers, MD – 1994  
George F. Kwass, MD – 1996

### **CAP Foundation Herbert Lansky Award**

Established in 1985 to honor a respected CAP leader, accidentally killed while serving as Secretary-Treasurer. Awarded to a board-certified pathologist, preferably less than 45 years of age, who has demonstrated respected leadership consistent with the goals of the Foundation and has made substantial contributions in the areas of pathology practice, education, research, or the organizational life of the profession.

Joseph P. Leverone, MD – 1986  
Kenneth D. McClatchey, MD, DDS – 1987  
Jared N. Schwartz, MD, PhD – 1987  
Raymond D. Aller, MD – 1988  
Peter J. Howanitz, MD – 1989  
Suzanne S. Mirra, MD – 1990  
Cathy O. Blight, MD – 1991  
Richard J. Hausner, MD – 1992  
Rebecca L. Johnson, MD – 1993  
Richard P. Vance, MD – 1994  
Susan M. Strate, MD – 1995  
Gene N. Herbek, MD – 1996

### **Frank C. Coleman Award for Public Service**

Established in 1989 in memory of the CAP's sixth president; given to a CAP Fellow who exemplifies Dr. Coleman's political, citizenship, and leadership qualities, for accomplishments and dedication to political and civic life and to public service in the U.S. Presented no more often than annually.

Jerald R. Schenken, MD – 1989  
Pierre W. Keitges, MD – 1994

† Deceased

**William H. Kuehn, PhD, Outstanding Communicator Award**

Established in 1991 in memory of the CAP's first full-time Director of Public Services; presented to a person who has made outstanding communications contributions strengthening the image of pathology.

Gordon L. Johnson, MD – 1991

Ronald P. Spark, MD – 1994

Kay H. Woodruff, MD – 1996

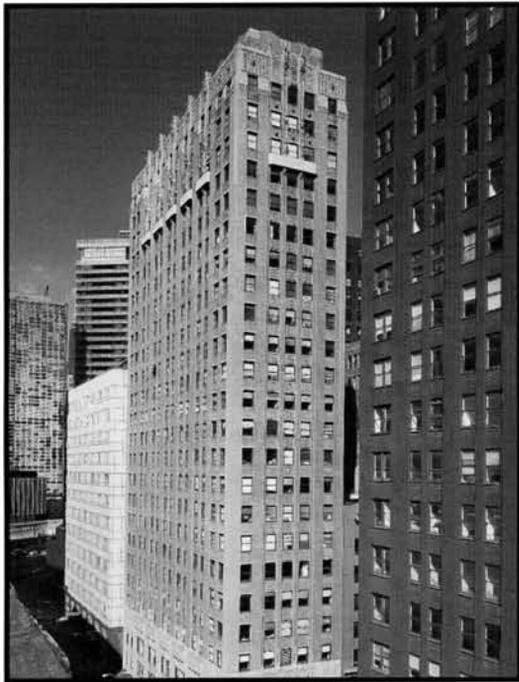
**Major General Joe M. Blumberg Award for Outstanding Contributions to the Laboratory Accreditation Program**

Established in 1995 in memory of General Blumberg, Chair of the Commission on Laboratory Accreditation from 1969 through 1978. Presented annually to an individual who has contributed exceptional and outstanding service to the College's Laboratory Accreditation Program.

1995 John K. Duckworth, MD

1996 William E. Williamson Sr.

Appendix H  
*CAP Offices*



*Fig. H-1. 203 North Wabash Avenue, Chicago, Illinois  
1947–1956*

*(Photo courtesy of Marc Realty)*



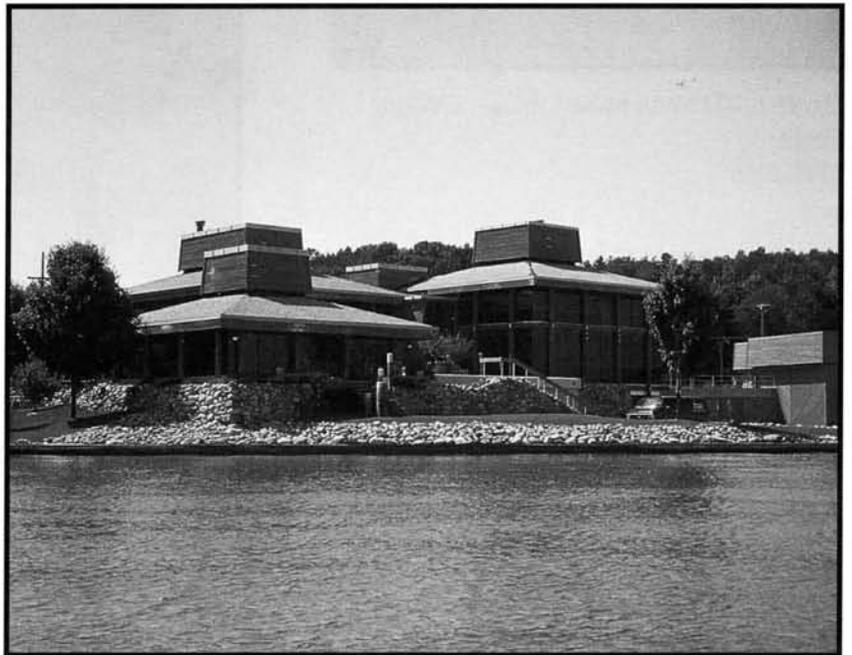
*Fig. H-2. Prudential Plaza, Chicago, Illinois  
1956–1965*

*(Photo by E.C. Bunting, courtesy of Chicago Historical Society; negative # ICHi-01057)*



*Fig. H-3. Carbide and Carbon Building  
230 North Michigan Avenue, Chicago, Illinois  
1965–1974*

*(Photo courtesy of Chicago Historical Society;  
negative # ICHi-13922)*



*Fig. H-4. Belfour & Stulen/CAP Computer Center, Traverse City, Michigan  
1972–1989*

*Fig. H-5. 7400 Skokie Boulevard, Skokie, Illinois  
1974–1985*



*Fig. H-6. 5202 Old Orchard Road, Skokie, Illinois  
1985–1989*



**Fig. H-7.** 325 Waukegan Road, Northfield, Illinois 1989–Present

## Washington, DC Offices

*1775 K Street, NW  
1970–1978*

*1333 New Hampshire Ave., NW  
1978–1981*

*1101 Vermont Ave., NW  
1981–1993*

*1350 I Street, NW  
1993–Present*

# Index

- academies 23
- Accreditation Council for Continuing Medical Education (ACCME) 28
- accreditation programs, joint 143
- accreditation, hospital 114, 139
- accreditation, laboratory 41, 54, 61–72, 117, 122, 125
- accreditation, laboratory *See also*: Laboratory Accreditation Program
- acquired immunodeficiency syndrome (AIDS) 28
- ACR/CAP Patterns of Care Steering Committee 99
- advertising 31, 115, 117
- Affiliate Members 26
- Agency for Health Policy and Research (US) 102
- aircraft accidents 98–99
- Alabama 51, 76
- Allen, Hollis N. 63–64
- American Academy of Family Practice 55
- American Academy of Microbiology 138
- American Academy of Pediatrics 55
- American Association for Clinical Chemistry 48, 70–71, 138–139
- American Association of Blood Banks (AABB) 67, 70, 142–143
- American Association of Pathologists and Bacteriologists 5, 10
- American Blood Commission 143
- American Board of Nuclear Medicine 141
- American Board of Pathology 2–3, 24–26, 98, 100, 141
- American Cancer Society 100–101, 143–144
- American College of Nuclear Physicians (ACNP) 56, 143
- American College of Physicians 99, 102, 139
- American College of Radiology 5, 19, 99, 138
- American College of Surgeons 2, 99, 114, 139
- American Diabetes Association 87
- American Fertility Society 71
- American Hospital Association (AHA) 29, 64, 96, 139
- American Journal of Clinical Pathology* 32, 60
- American Medical Association (AMA) 2, 20, 26–28, 32–33, 45, 68, 95, 102, 111–112, 122, 127–129, 137–139, 142
- American National Metric Council 48–49
- American National Standards Institute (ANSI) 48
- American Nursing Home Association 132
- American Osteopathic Association 55
- American Pathology Foundation 14–15
- American Red Cross 142
- American Registry of Pathology (ARP) 100, 124
- American Society for Quality Control (ASQC) 48
- American Society of Clinical Pathologists (ASCP) 2–5, 10, 12, 18, 20, 27, 32, 51–52, 70, 97, 99–100, 123–124, 128, 135–137
- American Society of Experimental Pathologists 5, 10
- American Society of Internal Medicine (ASIM) 55, 143
- analytic error 76
- analytic precision 82–83
- anatomic pathology 2, 12, 27, 85, 103–106
- Anatomic Pathology, Committee on 96
- Anderson, Robert E. 26
- antitrust litigation 116–118, 124
- Archive of Standards* 47
- Archives of Pathology & Laboratory Medicine* 25, 30, 32–34, 60
- Arkansas Society of Pathologists 130
- Arkansas, Pathology Laboratories of 119
- Arkin, Charles F. 82
- Armed Forces Institute of Pathology (AFIP) (US) 35, 98–99, 123–124
- Arnold, Richard 130
- asbestos 96
- Aspen, Colo. 30
- Assembly 13–14, 62, 116, 136
- Assembly *See also*: House of Delegates
- Association of Pathology Chairs 67, 142
- Association Service Office 37

- athletic drug testing laboratories 71
- Atlas of Tumor Pathology* 124
- Australia 56, 85
- Australia, College of Pathologists of 103
- autopsy 1, 34, 95–98, 140
- Autopsy Committee 34, 95
- Autopsy, Ad Hoc Committee to Study 96
- aviation accidents 99
- Bacteriology Surveys 51
- Barger, James D. 62, 103
- Barnett, Roy N. 47, 57, 75
- Basic Survey 54, 58
- Batjer, John 70
- Batsakis, John G. 83
- Beckman Instruments 83
- Belfour & Stulen, Inc., Traverse City, Mich. 19, 54, 66
- Belfour, Al 19
- Belgium 85
- Belk, William P. 42, 61
- benchmarking (quality assurance) 85–87
- Bennett, Granville 5
- Bergnes, Manuel A. 142
- Bethesda System (Pap reporting) 102
- bidding, competitive 118, 132
- Bierig, Jack R. 130
- billing 118
- billing, direct 113, 115, 118
- billing, professional component 115, 119, 123, 127–128, 131
- Birge, Richard 13
- Bishop, Everett L. 5, 111
- black lung disease 96
- bladder lesions 99
- blood banks 70, 130–131, 142–143
- blood transfusions 143
- Blue Cross/Blue Shield 2–3, 5, 102, 114
- Blumberg, Joe M. 66, 69, 123
- Blumenfeld, Charles 76
- Board of Governors 5–6, 10–11, 13–14, 16, 27, 31, 62, 96, 101, 111, 113, 121, 125, 130, 136
- Bogdanich, Walt 101, 126
- Bowman, John G. 139
- Boyd, William 26, 95
- Brazil 85
- breast lesions 99, 104–105
- brochures 100–101, 114
- Brown, Donald E. 41, 51
- Broz, John 128
- Bruce, Tom 130
- budget 5
- Budget Planning and Review Committee 16
- budget reconciliation (federal) 130
- Buhler, Victor B. 63
- Bulletin*, CAP 31
- Burdick, Ward 2
- Bureau of Standards (CAP) 42, 62
- bylaws 5, 117
- Cahal, Max 5
- California Medical Association 131
- California Society of Internal Medicine 55, 143
- California Society of Pathologists 76, 123
- Canada 56, 85
- Cancer Committee 99, 138
- CAP *Bulletin* 31
- CAP Certification Laboratory 45
- CAP Conferences 29–30, 60, 77, 87, 98, 102
- CAP Foundation 35–36, 97
- CAP Foundation Conferences 97
- CAP Reference Laboratory 45
- CAP Reference Preparation for Serum Proteins 45
- CAP TODAY 18, 32
- Carbide and Carbon Building, Chicago, Ill. 18
- Carlson, Dennis J. 67, 69
- Cartwright, Howard E. 18, 35
- Catholic Hospital Association (CHA) 64, 96, 113
- Centers for Disease Control (CDC) (US) 43, 45, 47, 65–67, 71, 101, 124
- Centers for Disease Control *See also*:
  - Communicable Disease Center
- Central States Pension Fund 119
- Certification Laboratory, CAP 45
- certification, board 24–26, 98, 100, 141
- cervical cytology 105
- Chambers, Jayne Hart 132
- Check Sample Program (ASCP) 51–52
- checklists 47, 64, 66–67, 69–70, 143
- chemistry, clinical, quality control 76, 83
- CIGNA 37
- Cleveland Clinic Foundation 45
- clinical chemistry, quality control 76, 83
- clinical laboratories 1–2, 111, 117–118, 124, 140

- Clinical Laboratories Improvement Act of 1967 (CLIA- 67) 19, 58, 62, 65–66, 101, 124–125
- Clinical Laboratories Improvement Amendments of 1988 (CLIA-88) 58, 62, 71, 84, 101–102, 126
- Clinical Laboratory Standards Committee 15
- Clinical Pathology Standards Program 43
- Clinical Pathology Standards Program Committee 41
- Clinical Pathology Commission 57
- coagulation, quality control 76
- Coagulation Surveys 83
- Code of Ethics 5–6, 111–112, 116–117
- Codman, Ernest A. 139
- Cohen, Wilbur 127
- Coleman, Francis C. (Frank) 15, 63, 115, 117, 121, 123, 128–129, 131
- Collier's* magazine 34, 95
- Colombia 56
- Colorado 75
- colorectal lesions 99
- Columbia University 114
- Commission on Clinical Pathology 57
- Commission on Laboratory Accreditation 42, 63, 69, 102
- Commission on Public Services 35
- commissioners (LAP) 66, 72
- commissioners, interstate (LAP) 68
- commissioners, regional (LAP) 64, 70–71
- commissioners, special (LAP) 67, 71
- commissioners, state (LAP) 66
- commissions 16
- Committee on Anatomic Pathology 96
- Committee on Autopsy 34, 95
- Committee on Budget Planning and Review 16
- Committee on Cancer 99, 138
- Committee on Clinical Laboratory Standards 15–16
- Committee on Clinical Pathology Standards Program 41
- Committee on Constitution, By-laws and Resolutions 16
- Committee on Cytopathology 103, 107
- Committee on Ethics 6, 15, 111–114, 116–117
- Committee on Evaluation of Hospital Laboratories 6, 15, 61
- Committee on Exfoliative Cytology 100
- Committee on Finance 15
- Committee on Forensic Pathology 98
- Committee on Government Affairs 122
- Committee on Histopathology and Cytology 103
- Committee on Hospital and Institutional Relations 112, 114–115, 117
- Committee on Insurance 37
- Committee on Laboratory Accreditation, Ad Hoc 62–63
- Committee on Laboratory Evaluation 62
- Committee on Laboratory Fiscal Management 29
- Committee on Laboratory Management and Planning 28–29
- Committee on Laboratory Standards 41
- Committee on Legislation and Related Affairs 122
- Committee on Legislative and Regulatory Activities 122
- Committee on Membership 113
- Committee on Nomenclature and Classification of Disease 37
- Committee on Plans and Scope 15, 62
- Committee on Practice Guidelines 103
- Committee on Product Evaluation 46
- Committee on Professional Affairs 122
- Committee on Professional and Economic Affairs 122
- Committee on Professional Relations 117
- Committee on Publications 31
- Committee on Quality Practices 85
- Committee on Recruitment 27
- Committee on Reimbursement 122
- Committee on Residents, Young Physicians, and General Membership 142
- Committee on Sections 15
- Committee on Standards 6, 33, 42, 45, 51, 75, 103
- Committee on Surgical Pathology 103

- Committee on Survey Contract Development 59  
 Committee on Surveys 42, 57  
 Committee on the Pathologist as a Consultant in  
   Cancer Patient Management 99  
 Committee on Workload Recording 29  
 Committee to Study the Autopsy, Ad Hoc 96  
 Committee, Editorial 34  
 Committee, International 48  
 Committee, Legislative 121–122  
 Committee, Legislative, National 118, 121  
 Committee, Legislative, State 121, 125  
 Committee, National Legislative 118, 121  
 Committee, National, for Clinical Laboratory  
   Standards 42, 47  
 Committee, Nominating 11  
 Committee, Patterns of Care (CAP/ACR) 99, 138  
 Committee, State Legislative 121, 125  
 committees 10–11, 13, 15–16, 20, 27–28  
 committees, joint 62, 99, 135–136, 138, 143  
 committees, reference 13  
 committees, regional 5, 12–13  
 committees, resource 16, 29–30, 42, 56–57, 67, 84  
 committees, tissue 114  
 Communicable Disease Center (US) 43, 58, 65–66  
 Communicable Disease Center *See also*: Centers  
   for Disease Control  
 competitive bidding 118, 132  
 Comprehensive Surveys 53, 66  
 computers 19, 28–29, 54, 59, 67, 70, 72  
 Conferences, CAP 29–30, 60, 77, 87, 98, 102  
 Conferences, CAP Foundation 97  
 consent decree, antitrust 116–117, 124  
 constitution 5, 9  
 Constitution, By-laws and Resolutions Committee  
   16  
 continuing medical education (CME) 28, 68, 141  
 contracts 12, 58–59, 112–114, 117–118, 128,  
   130, 139  
 contracts, percentage 113–114, 118  
 control materials 75–77, 82–83  
 Cook, Ward H. 5, 111  
 Copeland, Bradley E. 47, 57–58  
 coroners 98  
 Coté, Roger A. 37–38  
 Council of International Organization of Medical  
   Science (CIOMS) 38  
 Council on Education and Information Services 16  
 Council on Education and Membership Services 20  
 Council on Government Affairs 122  
 Council on Government and Professional Affairs  
   122, 126  
 Council on Government Relations 125  
 Council on Government Relations and Liaison 16  
 Council on Laboratory Administration 16  
 Council on Pathology Practice 20  
 Council on Practice Management 85  
 Council on Public Affairs 35  
 Council on Quality Assurance 16, 48  
 Council on Scientific Affairs 57, 72, 85  
 Council on World Standards (WASP) 48  
 councils 15–16  
 Crane, A. Reynolds 136  
 Culbertson, Clyde 3  
 Cumulative Survey Management Report 67  
 Cunningham, Joseph A. 64  
*Current Procedural Terminology (CPT)* 138  
 cyanmethemoglobin standards 44–45  
 cytology & cytopathology 12, 27, 100–102, 104,  
   126, 141, 144  
 cytology, effusion 105  
 Cytopathology Committee 103, 106–107  
 cytotechnologists 100, 102, 107  
*DATA ReCAP* 60  
 Davidsohn, Israel 61  
 Dean, Gerald S. 57  
 Dearing, Arthur H. 17–18, 31  
 death certificates 97  
 deeming authority (CLIA-88) 71  
 DeLand, Frank 56  
 Delegates, House of 11, 14, 27, 68, 70, 101  
 Delegates, House of *See also*: Assembly  
 Derman, Herbert 103, 131  
 Diagnosis Related Groups (DRGs) 102, 118  
 Diamond, Israel 67  
 direct billing 113, 115, 118  
 directors, laboratory 70, 123, 125  
 DiSilvio, Thomas V. 82  
 Doctor's Company of California 37  
 Dorsey, Dennis B. 16, 31, 41, 47, 64–66  
 Douglas, Paul 127  
 Drunkometers 114  
 Duckworth, John K. 69

- dues 5–6, 15, 24–25, 27  
 Dunn, Thelma B. 26  
 Editorial Committee 34  
 education 12, 27–29, 51–52, 66–67, 69, 96,  
     98–100, 105–106, 124, 128, 135, 141–144  
 Education and Information Services, Council on 16  
 Education and Membership Services, Council on  
     20  
 education, medical, continuing (CME) 28, 68, 141  
*Effective Laboratory Testing* 102  
 effusion cytology 105  
 Eilers, Russell J. 46, 57, 75  
 elections 11, 14  
 electrophoresis 130  
 Emeritus Fellows 26  
 Emory University 43  
 enablers (quality assurance) 85–87  
 Enders, John F. 26  
 endometrial lesions 104  
 England 85  
 Enzymology Surveys 55, 143  
 epithelial skin lesions 104  
 equipment, laboratory 42, 46  
 equipment manuals 46  
 Ercolano, Alfred S. 132  
 error, analytic 76  
 Ethics Committee 6, 15, 111–114, 116–117  
 Ethics, Code of 5–6, 111–112, 116–117  
 Evaluation of Hospital Laboratories, Committee on  
     6, 15, 61  
 evaluation service, surgical pathology 115  
 Ewing, Margaret Blake 34  
 Exception Summary, Proficiency Testing 67  
 executive staff 17–18  
 Exfoliative Cytology, Committee on 100  
 External Comparative Evaluation of Laboratories  
     (EXCEL®) 55  
 fee splitting 111, 115  
 Fellows 6, 24–25  
 Fellows, Emeritus 26  
 Fellows, Founding 6, 25  
 Fellows, Honorary 25–26  
 Fellows, Life 25  
 fellowships 26, 47, 54, 98  
 Finance Committee 15  
 Fisher, Russell S. 98  
 Florida 76  
 Florida Association of Pathologists 116  
 Florida Medical Association 123  
 Forensic Identity and Parentage Testing Surveys 55  
 forensic pathology 35, 98–99, 141  
 Forensic Pathology Committee 98  
 Forensic Urine Drug Testing (FUDT) Accreditation  
     Program 138–139  
 forensic urine drug testing (FUDT) laboratories 70  
 Foundation, CAP 35–36, 97  
 Founding Fellows 6, 25  
 Fraser, Martin D. 82  
 Gall, Edward A. 61  
 Gausewitz, Phillips 122  
 genetic testing 132  
 Georgia 76  
 Gilbert, Roger K. 47, 54, 60  
 Giordano, Alfred S. 2–3, 137  
 Glenn, Guy 103  
 glucose monitoring, quality assurance 87  
 Glucose Surveys 56  
 Gould, S.E. 31  
 Government Affairs, Committee on 122  
 Government Affairs, Council on 122  
 Government and Professional Affairs, Council on  
     122, 126  
 Government Interface Program 125–126  
 Government Relations and Liaison, Council on 16  
 Government Relations, Council on 125  
 Governors, Board of 5–6, 10–11, 13–14, 16, 27,  
     31, 62, 96, 101, 111, 113, 121, 125, 130, 136  
 grading, Surveys 56, 58  
 guidelines, practice 98–100, 102–103, 138–140  
 Hamlin, William B. 72  
 Hanson, Daniel J. 57  
 Hartman, Frank W. 3–5, 9, 31, 141  
 Hass, George M. 26  
 Health Care Financing Administration (HCFA)  
     (US) 58, 67, 71, 119, 126, 129–130, 138

- Health Industry Manufacturers Association (HIMA) 48
- Health, Education & Welfare, Dept. of (HEW) (US) 66, 128
- Healthcare Forum 87
- Hektoen, Ludvig 25, 32–33, 95
- hematology 130–131
- Hematology Surveys 51
- hematology, quality control 76
- hemochromatosis (practice parameter) 103
- hemoglobinometry 44–45
- Henson, Donald E. 99, 138
- hepatitis B 143
- Herrera, Nilo 56
- Heustis, Douglas W. 57
- Hicklin, Martin 103
- Hillkowitz, Philip 2
- histologic diagnosis surveys 103
- histology, surgical 34
- Histopathology and Cytology Committee 103
- Histopathology I (project) 104
- Histopathology II (project) 104
- Hodgkin's disease 99
- Hong Kong 85
- Honorary Fellows 25–26
- Hormone Receptor Assay Surveys 55
- Horn, Robert C. 125
- Hospital and Institutional Relations Committee 112, 114–115, 117
- hospital laboratories 123
- hospitals 4, 112–114, 128, 139–141
- hospitals, accreditation 84, 114, 139
- House of Delegates 11, 14, 27, 68, 70, 101
- House of Delegates *See also*: Assembly
- Howanitz, Peter J. 82
- Hsiao, William 132
- human growth hormone 142
- human immunodeficiency virus (HIV) 143
- Human Pathology* 33
- Hunter, Oscar B., Jr. 116
- Hunter, Oscar B., Sr. 5
- Hutchens, Tyra T. 16, 48, 55, 75
- Hutter, Robert V.P. 99, 138
- I & A Newsletter* 67
- Illinois 58, 76
- incorporation (CAP) 6, 9
- India 66
- Indian Health Service (US) 67, 69
- Indiana 3, 51, 76
- Indiana University 28
- inspections, accreditation 68
- inspectors (LAP) 66, 72
- Instrument Maintenance and Function Verification Manual* 67
- Instrument Maintenance Program 67
- Instrumentation Surveys 55, 143
- instrumentation, laboratory 42, 46, 54, 67
- Insurance Committee 37
- insurance, life 37
- insurance, malpractice 37
- insurance, medical 2, 37, 113, 137
- International Academy of Pathology 56, 99
- international activities 56, 69
- International Committee 48
- International Council of Societies of Pathology 97
- International Standards Organization 49
- Intersociety Committee on Pathology Information (ICPI) 35
- Intersociety Committee on Quality Assurance Programs 138
- Intersociety Cytology Council 100
- interstate commissioners (LAP) 68
- Iowa Association of Pathologists 115, 123
- Iowa Board of Medical Examiners 114–115
- Iowa Hospital Association 114–115, 123
- Iowa Medical Society 114–115
- Israel 85
- Jakob-Creutzfeld disease 142
- Jardine's Group Services Corporation 37
- Javits, Jacob 124
- joint accreditation programs 143
- Joint Blood Council 142
- Joint Commission on Accreditation of Healthcare Organizations (JCAHO) 71, 84, 139–141
- Joint Commission on Accreditation of Hospitals (JCAH) 62, 64–67, 69–70, 96, 114, 139–141
- joint committees 62, 99, 135–136, 138, 143
- Joint Pathology Task Force 131
- joint surveys 55, 143
- journals 32–34
- Junior Members 6, 25, 27
- Juran Institute 88

- Justice Department (US) 116–117  
 Karsner, Howard T. 26  
 Kaump, Donald H. 63  
 Keitges, Pierre 75  
 Kennedy, Edward M. 124  
 Kennedy, John F. 127  
 Kentucky 76  
 Kerr, Robert S. 127  
 Kerr-Mills Bill 127  
 key contact program 123  
 Kiefer, Lester J. 67  
 Kietges, Pierre 35  
 Kirby-Bauer method (microbiology sensitivity testing) 76  
 Knox, Victor 127, 132  
 Kokko, U. Pentti 26  
 Konzelmann, Frank W. 2  
 Koss, Leopold G. 103  
 Kuehn, William 35  
 laboratories, athletic drug testing 71  
 laboratories, accreditation 41, 54, 61–72, 117, 122, 125  
 laboratories, clinical 1–2, 111, 117–118, 124, 140  
 laboratories, directors 70, 123, 125  
 laboratories, forensic urine drug testing (FUDT) 70  
 laboratories, hospital 123  
 laboratories, leasing 114, 118, 127–128  
 laboratories, licensure 122, 125  
 laboratories, physician office 125–126  
 laboratories, reproductive biology 71  
 Laboratory Accreditation Commission 42, 63, 69, 102  
*Laboratory Accreditation News* 67  
 Laboratory Accreditation Program (LAP) 18, 41, 47, 61–72, 75, 83–84, 107, 123, 140–141  
 Laboratory Accreditation, Ad Hoc Committee on 62–63  
 Laboratory Administration, Council on 16  
 laboratory equipment manuals 46  
 Laboratory Evaluation Committee 62  
 Laboratory Fiscal Management Committee 29  
 Laboratory Improvement Seminars 66–67  
 Laboratory Inspection and Accreditation Commission 63–64  
 laboratory instrumentation 42, 46, 54, 67  
 laboratory management 28, 141  
 Laboratory Management and Planning Committee 28  
 Laboratory Management Index Program (LMIP®) 29  
 Laboratory Standards Committee 41  
 laboratory technicians 42  
 Lamb, Frederick H. 5, 11  
 Lansky, Herbert 36  
 Larson, Leonard W. 26  
 Law Enforcement Assistance Administration (US) 98  
 lawsuits *See*: litigation  
 leasing, laboratories 114, 118, 127–128  
 Legislation and Related Affairs Committee 122  
 Legislative and Regulatory Activities Committee 122  
 Legislative Committee 121–122  
 Legislative Committee, National 118, 121  
 Legislative Committee, State 121, 125  
 legislative keyman program 123  
 licensure, laboratories 122, 125  
 licensure, medical 2, 28, 113  
 licensure, medical technologists 122  
 Life Fellows 25  
 life insurance 37  
 ligand assay, quality control 76, 83  
 litigation 114–115, 119, 123, 130, 143  
 litigation, antitrust 116–117, 124  
 liver lesions 104  
 Lloyd's of London 37  
 lobbyists 127, 132  
 logo, CAP 16–17, 46  
 Louisiana 76  
 lymphoma, non-Hodgkin's 104  
 Magath, Thomas B. 5  
 Mallory, Tracy B. 5  
 malpractice insurance 37  
 management, laboratory 28, 141  
 manpower, medical 26–27, 142  
*Manual of Contractual and Ethical Relations* 114  
*Manual of Physician and Hospital Relations* 117  
 manuals 67, 69, 98–99  
 manuals, laboratory equipment 46  
 marketing, Surveys 58–59  
 Massachusetts 76  
 matrix effects (control materials) 77

- McClatchey, Kenneth 48  
 McLendon, William W. 33  
 McNaught, James B. 5  
 medical education, continuing (CME) 28, 68, 141  
 medical examiners 98  
 medical insurance 2, 37, 113, 137  
 Medical Laboratory Associates (Birmingham, Alabama) 64  
 Medical Society of the State of Pennsylvania 42  
 medical technologists, licensure 122  
 Medicare 19, 62, 65, 96, 118–119, 123, 127–132, 138  
 Medicare and Medicaid Administrative and Reimbursement Reform Act 128–129  
 Mexico 85  
 meetings 27, 136–137  
 Members, Affiliate 26  
 Members, Junior 6, 25, 27  
 membership 6, 24–26, 113  
 Membership Committee 113  
 Miale, John B. 57  
 Michigan 76  
 Michigan Hospital Association 3  
 Michigan Pathology Society 3–4  
 Michigan State Health Department 58  
 micro-fellowships 29  
 microbiology 30, 137  
 microbiology sensitivity testing, quality control 76–77  
 Microbiology Resource Committee 30  
 Milles, George 31  
 Mills, Wilbur 127  
 minutes, meeting 136  
 Mississippi 76  
 Moore, H. David 132  
 Moore, Josiah J. 5  
 Morrissey, Robert W. 103  
 motion pictures 34–35  
 motto, CAP 16–17  
 Mueller, Rudolph J., Jr. 57  
 mutual working agreements 128  
 Nakamura, Robert M. 45  
 National Academy of Sciences 97, 124  
 National Advisory Cancer Council 103  
 National Autopsy Data Bank (NADB) 96  
 National Bureau of Standards (NBS) 47, 54, 61, 104  
 National Cancer Institute (NCI) 97, 99  
 National Center for Health Statistics 96  
 National Committee for Clinical Laboratory Standards (NCCLS) 42, 47, 70  
 National Fire Prevention Association 69–70  
 National Funeral Directors Association 96  
 National Institute of Criminal Justice 98  
 National Institute of Standards and Technology (NIST) 47  
 National Institutes of Health (NIH) 37, 44, 97  
 National Legislative Committee 118  
 National Pituitary Agency 142  
 National Reference System for the Clinical Laboratory 47–48  
 National Registry of Forensic Pathology 98  
 National Research Council (NRC) 44, 124  
 National Select Morticians 96  
 Nebraska 76  
 Neibel, Oliver J. 18  
*New England Journal of Medicine* 54, 60  
 New Jersey 76  
 New York (state) 75–76  
 New York City municipal hospitals 112–113  
 New York State Association of Public Health Laboratories 103  
 New York State Health Department 58  
 New Zealand 85  
 Nickerson, Donald A. 46  
 nomenclature 37–38, 103–104  
 Nomenclature and Classification of Disease, Committee on 37  
 Nominating Committee 11  
 non-Hodgkin's lymphoma 104  
 Northfield, Ill. 19  
 nuclear medicine 141, 143  
 Nuclear Medicine Resource Committee 56  
 Nuclear Medicine Survey 56  
 Nunn, Sam 124  
 O'Leary, Dennis 84  
 objectives, CAP 9  
 officers 11–12  
 offices, CAP 6, 18–20  
 Ohio 76  
 Oregon 58  
 Palmer, Richard E. 137  
 panel testing (practice parameter) 103  
 Pap mills 101

- Papanicolaou smears 30, 100–102, 137, 144  
 Papanicolaou, George 25  
 parameters, practice 102–103  
 Parasitology Surveys 51  
 Parentage Testing Surveys 143  
 Parnell, B.L. 104  
*Pathologist* 31, 33  
 Pathologist as a Consultant in Cancer Patient Management, Committee on 99  
 Pathology Laboratories of Arkansas 119  
 Pathology Practice, Council on 20  
 PathPAC 126  
 Patterns of Care Steering Committee (CAP/ACR) 99, 138  
 Penner, Donald W. 57, 103, 106  
 Pennsylvania 76  
 Pennsylvania State Medical Society 42  
 percentage contracts 113–114, 118  
 Performance Appraisal Program (PAP) 106  
 Performance Improvement Program in Diagnostic Surgical Pathology and Cytopathology (PIP) 102, 106  
 Peru 56  
 Petite Survey 55  
 Philadelphia County Medical Society 42  
 physician office laboratories 125–126  
 pituitary gland 142  
 Placement Bureau 6, 17  
 planning 21, 68  
 Plans and Scope Committee 15, 62  
 plasma, fresh frozen (practice parameter) 103  
 platelet counting, quality control 76  
 Platt, Ron 83  
 pneumoconiosis 96  
 point of care testing 70, 77, 87  
 political action committees (PACs) 125  
 practice expense costs 132  
 practice guidelines 98–99, 102–103, 138–140  
 Practice Guidelines Committee 103  
 Practice Management, Council on 85  
 practice parameters 102–103  
 practice protocols 99–100, 138  
 practicums 29  
 preceptorships 67  
 precision, analytic 82–83  
 president-elect 11–12  
 president 11  
 Preston, Joseph 75  
 Private Practitioners of Pathology Foundation 14–15  
 product evaluation 46  
 Product Evaluation Committee 46  
 Professional Administration Development Seminars 28  
 Professional Affairs Committee 122  
 Professional and Economic Affairs Committee 122  
 professional component billing 115, 119, 123, 127–128, 131  
 Professional Laboratory Management Institutes 28  
*Professional Relations Manual* 114  
 Professional Relations Committee 117  
 Proficiency Evaluation Program (PEP) 55  
 proficiency testing (PT) 51, 54–55, 61, 64, 66, 69, 72, 83, 101–107, 125  
 proficiency testing *See also*: Surveys  
 Proficiency Testing Exception Summary 67  
 Proficiency Testing Service (PTS) 51  
 prostate lesions 99, 105  
 protein standards 45  
 Prothrombin Surveys 52  
 protocols, practice 99–100, 138  
 Prudential Plaza, Chicago, Ill. 18  
 Public Affairs, Council on 35  
 Public Health Service (US) 124  
 public relations 5, 16–17, 34–35, 101, 113  
 Public Services, Commission on 35  
 publications 27, 30–34, 61, 67, 77–82, 87, 114, 124  
 Publications, Committee on 31  
 Q-PROBES™ 84–87  
 Q-Track 85  
 QAS Today (program) 83  
 Quality Assurance Service (QAS) 57, 75–84  
 Quality Assurance, Council on 16, 48  
 quality control 75–84  
 quality control, regional 75–76, 83  
 Quality Practices Committee 85  
 Quigley, Philip J.G. 98  
*Quintana vs. United Blood Services* 143  
 radiologists & radiology 113–114  
 radionuclides 12, 141  
 Rappoport, Arthur E. 57, 65

- Raslavicus, Paul A. 132  
reagents 46, 59  
Reals, William J. 14, 62, 98–99  
recertification 141  
recruitment 26–27  
Recruitment Committee 27  
Red Cross 142  
reference committees 13  
Reference Laboratory, CAP 45  
Reference Preparation for Serum Proteins 45  
regional commissioners (LAP) 64, 70–71  
regional committees 5, 12–13  
regional quality control 75–76, 83  
Registry of Cytologic Diagnosis 100  
Registry of Medical Technologists 135  
Reimbursement Committee 122  
relative value schedules 118, 128, 131–132, 138  
reproductive biology laboratories 71  
Residents Forum 16, 27  
residents & residencies 6, 16, 25, 69, 98, 112, 114, 141–142  
Residents, Young Physicians, and General Membership Committee 142  
Resource Committee, Nuclear Medicine 56  
Resource Committee, Safety 69  
resource committees 16, 29–30, 42, 56–57, 67, 84  
Rippey, John H. 36  
Roberts, Kenneth 132  
Rokitansky, Karl 1, 95  
Rose, S. Brandt 57  
Ross, John W. 82  
Rothwell, David J. 38  
Safety Resource Committee 69  
salaries 111, 113–114, 116, 118  
Sanford, Arthur H. 61  
Saphir, Otto 5  
*Saturday Evening Post* 34  
Saudi Arabia 85  
Schaeffer, Morris 58  
Schenken, Jerald 76  
Schenken, John R. 3–4, 62  
Scientific Affairs, Council on 57, 72, 85  
scientific societies 23  
Scotland 85  
*Secretary's Newsletter* 17, 31  
secretary-treasurer 12  
sections 14–15, 27  
Sections, Committee on 15  
seminars 66–67, 98–99, 124  
Senhauser, Donald A. 122  
sensitivity testing, microbiology, quality control 76  
Shared Pools program (Surveys/QAS) 82–83  
Sidley & Austin 130  
Silverstein, Arthur 124  
Simard, Ernest E. 18, 63  
Simon, Thomas 103  
Singapore 85  
Skendzel, Laurence P. 54, 57, 75  
Skokie, Ill. 19  
Sloane, Margaret 44  
Small Hospital Survey 54, 58  
SNOMED® *See: Systematized Nomenclature of Medicine*  
societies, scientific 23  
Society for Nuclear Medicine 55–56, 143  
solutions, standard 42–46  
South Carolina 76  
special commissioners (LAP) 67, 71  
spectrophotometers 47  
stability (control materials) 77  
standard solutions 42–46  
Standards Committee 6, 33, 42, 45, 51, 75, 103  
standards, accreditation 63–64, 70  
Standards, Bureau of 42  
standards, cyanmethemoglobin 45  
standards, protein 45  
State Legislative Committee 121, 125  
Stembridge, Vernie 128  
Stulen, Frank 19  
Sudan 56  
Sunderman, F. William 4–5, 43, 61, 111  
surgical histology 34  
surgical pathology 99–100, 140  
surgical pathology evaluation service 115  
Surgical Pathology Committee 103, 106  
Survey Contract Development Committee 59  
Survey Management Report, Cumulative 67  
Survey Surveillance Summary 67  
Surveys 18–19, 27, 29, 32, 41–43, 51–61, 66, 75, 83  
Surveys Committee 42, 57

- Surveys Validated Reference Materials (SVRMs) 45, 54
- Surveys, Bacteriology 51
- Surveys, Basic 54, 58
- Surveys, Coagulation 83
- Surveys, Comprehensive 53, 66
- Surveys, Enzymology 55, 143
- Surveys, Forensic Identity and Parentage Testing 55, 143
- Surveys, Glucose 56
- Surveys, grading 56, 58
- Surveys, Hematology 51
- Surveys, histologic diagnosis 103
- Surveys, Hormone Receptor Assay 55
- Surveys, Instrumentation 55, 143
- Surveys, joint 55, 143
- Surveys, marketing 58–59
- Surveys, Nuclear Medicine 56
- Surveys, Parasitology 51
- Surveys, Parentage Testing 55, 143
- Surveys, Prothrombin 52
- Surveys, Small Hospital 54, 58
- Surveys, Toxicology 55
- Surveys, Virology 55
- syphilis 140
- Systematized Nomenclature of Medicine (SNOMED®)* 37–38, 96, 132, 138
- Systematized Nomenclature of Pathology (SNOP)* 37–38, 104
- Talmadge, Herman 118, 128
- Tax Equity and Fiscal Responsibility Act of 1983 (TEFRA) 102, 118, 130–131
- tax exemption 6, 9
- Technical Improvement Service (ASCP) 51–52
- technicians, laboratory 42
- Technicon Corp. 34
- television 35
- Tennessee 76
- Tennessee Society of Pathologists 123
- Texas Society of Pathologists 117
- therapeutic drug monitoring, quality control 76, 83
- tissue committees 114, 139
- Tompkins, Victor N. 57
- Toronto Institute of Medical Technology 29
- Townsend, Frank M. 68–69
- Toxicology Surveys 55
- transfusions, blood 143
- Traverse City, Mich. 19
- treasurer *See*: secretary-treasurer
- tuberculosis 28
- United Medical Laboratories 123
- universities 69, 114
- urinary bladder lesions 99
- Valaske, Martin J. 31
- VanBremen, Lee 18
- Veterans Administration (US) 67, 70
- vice-president 11–12
- Virchow, Rudolph 1, 95
- Virginia Pathology Society 51
- Virology Surveys 55
- Wall Street Journal* 101, 126
- Washington (state) 58
- Washington, DC 3, 19–20, 118, 130–131
- Welch, Michael 47, 54
- Westgard, J.O. 83
- Westmoreland, Melbourne G. 6, 17, 31
- Whipple, George H. 26
- Williams and Wilkins Company 32
- Williams, Greer 34
- Williams, Marjorie J. 29
- Williamson, William E., Sr. 69
- Wollenweber, Henry L. 14
- Wood, David A. 4, 11, 37, 99, 101, 114, 144
- workload recording 28–29, 75
- Workload Recording Committee 29
- workshops 67
- World Association of Societies of Pathology (Anatomic & Clinical) (WASP) 48, 56
- World Health Organization (WHO) 45, 61
- Youden, W.J. 104
- Zeiler, Geraldine Colby 36
- Zeiler, William B. 102

# Index of Authors Cited

*References consist of chapter number and note number*

- Abell MR 1-4  
Alpert L 6-6  
Andujar JJ 1-8  
Arkin C 7-48, 7-49  
Arvin D 6-6  
Austin RM 3-12, 8-18  
Bachner P 7-63, 7-64, 7-69, 7-70, 7-71, 10-7  
Baker PB 7-68  
Barbierato D 8-4  
Barnett RN 3-20, 7-45  
Batsakis JG 3-19, 7-32  
Bawa N 7-54  
Belk WP 4-3  
Blumenfeld CM 7-6  
Bowman HE 8-5  
Bradford S 8-27  
Brown DE 4-6, 5-2  
Burdick W 1-2  
Cannon RK 4-5  
Cembrowski GS 7-47, 7-64  
Chandler FW 8-23  
Coleman FC 6-2, 6-3, 9-6, 9-10, 10-6, 10-8, 10-9  
Copeland BE 3-20, 7-7, 10-4  
Crosby WH 8-20  
Culbertson C 1-6  
Davis L 11-1  
Derman H 8-23, 8-24  
DiSilvio TV 7-8, 7-28, 7-33, 7-36, 7-38, 7-39  
Dolan CT 3-11  
Dorsey DB 6-4  
Edwards CQ 8-20  
Eilers RJ 3-17, 7-9  
Elevitch FR 3-14, 5-6  
Ercolano AS 10-12  
Ewing MB 3-22, 8-1  
Farrow G 8-13  
Fraser MD 7-18, 7-23, 7-26, 7-29, 7-35  
Gavan TL 3-11  
Gephardt G 7-67  
Gilbert RD 7-25  
Gilmore BF 7-34, 7-41, 7-44  
Glenn GC 8-22 Gobbato F 8-4  
Goldman L 8-3  
Gruhn JG 3-3  
Hamlin WB 10-7  
Hammond EH 8-16  
Haven GT 7-2, 7-4, 7-13, 7-16, 7-19, 7-20, 7-22, 7-24, 7-27, 7-31, 7-33, 7-36, 7-37, 7-39  
Hawk WA 6-5  
Henson DE 8-12, 8-13, 8-14, 8-15, 8-16, 8-23  
Hoeltge GA 6-5, 6-6  
Hoffman GG 7-66  
Howanitz JH 7-40, 7-56  
Howanitz PJ 7-40, 7-55, 7-56, 7-59, 7-61, 7-62, 7-63, 7-64, 7-65, 7-66, 7-67, 7-69, 7-70, 7-72  
Hutchens T 7-3  
Hutchins GM 8-6, 8-7, 8-8  
Hutter RVP 8-12, 8-13, 8-14  
Hyman MP 8-27  
Jones BA 7-65, 7-70  
Kafka MT 7-43  
Keitges PW 7-11  
King DW 8-5, 10-2  
King JW 3-11, 3-18  
Kirby NM 1-4  
Knowles RC 7-17, 7-34, 7-41  
Koepke JA 3-13  
Konzelmann FW 1-1  
Lamberson HV 7-40  
Lambird PA 10-11  
Langdell RD 3-10  
Larson CP 8-10  
Lawson NS 3-19, 7-4, 7-19, 7-20, 7-21, 7-22, 7-24, 7-27, 7-31, 7-33, 7-36, 7-37, 7-39, 7-44, 7-46, 7-47, 7-50, 7-51, 7-53  
Lawson PL 7-50  
Lent RW 7-69  
Lohff MR 7-14, 7-30, 7-38  
Long T 7-46  
MacEachern MT 1-3  
Marquardt VC 7-3, 7-15  
McLendon WW 3-12, 3-16, 3-21, 7-71, 8-6, 8-18  
McWhorter CA 7-1  
Meier FA 7-60, 7-65

Moore TD 7-17, 7-22, 7-24, 7-27, 7-29  
Moses TD 7-8  
Muelling RJ 5-3  
Nash G 8-14  
Neibel OJ 2-6  
Nielsen ML 8-15  
Noce PS 5-6  
O'Leary DS 7-57  
Penner DW 8-27  
Platt R 7-32  
Pontius EE 3-27  
Powers JM 8-9  
Queen FB 2-3, 3-26  
Reals WJ 6-1  
Reimer CB 4-7  
Renner SW 7-63  
Robbins S 8-3  
Rosenbaum JM 7-5, 7-7, 7-25, 7-42  
Ross JW 7-18, 7-21, 7-23, 7-26, 7-29, 7-31, 7-35,  
7-38, 7-46, 7-50, 7-51, 7-53, 7-54  
Saladino AJ 7-68  
Sasenick SM 7-73  
Sax SM 7-8  
Sayson R 8-3  
Schenken JR 1-5, 1-7  
Schifman RB 7-60, 7-72  
Scottolini AG 8-2  
Scully RE 8-15  
Skendzel LP 3-20, 5-3  
Smith SJ 4-7  
Sobin LH 8-12  
Sodeman TM 6-5  
Sox HC 8-19  
Steigmann FS 3-3  
Steindel SJ 7-61  
Sunderman FW 4-2, 4-3, 4-4, 5-1, 9-1  
Tetrault GA 7-52  
Tholen DW 7-44  
Valenstein PN 7-62  
Vecchiet F 8-4  
Weinstein SR 8-2  
Wells TW 4-7  
Wertz RK 7-10, 7-12  
Westgard JO 7-54  
Westmoreland MG 2-7  
Williams G 3-24  
Williams GW 7-37  
Williams MJ 8-5  
Williams TL 7-53  
Wissler RW 3-2  
Witte DL 8-20  
Wood DA 3-25  
Youden WJ 8-26  
Zarbo RJ 7-66, 7-67, 7-72