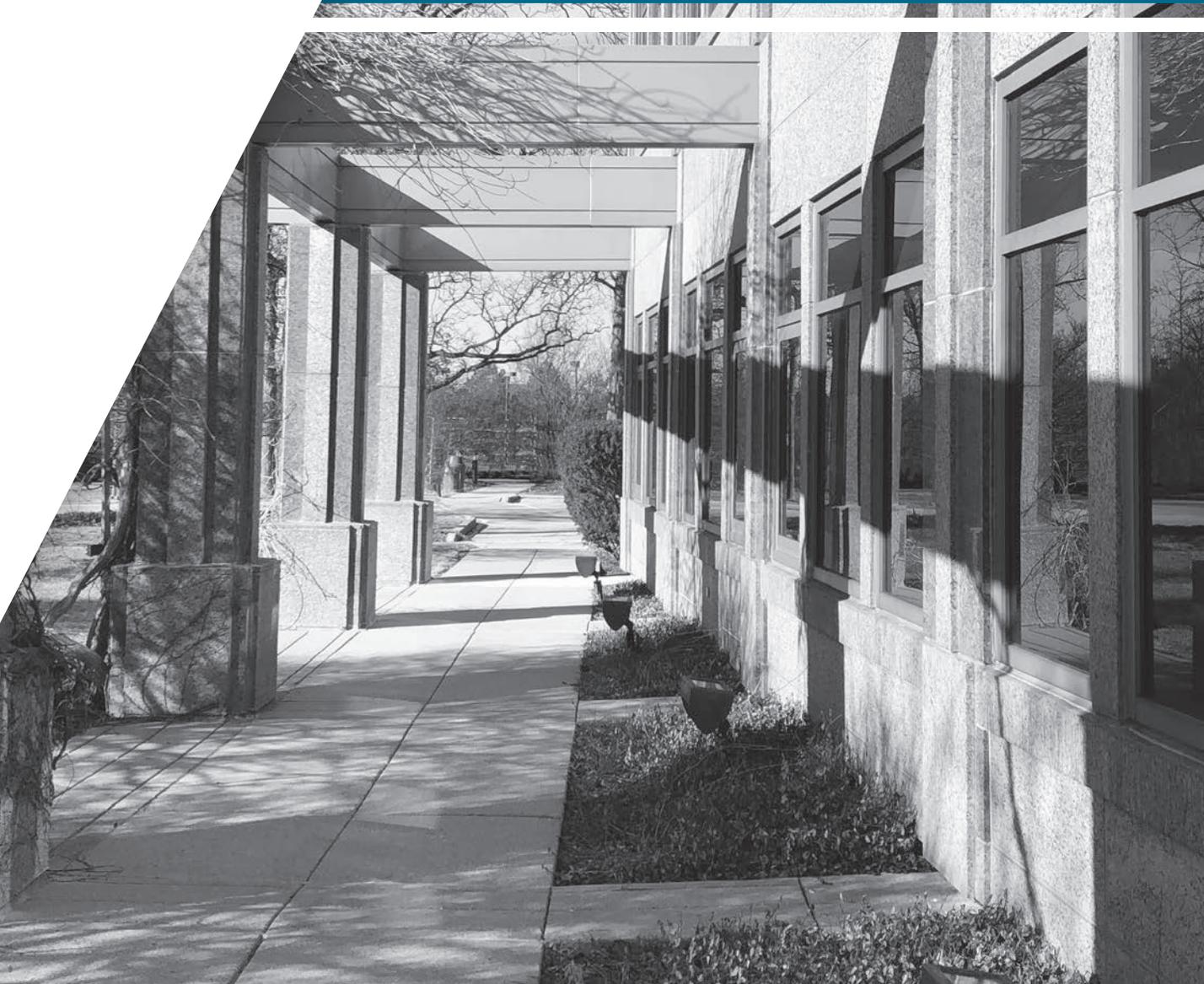




COLLEGE of AMERICAN  
PATHOLOGISTS

In Further Pursuit of Excellence

75 YEARS



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# Dedication



Dedicated to the Memory of  
Gene Herbek, MD, FCAP  
Pathologist, CAP President 2013-2015,  
Husband, Father, and Friend



Dedicated to the Memory of  
Liz Cramer  
CAP Staff 1977–2020, Friend, and Mentor for Many

In Further Pursuit of Excellence



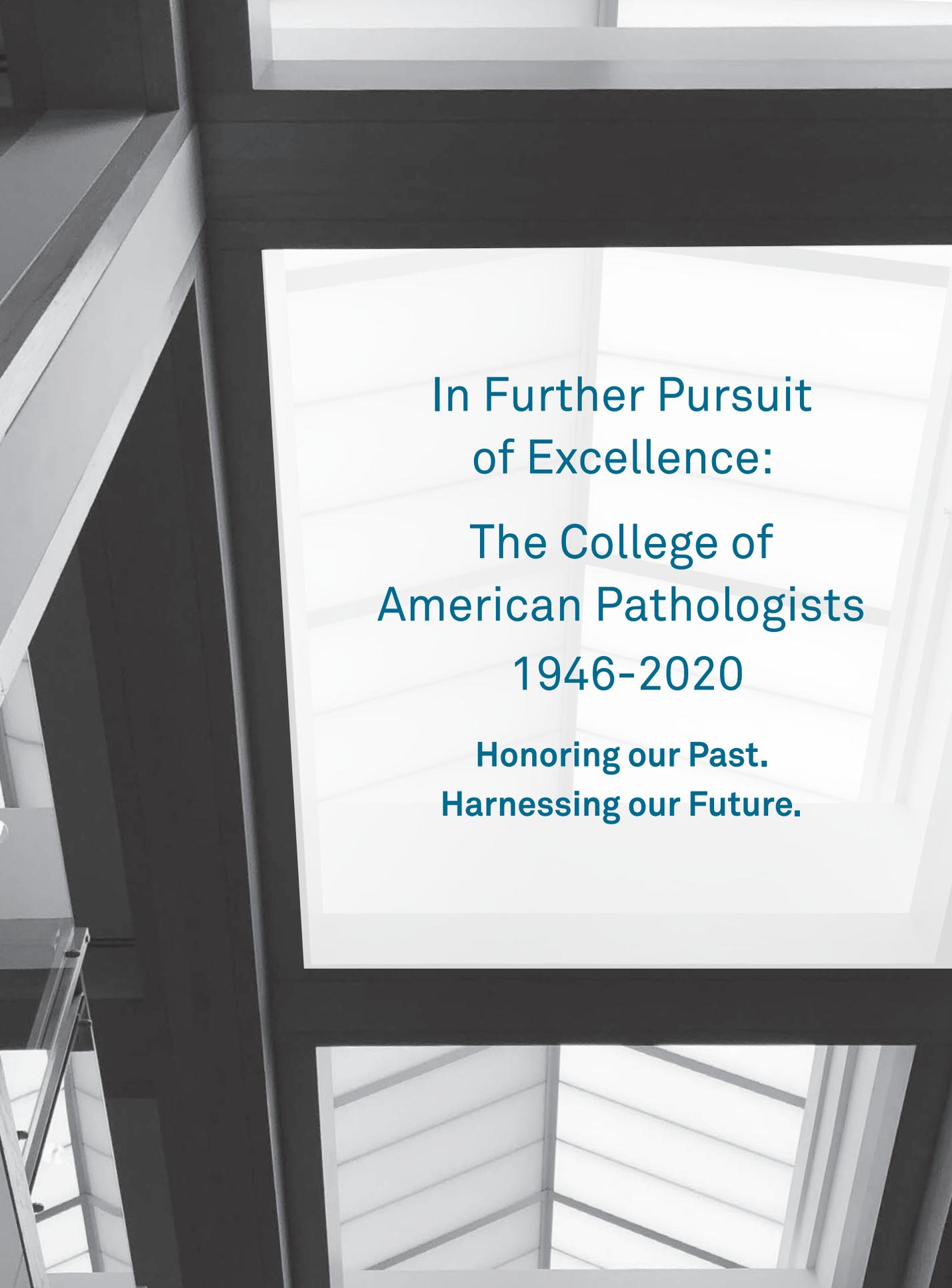
# Acknowledgments

As Senior Editor I would like to begin by recognizing the sustained and invaluable contributions to this book by the “75 team.” Jim Crumley, our Managing Editor, ensured editorial, literary, and textual quality; Drew Davis, CAP Archivist, was our fact-checker and the structural “glue” for the team; Nancy Johnson gave invaluable advice on content and was the principal author for Chapter Eight and the Epilogue; Mary Katherine Krause stepped in to provide exceptional leadership and guidance to the team after the sudden and tragic loss of Liz Cramer. I thank all of them for their hard work, support, perseverance, and wisdom! The composition, graphics, and “look” of this book are due to the efforts and skill of our graphics and production team of Opel Aguila, Clemmie Lozano, and Laurie Vitek. They have done a remarkable job of matching eye-catching graphics to the text and enlivening the look of the book.

Many CAP members and staff both current and past have made significant contributions to portions of this book (chapters, portions of chapters, major segments, historical information) and deserve special recognition and thanks. They include Bob Baisden, Mary Ann Bartlett, Adam Booth, Pam Cramer,

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The editor and the 75 team are also appreciative to the following members and staff who have provided support to this book. It would not have been possible without their care and assistance. I want to personally thank Dr. Bruce Williams for asking me to take on the role of editor. I also want to thank the CAP Board of Governors and the officers for their support throughout this endeavor: Dr. Pat Godbey, President; Dr. Emily Volk, President-Elect; Dr. Rick Gomez, Secretary-Treasurer. Thanks for their support are also extended to Lisa Fatheree, George Fiedler, Greg Gleason, Bill Groskopf, Geoff Jaroch, Maryrose Murphy, Stephen Myers, Ann Neumann, and Sally Weintraub.



**In Further Pursuit  
of Excellence:**

**The College of  
American Pathologists  
1946-2020**

**Honoring our Past.  
Harnessing our Future.**

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# Introduction

*In Pursuit of Excellence: The College of American Pathologists, 1994–1996* was published in 1997 to recognize the 50th Anniversary of the CAP. Dr. Loyd Wagner, the 21st President of the CAP, was the senior editor of this book which described the history of the first 50 years of the CAP. The book recounted many years of CAP history including evolving organizational structures and modifications as well as many scientific, political, and regulatory events that occurred during those 50 years. The focus was on the core missions of the CAP and the focus of this book—now celebrating the 75th Anniversary of the CAP—will remain the same.

Quality and excellence in all aspects of laboratory and pathology practice remain the central focus of the CAP, closely linked to education and advocacy for the profession. The first three chapters of this book are a brief reprise of the early history of the CAP, and our traditional missions as well as a description of the current organizational and fiscal infrastructure of the CAP. Chapters four through seven are about our core missions—science and laboratory improvement; advocacy for the profession and for patients; education and standard setting; and services to members and the public. Chapter eight covers the responses of the CAP to the COVID-19 pandemic. Chapter nine is an attempt to look into the future and provide insights by CAP experts into new technologies and opportunities. A final section is the Epilogue that describes events that have occurred in the last quarter of 2020 and the first

quarter of 2021 that have not been captured in the first nine chapters and primarily addresses ongoing CAP responses to the pandemic. This Coronavirus descended upon us during the writing of this book. It is not possible to think of any historical happening that rivals the COVID-19 pandemic in the impacts on the world, the US, and the medical community. In parallel to the horrendous morbidity and mortality as well as the devastating social, economic, educational, and political effects, the practice of medicine and of pathology has been significantly affected. In the Epilogue, a brief list of significant events and trends that have taken place in late 2020 and early 2021 are identified, along with the CAP responses.

The Team responsible for the preparation of this book made a decision in the beginning to focus on the history of the organization rather than individuals. Of course, the achievements of the CAP are the direct result of the work and dedication of countless members and staff, current and past. While explicitly recognizing in the Acknowledgments section the contributions of many CAP members and staff to the accomplishments of the CAP as well as the contents of this book, it has not been possible to specifically identify all of the many who would have deserved mention. This book, therefore, concentrates less on individuals but rather on the history of the last 25 years of the CAP written on the occasion of the 75th Anniversary of this incredible organization.



Chapter One

LOOKING BACK  
(1946–1996):  
ON THE SHOULDERS  
OF GIANTS

# Chapter One

*If I have seen further it is by standing  
on the shoulders of giants.* —Isaac Newton

## **To meet the moment of the present and to prepare for the future, there is no greater teacher than the past.**

In recognition of its 50th Anniversary, in 1997 the College of American Pathologists (CAP) published the book, *In Pursuit of Excellence: The College of American Pathologists, 1946–1996*. Dr. Loyd Wagner, the 21st president of the CAP (1989–1991), served as senior editor. The book chronicled the first 50 years of an organization devoted to serving the interests of pathologists, thereby ultimately serving the greater good of patients.

The centrality of the pathologist's role in medicine necessitated the right organization to support, protect, and strengthen those who fulfilled that role. It was from this core belief that the College of American Pathologists began to take root.

Dr. Wagner's first two chapters, "The Beginning" and "Building the Structure," described in considerable detail the history of the CAP's first 50 years, as well as the evolution of the operating and governance structures of the organization. This chapter summarizes Dr. Wagner's first chapters by way of providing necessary background for the rest of this book, which explores the evolution and changes in the programs of the CAP between 1996 and 2021.

Dr. Wagner addressed the at-the-time low professional status of hospital-based pathologists. In 1926 the American College of Surgeons (ACS) revised its standards for hospitals, requiring that clinical laboratories be under the direction of an MD physician with special training in clinical pathology. The ACS further required that all tissues removed

during operations should be examined in the laboratory and a report be issued. The professional status of pathology was further advanced in 1936 with the establishment of the American Board of Pathology. Despite these advances, it was not until 1943 that the American Medical Association (AMA) recognized pathology as the practice of medicine. However, relations between pathologists and hospital administrations remained problematic, particularly in payment for pathologist services. It became increasingly evident that existing pathology organizations were not equipped to help pathologists with economic issues.

A letter-writing campaign began and Frank Hartman, MD, FCAP, organized dinner meetings of pathologists around the country. They gathered to discuss the need for an organization that could ensure consistent quality in laboratory testing and adequate reimbursement for their life-saving work. On December 13, 1946, more than one-hundred pathologists met in Chicago and founded the College of American Pathologists. They chose Dr. Hartman to be their first president.

The Board of Governors initially included representatives of the American Association of Pathologists and Bacteriologists, American Society for Clinical Pathologists, and the American Society of Experimental Pathologists. Membership was limited to board-certified pathologists, with a provision for junior membership by residents.

The CAP's constitution clearly stated the original objectives for the organization: to foster the highest standards in education, research, and the practice of pathology; to advance the science of pathology and improve medical



*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.*

## Historically, the CAP's core structure has always consisted of a Board of Governors providing leadership.

laboratory service to physicians, hospitals, and the public through study, education, and improvement of the economic aspects of the practice of pathology; and to maintain the dignity, precision, and efficiency of the specialty of pathology for the service of the common good. Over the years the CAP has endeavored to achieve these objectives through the interrelated missions of laboratory excellence, education, advocacy, and membership services. The CAP was incorporated under the not-for-profit corporate statutes of Illinois in 1947, and the CAP's income-tax exemption was approved by the federal government in 1948 under

section 101.7 of the then-current Internal Revenue Service code (now section 501(C)(6)). Today, this tax-exempt status remains in effect, allowing the CAP to lobby for legislative and regulatory issues.

The organizational structure of the CAP has evolved over the last 75 years; the current structure is detailed in a subsequent chapter. Historically, the CAP's core structure has always consisted of a Board of Governors providing leadership; a body (originally the Assembly and now the House of Delegates) providing input and guidance to the Board; and committees composed primarily of CAP members as well as staff

engaged in the daily activities that support CAP programs. Between the founding of the CAP and 1996, several organizational changes occurred; the most significant changes are summarized below.

### Board of Governors and Officers

Beginning in 1955, the composition of the Board changed, requiring that all 12 governors be elected by the general membership; as well, formal representation of other pathology societies was discontinued. Subsequent years saw a series of additional changes to the process for electing governors and officers. Those changes included shifts in the

composition of the Nominating Committee and a transition from ballot box voting at the national meeting to a mailed written ballot. At present, most members vote by electronic ballot. In 1955 the position of president-elect was created. Initially, this position did not automatically succeed to that of president, but with the elimination of the position of vice-president in 1991, the president-elect automatically succeeded to president.

### **Assembly/House of Delegates**

In 1957 the Board approved the creation of an Assembly with the primary purpose of improving communications between members and the Board. The early years of the Assembly as detailed in the *Pursuit of Excellence* are well worth reading to appreciate the controversies surrounding the role of the Assembly and its relationship to the Board. In 1970, the Assembly was converted to the House of Delegates (HOD) with some explicit policy development responsibilities. The speaker and vice-speaker of the House attended Board meetings initially as guests and then as voting members beginning in 1984. During these years, the issue of the policy-making role of the House remained controversial and, at times, contentious. The ongoing evolution of the House of Delegates between 1996 and the present is discussed later in this book.

### **Committees**

In an attempt to ensure participation in the programs of the CAP by members from all parts of the country, the CAP created regional committees charged with the primary responsibility for scientific post-graduate medical education. As well, the regional committees served as a grassroots network providing input to the Board and membership on issues concerning billing, compensation, and hospital contracts. The regional committees were discontinued in the late 1960s. Sections were established by the Board of Governors in 1960, with specific functional assignments such as private practice and practice in institutions. During this time, numerous other committees became important, including a Committee

on Clinical Laboratory Standards designed to oversee the growing number of programs dedicated to laboratory improvement. Most significantly, resource committees comprised of experts in specialized areas became responsible for the design and monitoring of the increasing number of Proficiency Testing Surveys. In 1974, the growth in the number and diversity of committees led to the creation of what is now the current council/commission/committee structure of the CAP. The councils—whose names and functions have evolved over time—were Quality Assurance; Government Relations and Liaisons; Education and Information Services; and Laboratory Administration.

### **CAP Foundation**

Established in 1963, the CAP Foundation's mission is "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." The Foundation, initially funded by contributions from the CAP Board, was and remains structured as a tax-exempt 501(c)(3) corporation. With continuing support from the CAP Board, over the years the Foundation has engaged in various activities, with initial emphasis on sponsoring national conferences but that emphasis has shifted to support of young investigators and of educational opportunities for young pathologists in new technologies and informatics. The Geraldine Colby Zeiler Professorship in Cytopathology was established at the Mayo Medical School through a major contribution by William Zeiler, MD, FCAP, CAP president 1987-1989. Also established was the John H. Rippey Memorial Fund for Laboratory Quality Assurance. More recent areas of activity of the Foundation are described in a later chapter.

### **Residents Forum**

In 1988 a Residents Forum was created with a structure and operating features similar to the House of Delegates. The Forum chair attended meetings of the HOD and in 1996 became an ex officio voting member of the Board of

Governors. In support of the Residents Forum's intention to interest young pathologists in the CAP and to identify them for leadership roles in the CAP, the Board voted to budget for the addition of a Junior Member position on most CAP committees.

### Executive Staff

In response to the growing number and complexity of CAP programs, the size of the CAP staff has expanded greatly over the years. Beginning in 1947 and in recognition of the need for internal leadership, the CAP created the post of executive secretary (later executive director, executive vice-president, and finally chief executive officer). Since that time numerous individuals have served in this position:

- **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, 1989–2001**
- **Nicki M. Norris, 2001–2008**
- **Charles Roussel, 2009–2016**
- **Stephen R. Myers, 2016–present**

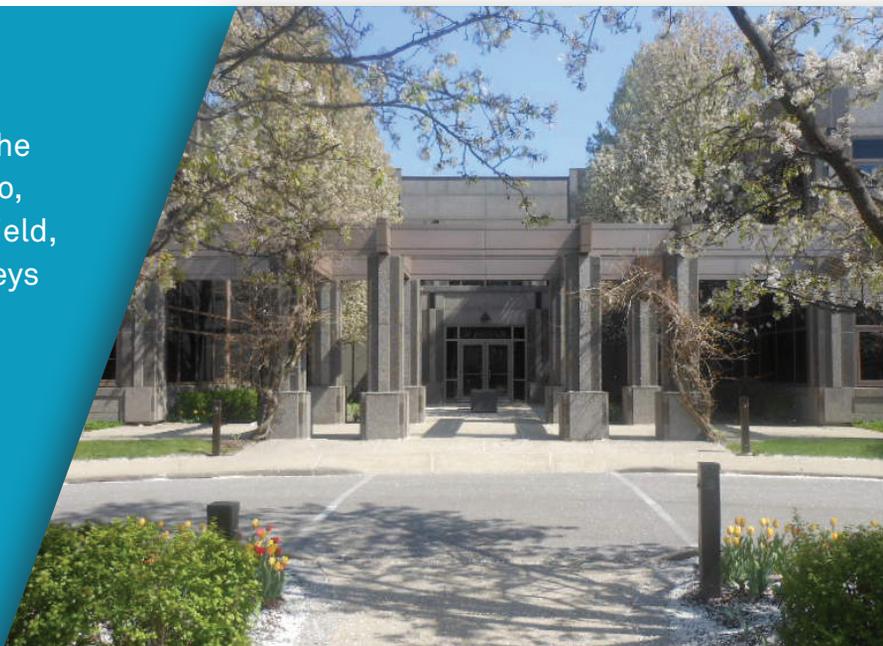
### CAP Headquarters and Locations

The CAP operated from various headquarter locations during the first 50 years, including Chicago, Skokie, and in 1989, Northfield, Illinois. For several years, Surveys data analysis was located in Traverse City, Michigan, and eventually consolidated in 1989 at the current Northfield location. The CAP's first Washington, DC, office opened in 1970. The DC office engages in response to the increasing impact of Federal legislation and regulations (the Medicare Act of 1965, the Clinical Laboratories Improvement Act of 1967 (CLIA '67)) upon the practice and economic stability of pathology.

### Summary, 1946–1996

This chapter has briefly summarized key events in the CAP's first 50 years from its founding in 1946 to 1996. Readers wanting to know additional details are strongly encouraged to read *In Pursuit of Excellence: The College of American Pathologists, 1946–1996*. It reveals the contributions of many of our founders. Their vision, perseverance, and dedication to the profession laid a secure foundation that would guide the CAP in the next 25 years (1996–2021). The subsequent chapters that continue the story are a direct result of their efforts.

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EDUCATION

MEMBERSHIP

SCIENCE AND LABORATORY  
IMPROVEMENT

ADVOCACY



Chapter Two

TRADITIONAL MISSIONS  
OF THE COLLEGE  
OF AMERICAN  
PATHOLOGISTS:  
THE FIRST 50 YEARS  
(1946–1996)

## Chapter Two

*Tradition is not the worship of ashes, but  
the preservation of fire.* —Gustav Mahler

**All successful organizations are guided by missions that allow them to survive even through difficult times. The CAP identified its own missions in the early years and those continue to serve as guiding lights today.**

The CAP constitution identified the following goals: “to foster the highest standards in education, research, and the practice of pathology; to advance the science of pathology and improve medical laboratory service to physicians, hospitals, and the public through study, education, and improvement of the economic aspects of the practice of pathology; and to maintain the dignity, precision, and efficiency of the specialty of pathology for the service of the common good.”

Over the decades, these ambitious goals have crystallized into several broad and historic missions: Science and Laboratory Improvement, Advocacy, Education, and Member Services. Subsequent chapters will address in detail how the leaders, members, and staff of the CAP have advanced these broad missions, with particular emphasis on the last 25 years. This chapter reviews and highlights the implementation of these missions during the first 50 years of the CAP. Over time the structural features (leadership organization, committees, commissions, and councils) have frequently changed, but this chapter will focus on broad themes of how the missions established the foundation for how pathology and laboratory medicine are practiced today.

### **Laboratory Improvement: Standards, Proficiency Testing, Accreditation Standards**

Since the beginning of the CAP’s commitment

to laboratory improvement, the standards, Proficiency Testing, and accreditation programs have been closely intertwined although typically configured and managed as discrete initiatives. During the period from 1946 through 1996, these initiatives grew in size and complexity, and each positively impacted the quality of laboratory performance in the US and internationally.

In the early days, the Standards Committee conducted initial surveys and oversaw the production of standardized solutions for use in the laboratory. These efforts grew into a broader mission for evaluation, certification, and Proficiency Testing. Over time, they led to the Inspection and Accreditation Program (I&A), the precursor to the current Laboratory Accreditation Program (LAP). The Commission on Laboratory Accreditation (CLA) and numerous discipline-specific resource committees were created to support LAP. In the 1950s, the CAP embarked upon a program to provide standards manufactured by commercial firms for CAP members; designated the “Clinical Pathology Standards Program,” distribution of standards alternated between commercial vendors and directly from the CAP before the program was sunsetted.

Current CAP standards programs are closely linked with the National Committee for Clinical Laboratory Standards (NCCLS) and the National Institute of Standards and Technology (NIST). Since the 1970s, the CAP has cooperated with the World Association of Societies of Pathology and Laboratory Medicine (WASPaLM) and its related entity, the Council on World Standards (COWS), in fostering international standard-setting efforts. The CAP standards programs, as well as the Proficiency Testing program, have

led to cooperative relationships with numerous societies and organizations including the American National Standards Institute (ANSI), the American Society for Quality Control (ASQC), the Health Industry Manufacturers Association (HIMA), and the International Standards Association (ISO).

### Proficiency Testing

The origins of proficiency testing in the United States began in Pennsylvania, inspired by the efforts of Dr. F. William Sunderman and colleagues, who identified wide variation in test results for common chemical and hematologic analytes in Philadelphia hospital laboratories. One consequence of such wide variation: When having lab work performed, patients could never be certain of the accuracy of their test results. These unsatisfactory results were attributed to poor training of insufficient numbers of analysts, and also to poor equipment. Subsequent national studies confirmed clinically-significant variation in a much larger group of laboratories. In the drive for quality-improvement, Dr. Sunderman's Proficiency Testing Service (PTS) grew in popularity and was purchased in 1985 by the American Society of Clinical Pathologists (ASCP). ASCP, however, never implemented PTS.

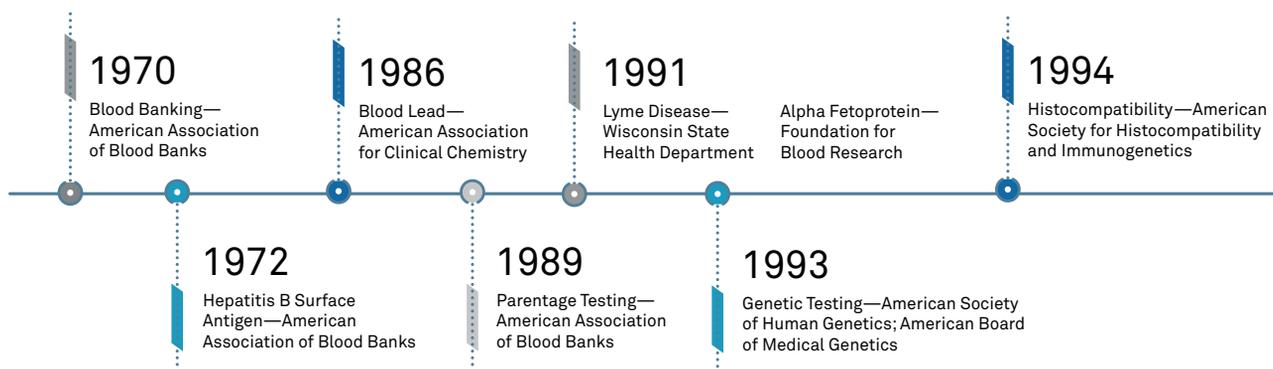
The first CAP Survey was conducted in 1949 but results were never published. CAP Surveys continued sporadically until 1963, when the

CAP launched its Surveys as a regular, periodic, external interlaboratory comparison program focusing on a limited menu of chemical, blood bank, hematology, bacteriology, parasitology, and clinical microscopy challenges. Initially, samples were either water- or chloroform-based, but eventually were configured to better approximate patient samples. The CAP returned data to the participating laboratories, grouping the data by method and including the mean and standard deviations of all results.

As the Surveys developed in both size and complexity, computerization of the program became necessary, resulting in the establishment of a computer division of the CAP. Since aggregate values from many participants analyzing the same material by similar methods could be used to determine the "true" value of a continuously-variable analyte, excess material from Surveys soon became available as Surveys Validated Reference Materials (SVRM).

Several changes and enhancements to the original Surveys program took place between the start of the program and 1996. The Board began requiring CAP-accredited laboratories to participate in a CAP Survey, and in 1994 the CAP agreed to accept PT results from other PT providers. In 1969 a Survey for Physician Office Laboratories was created. There were a number of joint Proficiency Testing programs that were offered by the CAP and other organizations.

### Joint Proficiency Testing Programs Offered by the CAP and Other Organizations



Participating labs in the Q-PROBEST™ program receive data comparing their performance against the general population of labs in the study.



In subsequent years, numerous analytes were added to the program; by 1969 there were more than 5,000 subscribers; grading criteria underwent many changes and refinements; and the number of resource committees providing scientific guidance increased.

As certain states began to exert regulatory influence over laboratory testing, the CAP agreed in some instances to provide Survey data to the state-level. After the passage of CLIA '67, the Department of Health, Education, and Welfare (HEW) declared in 1968 that CAP Surveys met specifications for laboratories engaged in interstate commerce; additionally, Surveys were accepted by the Health Care Financing Administration (HCFA). Because of the increasing scope and complexity of the Proficiency Testing program and the need to help laboratories comply with regulatory requirements, all computer services were consolidated at the CAP Headquarters in Northfield, Illinois, in 1989. In 1995, the CAP Board approved a major overhaul of computer hardware and a rewrite of Proficiency Testing software. By September 1996 the Proficiency Testing program included 135 different Surveys, approximately 500 analytes, and subscriptions representing 29,283 laboratories.

### **Quality Assurance Service and Q-PROBES™/Q-TRACKS™**

A CAP program closely related to Standards and Proficiency Testing was the Quality Assurance Service (QAS), created in 1970 to provide support to internal quality-control practices in clinical laboratories. The QAS initiative developed from state and regional society programs using common pools of largely lyophilized control materials. These multilevel controls were analyzed by the laboratories using basic quality-control formulas (SD, multi rules) that were easily followed and displayed by wall charts. The regional programs generated significant literature and greatly contributed to the scientific practice of quality control. The shared pools program (Proficiency Testing and QAS) was developed in 1989, creating a large database that enabled the setting of

daily target values for daily quality-control materials. Over time, the QAS program was abandoned for reasons including a scarcity of volunteer support, lack of marketing capability, and competing “bundling” of quality-control materials by vendors of laboratory equipment.

A spin-off from the QAS program—the Q-PROBES™ studies—was started in 1988, along with a related program, Q-TRACKS™, a few years later. Prompted in part by the Joint Commission’s new emphasis on “outcomes” and requirements for quality assurance by CLIA '88, the Q-PROBES™ studies provide heightened focus on improving patient care. Upon its introduction, the Q-PROBES™ program represented an important undertaking to generate performance data from large numbers of laboratories. Q-PROBES™ programs gather pre-analytic, post-analytic, and in some instances analytic data from participating laboratories, then sift that data to elucidate quality practices key to improving patient-care outcomes. Select committee members curate the studies, after which the resulting data collection materials are sent to all participating laboratories. Subsequently, labs submit back to the CAP all data collected as part of the Q-PROBES™. The CAP performs statistical analysis of the data, generating reviews and commentaries that are returned to all participating laboratories. Each lab receives data comparing their performance against the general population of labs in the study. In addition, the CAP-generated post-study commentaries highlight the salient attributes of the better-performing laboratories.

Between 1988 and 2020, the CAP has offered 276 Q-PROBE™ studies. In the course of the 30-plus years the CAP has conducted these patient-care improvement programs, a large number of the studies’ conclusions regarding parameters of best performance have been published in the scientific literature.

### **Accreditation**

For CAP members and laboratory professionals, CAP accreditation of their laboratories signifies a major highlight and accomplishment. In

the United States and internationally, CAP accreditation represents the “gold standard” for laboratory performance assessment. Arising in conjunction with the matrix of chemical standards and Proficiency Testing, the CAP Laboratory Accreditation Program began in 1961. The initiative began with formation of an ad hoc Committee on Laboratory Accreditation, charged with developing the plan for accreditation. The plan’s key features included: 1) A Commission reporting directly to the CAP Board of Governors and charged with development of standards relative to physical plant, laboratory organization, equipment, technical personnel, quality control, and record keeping; 2) Strictly voluntary participation by hospitals and private laboratories; 3) Accreditation would remain in-force for a three-year period; 4) Participating institutions would be assessed an annual fee; and 5) No hospital or private laboratory would be “legacied in” to accreditation.

By 1963, in only the first two years, 222 laboratories had applied for accreditation; 55 of those were inspected and accredited. Additionally, the CAP developed a policy manual and checklists complete with explanatory notes to facilitate the inspection process. Also in those early years significant regulatory-related events helped to further establish the Accreditation Program as the “gold standard.” In one such

event, collaboration resulted in the issuance of identical, published standards by both the CAP and the Joint Commission on Accreditation of Hospitals (JCAH). Federal regulations (CLIA '67) recognized the CAP Inspection and Accreditation Program (the initial name), going so far as to stipulate that CAP standards were “equivalent to, or more stringent than” existing federal regulations.

By 1969 international interest in CAP’s accreditation program came from as far away as India, as a lab in Bombay (now Mumbai) applied for accreditation. And the next two decades from 1969 to the late 1980s witnessed significant expansion and growth of the Accreditation Program.

The value of CAP Accreditation for international labs is emphasized by Dr. R. Bruce Williams, CAP president from 2017-2019, who tells the story of one day when he was greeting visitors at the CAP booth at the MedLab Middle East meeting in Dubai, UAE. A laboratory director from one of the Emirates said he had served as director of a laboratory where the owners had insisted upon the lab becoming CAP-accredited. Initially beaming with pride, Dr. Williams’ smile quickly faded when the man said he had told the owners that CAP accreditation was a lot of self-hype and overblown public relations. In the man’s estimation the CAP could not do anything differently than anyone else in the world. But

By 1963, in only the first two years, 222 laboratories had applied for accreditation; 55 of those were inspected and accredited.



before Dr. Williams could offer a rebuttal, the former laboratory director said that despite his objection his lab was forced to undergo CAP accreditation to remain competitive. They began a three-year process of becoming accredited. They had an internal quality requirement to repeat laboratory tests for accuracy if they met certain criteria.

Before CAP accreditation, the man's lab had a retesting rate of twenty percent. Afterward, their retesting rate dropped to just two percent. That lab director is now retired but was asked to start a new laboratory. He had one requirement of the new owner before he agreed to take the job: His only condition was that the lab must become CAP-accredited.

Growth of the domestic and international Accreditation Program included infrastructure changes such as the appointment of regional and state commissioners, the implementation of educational programs and regional inspector training workshops, a publications program, liaisons with federal agencies and other professional organizations, and checklist update capabilities. A variety of software expansions also were implemented to preserve historical data, checklists, and data relating to accredited laboratories. A significant development was a change of the accreditation period from three to two years with a requirement for an interim year of self-evaluation by the accredited laboratory. In 1979, JCAH recognized CAP accreditation and announced that JCAH would no longer inspect laboratories if they were CAP accredited. 1979 was also the year that Proficiency Testing standards for CAP-accredited laboratories were adopted. In subsequent years, programs for inspecting "point-of-care" testing, forensic urine drug testing (FUDT), and joint inspection of blood banks by the CAP and the American Association of Blood Banks (AABB) were established. Another change that later occurred was the clarification in the Standards that appropriately-trained doctoral scientists were qualified to serve as laboratory directors.

The passage of the Clinical Laboratory

Improvement Amendments of 1988 (CLIA '88) has had a significant impact on the accreditation program. During the rule-making period, the CAP had submitted serious objections to many of the specific provisions of the act. However, when the act was officially implemented in 1992, the CAP pursued—after considerable internal deliberations—so-called "deeming authority" under the statute, and the CAP accreditation program was recognized as an "approved accrediting organization" in 1995. As of 1996, the CAP Laboratory Accreditation Program was accrediting over 5,000 laboratories worldwide with over 3,500 pathologists serving as volunteer inspectors and many more laboratorians also serving on inspection teams.

### **Legislation, Regulations, Politics, and Advocacy**

Today, fifty cents of every dollar spent on health care in the United States comes from Washington, DC, and the only national organization that can lobby on behalf of pathologists is the CAP. Pathologists recognized they needed a voice dedicated to protecting their interests. They needed foot soldiers, boots on the ground in the fight for fair regulation and payment.

This section delves into the history of those regulations and pieces of legislation concerning pathology and laboratory medicine in the context of CAP political advocacy—and at times legal activity—over the first 50 years of the CAP (1946–1996).

Upon review of this history, the evolution of CAP thinking and public positions under pressure from regulatory and government actions as well as from changing social and economic environments becomes evident. A subsequent chapter will attempt to bring this history up-to-date.

Pathologist compensation has always been a core issue for the CAP. During the 1940s and 1950s, CAP policy openly opposed salaried compensation, instead promoting direct billing of patients or percentage billing based upon a specified percentage of total laboratory

revenue. Additional key issues during this period were advocating for recognition of pathology as the practice of medicine, and the development of requirements for pathologists to become licensed physicians. These two stipulations were not required by all states or hospitals. In the mid 1950s the CAP became involved in litigation with the Iowa Hospital Association, which resulted in an important court ruling that pathology was indeed the practice of medicine.

Of historical interest is the publication by the CAP in 1954 of the first *Manual of Contractual and Ethical Relations*, which described four compensation options including lease of the department; independent contractor status; a percentage arrangement; and, salary if it correlated with the total profit from the laboratory. Subsequent editions of the manual, retitled *Manual of Physician and Hospital Relations*, were significantly updated to reflect policy changes driven by legislation and compliance with anti-trust statutes.

The single most significant event in CAP history in the mid-1960s was the agreement by the CAP to enter into a consent decree with the US Department of Justice to settle an allegation of violation of anti-trust statutes. The decision to enter into the consent decree was highly controversial within the CAP, and was based on estimates of steep costs to litigate and the risk of substantial financial harm to the CAP. The consent decree contained no admission that any of the allegations by the Justice department were true but agreed that the CAP and its members were restrained from any of the following actions:

1. Restricting 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 consent decree specifically permitted the

CAP to adopt reasonable and non-discriminatory standards for the operation or accreditation of laboratories. The decree also permitted the imposition of sanctions against CAP members deficient in moral character or professional competence, or guilty of professional misconduct.

The CAP won a significant advocacy victory in defeating legislation proposed in the late 1970s by Senator Herman Talmadge of Georgia, which would have prohibited lease, percentage, and direct billing for hospital-based physicians, including pathologists. Senator Talmadge's proposed bill would have mandated fee-for-service payments for direct services and salaries for "supervisory" activities. However, the impact of the CAP's legislative victory was subsequently mitigated by federal legislation.

Following the consent decree and the defeat of the Talmadge legislation, issues relating to professional compensation became entangled with the enactment of Medicare in 1965 along with its enabling legislation including Conditions of Coverage applying to laboratories. The passage by Congress in 1982 of the Tax Equity and Fiscal Responsibility Act (TEFRA) greatly impacted the practice of pathology. This law moved payment for many laboratory services into the government-paid Diagnosis Related Groups (DRG), and effectively prohibited component billing of most clinical laboratory services within the Medicare program. TEFRA was followed by a clinical laboratory fee schedule and the Resource Based Relative Value Schedule (RBRVS) which assigned numeric values to all pathology professional and technical services on the physician fee schedule. These numeric relative values were transformed into specific payments through a conversion factor determined annually by government action. Over the years these developments have significantly impacted the provision of pathology services, with an increased emphasis on anatomic pathology practice.

Many insurance companies implemented payment policies mimicking the federal TEFRA statute, including claims that pathology laboratory services were covered by payments

to hospitals. Several pathology groups, with legal and financial support from the CAP, challenged these claims in the courts. In one such case, the United States Court of Appeals for the Seventh Circuit ruled in favor of the pathology group and stated that the pathologists (Pathology Laboratories of Arkansas) provide “supervisory services of value to all patients, and interpretation services of value to some.” This landmark ruling was of value and subsequent litigations have been usually successful in affirming the professional and supervisory role of pathologists in providing patient care, as well as the importance of these activities in ensuring optimal patient care.

Over the years the CAP implemented many additional programs to support the socioeconomic goals of the profession. These included an expanded committee infrastructure supporting federal and state legislative initiatives as well as relationships with regulatory and accreditation entities. In 1970 the CAP created a separate Washington, DC, office fully staffed with a director (Alfred S. Ercolano) and supporting staff, including lobbyists. In 1992, a CAP PAC (PathPAC) was implemented to establish and maintain contact with members of Congress. The PathPAC continues to be supported by voluntary contributions from CAP members.

### Education and Learning

Being the best pathologist one can be requires staying current and up-to-date on the latest advances in the field of pathology and laboratory medicine. The educational programs in the first 50 years of the CAP were closely linked to the Laboratory Improvement Programs and were often designed to support the Proficiency Testing and accreditation programs. In the early years, CAP educational programs were predominantly regional and devoted to a variety of topics, principally in anatomic pathology. Educational programs have been a consistent component of national meetings. For many years annual national meetings were jointly sponsored by the CAP and the ASCP, but programming by the CAP was somewhat constrained by the need to avoid conflict with ASCP programming. CAP programming was the primary responsibility of CAP committees and educational programs were usually constructed based upon the interests of the individual committees, and as such there was no overarching, unifying educational goal.

The Workload Recording Method, a management tool that is no longer a CAP program, served as a vehicle for education in laboratory management. The Workload Program was replaced by the LMIP, Laboratory Management Index Program, which was also subsequently discontinued. Over the years, the CAP continued to sponsor regional and national meetings that were primarily



The educational programs in the first 50 years of the CAP were closely linked to the Laboratory Improvement Programs and were often designed to support the Proficiency Testing and accreditation programs.



From the founding of the CAP and for the next 50 years the CAP continued to provide educational conferences on a regional and national basis, including a joint national meeting with the ASCP.

educational, but again largely related to areas of concern of the CAP committees.

A large number of publications devoted to specific disciplines in anatomic pathology were published in areas such as autopsy and forensic pathology, surgical pathology, and cytopathology. A number of publications in laboratory medicine were also created, and the Practice Guidelines Committee was started in 1989 with the goals of reviewing guidelines of other organizations and producing guidelines for CAP members. The program was eventually discontinued, but the goals of the program have been incorporated into the CAP's Pathology and Laboratory Quality Center for Evidence-Based Guidelines (the Center). Programs designed to help pathologists improve their diagnostic skills were merged into the Performance Improvement Program (PIP).

### **Membership and Public Services**

By virtue of membership in the CAP, pathologists build upon their expertise, grow their careers, and expand their influence. The centralization of membership and public service programs and their increasing visibility within the CAP reflected a realization of the importance of identifying and meeting the needs of CAP members. It also reflected a desire to better communicate to the public, as well as to the medical community, the central role of pathology in the care and management of patients.

During the CAP's first 50 years, laboratory improvement programs (accreditation and Proficiency Testing) and advocacy initiatives were centralized as specific programs with dedicated staff and committee structures. Membership programs and public service programs were established in a less organized manner and only became more centralized in the last 25 years. That process will be detailed in a later chapter.

The category of Member was abolished in 1968 and the designation of Fellow became the membership standard, requiring certification by the American Board of Pathology. Although the category of junior member had been established in the constitution, the role of junior members

was enhanced by the creation of the Residents Forum in 1988, and by the appointment of residents to most committees starting in 1990. In 1996 the chair of the Residents Forum became a voting member of the Board.

The importance of communications with the general public and other clinicians was recognized by the creation of a PR “department” in 1965 and the appointment of the first director of that department in the mid-1980s.

A significant program to benefit CAP members and medicine as a whole was the Systematized Nomenclature of Medicine (SNOMED®). The leadership of the CAP had recognized the importance of standardization of nomenclature in pathology and medicine as early as the 1950s. However, several initiatives were not successful until a single editor was appointed and the first edition of the Systematized Nomenclature of Pathology (SNOP) was published in 1965. (SNOP was converted to SNOMED® in the mid-1970s.) The subsequent history of SNOMED®, including translation into many languages, the creation of a computer version, the development of microglossaries, and the internationalization of SNOMED® will be discussed in later chapters.

From the founding of the CAP and for the next 50 years the CAP continued to provide educational conferences on a regional and national basis, including a joint national meeting with the ASCP. The last joint meeting occurred in 2002 and was replaced by the first CAP national meeting (CAP’03). Consensus conferences were also held under CAP sponsorship and that of the CAP Foundation. A series of CAP publications led to the creation of *CAP Today*® in the late 1980s. The *Archives of Pathology & Laboratory Medicine*, founded in 1926, later became the official publication of the CAP. From 1984 to 1994 the CAP and the AMA co-published the *Archives*, but in 1995 ownership and publication reverted exclusively to the CAP.

The CAP Foundation (1963) has been a significant membership and public/professional service of the CAP since its inception. Since

its founding, the Foundation has engaged in a wide variety of educational, consensus building, and philanthropic endeavors, and has been supported in part by the CAP and by contributions by members of the CAP. Significant Foundation activities have included research grants for young pathologists (the Scholars Program); national invitational conferences; training awards in emerging technology and informatics; and memorial funds (the Lansky Award, the Rippey Memorial Fund for Laboratory Quality Assurance, and the Geraldine Colby Zeiler Professorship for Cytopathology funded by family and friends of William B. Zeiler, MD, FCAP, past CAP president).

In accordance with the practice of many professional societies, over the years the CAP has offered insurance programs tailored to the needs of CAP members. These have included life insurance and liability insurance, as well as others. The CAP does not currently offer any member life insurance programs.

The invention of the World Wide Web in 1989, followed by the first graphical browsers in the early 1990s, rapidly changed information sharing globally. During 1995, several CAP committees explored and worked on proposals to establish a CAP website. The website was seen as a member service to electronically connect pathologists and the public to CAP resources. The Board of Governors approved the development of the CAP’s first homepage at its November 1995 meeting and initiated a pilot project to introduce the site in the autumn of 1996 at the CAP annual meeting. The development and operation of the site was outsourced to a third party to be overseen by three member committees.

This expanded reach marked the beginning of the CAP’s greater influence as the premiere organization for advancing pathology and laboratory medicine with the ultimate goal of making people healthier.



Chapter Three

ANATOMY AND  
PHYSIOLOGY  
OF THE CAP:  
STRUCTURE AND  
INFRASTRUCTURE

*Do one thing but do not omit others.*

—Angelo Celli

**The foundation of pathology is human anatomy and physiology; in an organization, its structure operates much like the human body, each of the parts absolutely essential to the whole.**

Although the CAP is a professional organization that performs for its members many of the traditional functions of a membership organization, the CAP also can be described as a bipartite organization providing member services that are supported by revenue-producing components. These financial components most often result from the collaborative efforts of CAP members with special expertise working in conjunction with the CAP's large staff of professionals. As such, the complex organizational structure of the CAP far exceeds that of a traditional membership organization.

The organizational structure and the financial support for that structure has evolved over the past 75 years and the history of that evolution has been partially described in the previous two chapters. The strategy and daily operations of the CAP fall under the leadership of the Board of Governors, which includes three officers, the president, the president-elect, and the secretary treasurer, all of whom are elected by the general membership. Five councils report to the Board: the Council on Membership and Professional Development; the Council on Government and Professional Affairs; the Council on Education; the Council on Accreditation; and the Council on Scientific Affairs. Additionally, several

committees report directly to the Board (Finance, Audit, Investment, and others), and numerous other committees targeting specific areas of expertise report to the councils.

The CAP Board, councils, and committees are supported by a large number of staff. The staff is under the leadership of the Chief Executive Officer and eight vice presidents, each of whom has executive responsibility for specific functions and support of the Board, council, and committee structure.

**CAP Finances**

The CAP is devoted to multiple missions. One of them, Laboratory Improvement, generates

EXPENSE CATEGORY	2020 AMOUNT (MILLIONS USD)	% OF TOTAL EXPENSES
Personnel and Benefits <sup>1</sup>	\$ 97.7	44.5%
Cost of Materials and On-site Inspections	71.8	32.7%
Outside Services <sup>2</sup>	22.1	10.1%
Depreciation and Amortization	10.9	5.0%
Rental and Maintenance	8.5	3.9%
Office Expenses	2.7	1.2%
Council and Committee Expenses	1.5	0.7%
General and Administrative	1.3	0.6%
Travel	1.0	1.5%
Other Expenses	2.0	0.9%
<b>Total Expenses</b>	<b>\$ 219.7</b>	<b>100.0%</b>

1. Amounts for personnel and benefits and outside services have been reduced by the capitalized expenses of \$3.2 million and \$5.8 million, respectively.

**Figure 1**

an income stream that supports many of the other missions, including education, advocacy, and membership services. Under the direction of the Finance Committee, the Finance Division is responsible for management of revenues and expenses. The Finance Committee reports directly to the Board of Governors.

The historical financial growth of the CAP demonstrates the changes in products and services provided by the CAP over the past 25 years. In 1997 the CAP's revenue-growth was a direct result of the increase in Survey and accreditation enrollment driven by CLIA '88. At that time, the Surveys revenue of \$50.1 million and accreditation revenue of \$7.9 million combined to constitute 85 percent of total revenue. Since then, the laboratory improvement programs have grown to \$225.3 million, comprising 93 percent of total revenue in 2020.

The CAP's major expenses over the years are captured in the categories of cost of materials, onsite inspections, personnel, and benefits. The table (Figure 1) details the breakdown of 2020 expenses). In 1997, cost of materials was budgeted at \$23.7 million and by 2020 grew to \$73.4 million. In 2020, personnel and benefits were budgeted at \$104.6 million, compared to \$22.3 million in 1997. Increased costs are driven by many factors including merit increases, changes in

market value, and increased staff numbers to support increased volume in products and new services. Travel expenses, including committee travel, was \$5.0 million in 1997 and has grown to \$12.4 million in 2020. Contributing to this increase is the growing number of committees as well as organizational changes to add sales, marketing, and international departments. Overall expenses in 1997 totaled \$67.2 million; the 2020 budget itemized total costs of \$252.9 million. The table (Figure 2) details the CAP Operating Revenue from 2016-2020.

## A Strong Year for the CAP

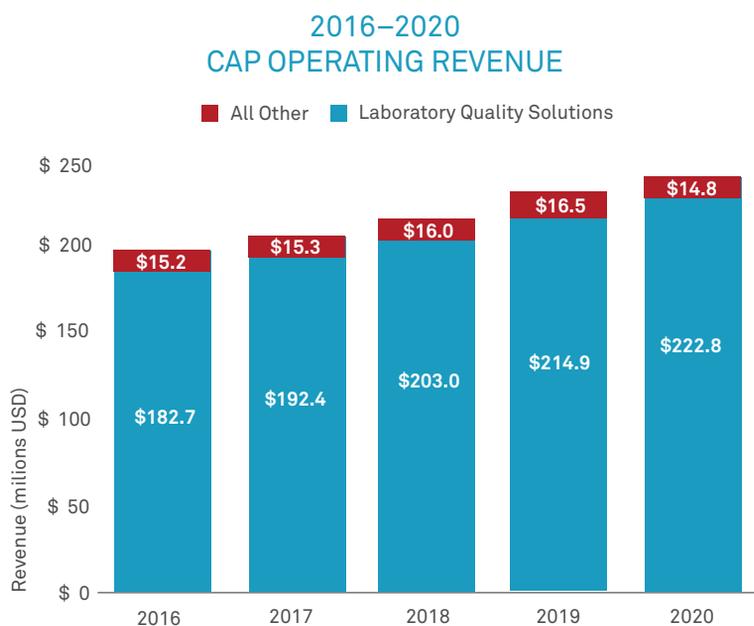


Figure 2



Chapter Four

# SCIENCE AND LABORATORY IMPROVEMENT

*Quality is not an act, it is a habit.*

—Aristotle

**Although the CAP was founded with the intent to address socioeconomic issues and to improve the status of pathology and pathologists, the CAP is clearly identified today as a leader in the science of pathology and medicine as well as a leading organization for establishing and maintaining worldwide standards of laboratory performance.**

While there are many CAP programs that support quality in laboratory performance, two programs—Proficiency Testing and laboratory accreditation (LAP)—stand out as the principal instruments for achieving standardization in the performance of laboratories. This chapter examines the history of the remarkable growth and diversity of these two programs over the past 25 years and highlights how they are interconnected. In this chapter, CAP Quality Management programs (Q-PROBES™, Q-TRACKS™) will also be discussed, as well as the history of development of guidelines culminating in the creation of the CAP Center. Finally, a unique CAP contribution to the nomenclature of pathology and medicine, SNOMED®, will be presented.

## **CAP Proficiency Testing**

The development of test standard solutions and Proficiency Testing (PT) were the first CAP initiatives in laboratory improvement (the first CAP Survey was distributed in 1949 but results were never published). Conceived as a program to foster continuous improvement in the laboratory and to support education, PT has been central to the mission of the CAP since its inception. Currently serving more than 22,700 laboratories, the Proficiency Testing program delivers high quality, science-based programs

for all areas of laboratory testing. In support of this charge, more than 700 programs are currently offered. On average, 20 new programs are introduced each year as the breadth and scope of laboratory testing increases. The CAP Proficiency Testing program provides PT for the highest complexity laboratories. However, many programs are designed for smaller laboratories, such as those found in physician offices or at point-of-care locations in hospitals.

Although participation in PT is mandated by CLIA, laboratories that participate in the CAP PT Program value quality. Participation in PT ensures accuracy of testing that improves with participation in the programs. All members of the laboratory team participate—pathologists, technologists, and laboratory scientists. At this point in time, some laboratories have participated in CAP PT for more than 50 years. CAP members are both the designers and recipients of the PT programs. The Council on Scientific Affairs, which is the council responsible for content and administration of the programs, creates the PT programs through more than 32 discipline-specific scientific committees comprised of more than 600 appointed member positions. These world class experts—working pathologists, doctoral-level, and other laboratory scientists—design the Surveys with an emphasis on identifying test attributes that relate to clinical requirements.

The PT program has undergone multiple phases of growth over the years. During the first 30 years, the program created Surveys for all major laboratory disciplines. During the next 30 years, the program experienced dramatic growth in all categories: number of laboratories participating, number of countries participating, and number



of products offered. This growth occurred before and after the passage and implementation of CLIA '88. More recently, the program is beginning to take on new attributes as the platforms for laboratory testing evolve and the need to share information in new ways increases. The past 25 years have witnessed remarkable advances in all areas of the science of laboratory testing. Programs for molecular oncology, biochemical and molecular genetics, flow cytometry, genomic medicine, molecular microbiology, chemistry, cytogenetics, immunohistochemistry for predictive markers, calibration verification and linearity, and anatomic pathology programs in all specialty areas of testing are being developed. In many instances, rapid changes in testing platforms and modalities have occurred at a pace that at times has outstripped the ability to develop meaningful PT in a timely manner.

Forces external to the PT Program have significantly impacted PT. The implementation of CLIA '88 imposed federal requirements on the frequency, grading, and nature of PT. The CAP provides input from scientific experts to the federal agencies that regulate PT, and at the same time ensures that CAP programs meet the needs of laboratories while also maintaining appropriate scientific and clinical standards,

all without imposing unneeded burdens on laboratories. Applications are submitted yearly for approval of the PT programs by the Centers for Medicare and Medicaid Services (CMS). The PT program is administered under the full scientific authority of the CAP and is required to maintain standards at least as stringent as those required by the federal statute. During the past 25 years, many internal CAP initiatives have been implemented to ensure that PT programs maintain the highest quality and are truly educational while at the same time fulfilling federal regulatory requirements. Other market trends such as consolidation of laboratories, the influence of industry, and how laboratories function all play into how the PT Programs are structured and offered.

Between 2010 and 2020 the number of new programs introduced varied from 20 to 51 each year. The 2010-2020 numbers include new PT programs in Calibration Verification/ Linearity (CVL), Quality Cross Check, and Quality Monitor programs. Examples of the increasing depth and scope of PT programs during the last 10 years include:

- Predictive markers for breast cancer such as HER2 and ER/PgR by immunohistochemistry and in-situ hybridization

The CAP Proficiency Testing program has undergone multiple phases of growth over the years.



- Predictive biomarkers (ie, BRAF, EGFR, KRAS) utilizing technology such as next generation sequencing and Sanger sequencing
- Non-invasive prenatal testing, cell-free tumor DNA
- Accuracy-based/Commutable Programs including Vitamin D, Lipids, Testosterone, Estradiol, Accuracy-Based Urine, Hemoglobin A1c, Glucose, Insulin, and C-Peptide

Not infrequently, review of the PT data by scientific committees reveals potential patient safety issues. Some such issues have resulted in collegial dialogue with instrument manufacturers and consequent improvements in methodology. In some instances, patient safety concerns have been escalated to the attention of the US Food and Drug Administration. These scientific committees often work directly with government agencies in addressing critical issues facing laboratories committed to improving patient care. Such initiatives have included updating the antimicrobial susceptibility test (AST) devices that apply obsolete breakpoints; addressing the lack of well-standardization of specific Direct Oral Anticoagulants (DOACs); the cardiac troponin issues; standardization of D-dimer reporting; and development of Cancer Protocols and the Electronic Cancer Checklists (ECC).

Furthermore and in support of laboratories' need to assess the quality of testing on more than one platform, the CAP developed the Quality Cross Check program, which allows laboratories to monitor performance of multiple instruments performing the same test. Additionally, whole-slide imaging for digital pathology has become an integral feature in many CAP PT programs that offer online, whole-slide images (powered by DigitalScope™ technology) to mimic clinical laboratory experience.

And of course while deploying new technologies in the ongoing refinement of quality patient-care, the CAP also continues to lead the way in development of new programs to address emerging health issues, not least among these

infectious diseases testing including SARS CoV-2, Zika testing, and testing for molecular microbiology multiplex panels. Finally, and with an eye toward the less-than-distant future, the CAP participates in ongoing initiatives in the areas of Artificial Intelligence and Machine Learning.

### The Laboratory Accreditation Program

The Laboratory Accreditation Program (LAP) has grown in size and complexity over the past 25 years and is widely recognized as the preeminent accreditation program for medical laboratories in the United States and continues to grow internationally. More than 8,000 laboratories are now accredited. The program includes many laboratories that have been continuously accredited since the 1960s and '70s—well over 50 years! The newest accreditation program—the Biorepository Accreditation Program—accredited its first laboratories in 2012. By mid-2019, more than 60 biorepositories have met the rigorous standards of this program and have become accredited. The CAP has also expanded offerings to include the CAP 15189<sup>SM</sup> program. This program provides an opportunity for CAP accredited laboratories to gain accreditation by the ISO (International Organization for Standardization) 15189 standard encompassing requirements for quality and competency. Through mid-2019, 70 laboratories have been accredited by the CAP 15189<sup>SM</sup> standard, with an additional 15 laboratories in progress. In addition to the above cited programs, Reproductive and Forensic Toxicology laboratories are also part of the accreditation program.

The CAP Laboratory Accreditation Program was initially approved in February 1995 by the Health Care Finance Administration (later renamed to CMS) through December 31, 1998. In the late 1990s, a validation process with a prescribed maximum allowable discrepancy rate of 20 percent was implemented.

At the core of the accreditation program are the CAP inspectors. More than 11,000 pathologists and other laboratory professionals volunteer their time to inspect laboratories. The CAP

maintains online education programs for the team leaders and inspectors as well as provides periodic live training events. On any given day there are eight volunteer teams performing inspections somewhere in the US.

The 21 CAP Checklists are the core documents used by the inspectors to assess laboratories. The inspection is an “open book test” in that all information provided to inspectors is also available to the laboratory prior to the inspection. The Checklists are a blueprint of how to operate a quality laboratory. The Checklists are updated annually by the Checklist Committee with the assistance of the CAP’s scientific committees (identified for many years as resource committees). In 2019, the Checklists featured 1,241 pages of detailed guidance for laboratories as well as inspectors and consisted of 3,385 requirements plus detailed clarifying notes including evidence of compliance and inspector instructions.

The historical goal of the accreditation programs has always been laboratory improvement through education and peer review. Since the CAP achieved deemed status from CMS, regulatory compliance with CLIA requirements has become a component of inspection and accreditation. In addition to the Checklists, the accreditation program maintains a large database of online resources to help laboratories provide quality and maintain continuous compliance. Among those offerings are inspection preparation courses and focus-on-compliance webinars addressing timely compliance topics. As well, a Proficiency Testing/external quality assurance toolbox provides guidance on Proficiency Testing troubleshooting and compliance.

A series of unfortunate events in 2002—2004 involving a midsize urban center hospital laboratory located in the Northeast resulted in significant changes in the CAP accreditation program, as well as the accreditation programs of other organizations providing accreditation services. Subsequent to a CAP inspection, the laboratory was found to have serious deficiencies in the quality-control

system as well as significant personnel safety lapses. In addition, there were allegations of falsification of records at the direction of hospital and laboratory leadership. As a result of a series of inspections by the CAP and the relevant state agency, all related to complaints from personnel and media attention, Congressional attention was brought to bear on the entire accreditation process. CAP leadership, including CAP presidents, testified before Congressional committees, and a report was issued by the Government Accounting Office. The CAP conducted an in-depth review of its accreditation process and several major changes in organization and process were implemented, including the start of unannounced inspections by the CAP as well as by TJC and other accrediting entities. In 2006, accreditation programs were moved from the Council on Scientific Affairs to a new Council on Accreditation; the new Council reports directly to the Board of Governors. The Accreditation Committee, reporting directly to the Council, was established to separate the accreditation decision function from policy and operational functions. Furthermore, committees were established to handle functions previously overseen by Special Commissioners: Accreditation Education, Checklists, Complaints and Investigations, Continuous Compliance, and Inspection Process committees. These committees report to the Commission on Laboratory Accreditation—the entity ultimately responsible for providing operational guidance to the accreditation programs and oversight of the regional and state commissioners. And, as the need arose, committees were established for CAP 15189<sup>SM</sup>, biorepository, and international accreditation. In addition, the CAP made available to all lab employees, patients, and lab clients a toll-free telephone number allowing for reporting of concerns and complaints; labs are required to prominently display a poster providing information about access to the line. The CAP modified accreditation requirements to promote self-reporting of performance concerns and required labs to have a process allowing employees to report

concerns internally without fear of reprisal. The CAP now meets regularly with CMS, state agencies, and the Joint Commission to improve communications between accrediting agencies.

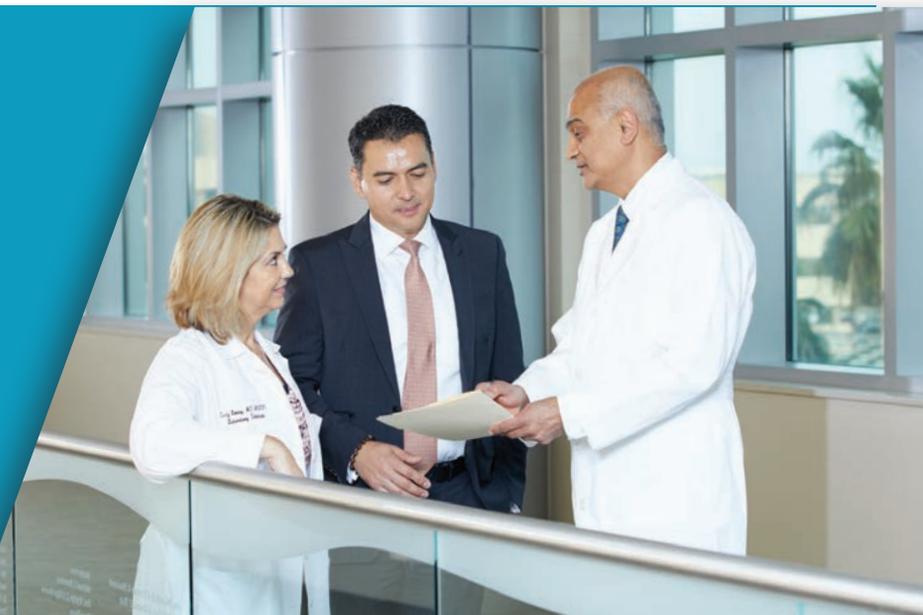
Laboratories outside of the US are being added to the list of accredited laboratories at a high rate. The CAP now accredits more than 450 international laboratories in 53 countries. CAP volunteers and staff spend approximately 1,100 days a year traveling to inspect on six continents. Some of the parameters of international accreditation have been modified in recognition of the travel and quarantine restrictions created by the Coronavirus pandemic. The CAP International Laboratory Accreditation Program reflects the CAP's uncompromising commitment to quality in laboratory testing around the world and makes the CAP Checklists available to pathologists, scientists, and technologists. During international inspections, CAP members and staff, sometimes assisted by regional pathologists and scientists, serve as facilitators to help implement good laboratory practices. By basing the inspections on compliance with the Checklists, requirements for an international laboratory to achieve accreditation are very similar to those of US laboratories. With some exceptions, international laboratories are not subject to CLIA requirements. As of 2020 there are 486 Civilian and 54 US Military and Veterans

Affairs accredited laboratories for a total of 540 accredited laboratories. This represents a 25 percent increase in the growth of accredited laboratories since 2016. In addition, approximately 3,470 international laboratories subscribe to the CAP PT Program.

International inspections place demands on inspectors not usually encountered during US inspections. An international inspector must be an experienced inspector who can inspect three checklists in one day and be able to be away from home 8-10 days, because inspections are geographically grouped and are usually sequenced over a working week. An inspector is allowed one day to rest after a long international flight. For reasons of economy, inspections are tightly scheduled. Approximately one half of the numbers of inspectors normally used in US inspections are used in international inspections.

Inspection teams are put together by the Team Leader who knows the skills of each team member. Cultural sensitivity is important during inspections in other countries. Interpreters are usually available, but humorous things can happen. An inspector once made a request to use the rest room and shortly discovered that the lab was making arrangements to rent a hotel room so that the inspector could "rest." A very experienced inspector has said that

The historical goal of the accreditation programs has always been laboratory improvement through education and peer review.



## Living Our Quality Mission

**23,176**

laboratories using  
the CAP's PT

**7,778**

CAP-accredited  
laboratories

**834**

pathologists  
participating  
in onsite inspections

## 2020 FACTS AND STATS LEADING LABORATORY QUALITY



“international Inspections are educational, exciting, and rewarding, but expect to work hard.”

As the accreditation programs continue to grow and expand the CAP continues to focus on improvements in the systems used to support the programs. In 2018 the CAP launched the Organization Profile application, providing laboratories the ability to update their data, test menu, and demographics online in real-time to ensure that the most accurate and current information is available. This ensures that appropriate Checklist requirements and accurate laboratory data are provided to the inspection team to enable the best inspection experience possible. The CAP continues to focus on this area, with evolving plans to provide inspection teams with electronic inspector packets as well as enabling online uploading capabilities for additional documentation requests. The goal is to ensure the most accurate data and updates, while providing the most efficient process for laboratories to interact with the CAP.

### Quality Management Program (Q-PROBES™ and Q-TRACKS™)

The CAP's Quality Management Program was launched in 1989 with the introduction of Q-PROBES™ studies. Q-PROBES™ are quality

improvement studies intended to assess aspects of laboratory testing extending beyond traditional analytical or measurement steps and focusing attention on the preanalytical and postanalytical phases of testing. The intent was to provide participating laboratories with an off-the-shelf program allowing them to compare their performance in select areas of laboratory practice with peer benchmarks. The conceptualization of the Q-PROBES™ program arose primarily from the long-term commitment of the College of American Pathologists and pathologists to well-established programs of quality assurance and improvement (ie, accreditation and Proficiency Testing).

The Q-PROBES™ studies resulted in benchmarks, or comparative measurements, that are now routinely monitored and which are cited in many articles and presentations. Articles published in the *Archives of Pathology & Laboratory Medicine* related to Q-PROBES™ are referenced more than 60 times in the CAP's Laboratory Accreditation Program Checklists. The first Q-PROBES™ studies were offered in 1989. These consisted of three studies in anatomic pathology and five studies in clinical pathology. The number of annual studies steadily increased through 1992, from which point the studies have been monitored and when necessary modified to meet customer needs.

The QAS-QA Committee was responsible for the oversight of the Q-PROBES™ studies. The committee consisted of members with expertise in multiple disciplines. In 1996, the QAS-QA Committee moved from reporting to the Council on Scientific Affairs to the Council on Practice Management, and in 1997 was renamed the Quality Practices Committee. Between 1989 and 2020, the Quality Practices Committee offered 276 Q-PROBES™ studies.

In 1999, the Quality Management Program added a new format called Q-TRACKS™. These were monitors developed to establish critical benchmarks in quality metrics and to monitor performance over time. Q-TRACKS™ focus on established quality measures with wide acceptance. Six Q-TRACKS™ were offered in 1999. Similar to Q-PROBES™ studies, these monitors concentrate primarily on preanalytical, postanalytical, and turnaround-time quality indicators. The Q-TRACKS™ program's most notable achievement has been the establishment of ongoing quality monitoring associated with continuous improvement. A total of 19 Q-TRACKS™ have been developed between 1999 and 2017. Over time the average number of Q-PROBES™ studies offered annually is four and 11 Q-TRACKS™ annually. The Quality Practices Committee continues to oversee the development of new Q-PROBES™ style studies and provide laboratories with analysis of Q-TRACKS™ data. In 2003 the QPC rejoined the Council on Scientific Affairs.

### **Standards, Protocols, Guidelines, and the CAP Center for Pathology and Laboratory Quality**

Since the early years of the CAP, development of standards in pathology and laboratory medicine has been a core competency of the CAP. The CAP Cancer Protocols are perhaps the most visible and important example of this. Other examples include the CAP LAP Checklists, SNOMED®, the Q-PROBES™ and Q-TRACKS™ programs, and the publication years ago of several guidelines for pathology practice by the CAP Outcomes Committee (1996-2002). CAP participation in international standard-setting organizations such as ISO and CLSI are additional examples.

The CAP Center for Pathology and Laboratory Quality continues this tradition as it expands upon the many years of CAP concentration on standards and protocols related to cancer care. The Center has evolved over many years since the creation (1978) of a Patterns of Care Steering Committee. That committee worked in collaboration with the American College of Radiology, and subsequently with subcommittees of the Cancer Committee, to establish task forces charged with determining how pathology specimens for breast cancer, colon cancer, and Hodgkin's disease should be examined and



The CAP Center for Pathology and Laboratory Quality continues this tradition as it expands upon the many years of CAP concentration on standards and protocols related to cancer care.

reported. Subsequently, multidisciplinary task forces were created to address all cancers and to publish their findings in order to help pathologists provide clinicians with AJCC staging information. To deal with some confusion on the part of practicing pathologists, two CAP Conferences (Utah 1994; Chicago 1999) focused on the use of biomarkers in cancer. In order to improve educational opportunities for pathologists, the recently created Council on Education acquired professional expertise in instructional design and course evaluation to improve educational efforts in biomarkers and associated reporting requirements. Parallel efforts have included modification of Laboratory Accreditation Checklists to include new knowledge.

The starting concept of the CAP Center was exemplified by a guideline jointly published in *Archives of Pathology & Laboratory Medicine* (“Human Epidermal Growth Factor Receptor 2 (HER2) Testing in Breast Cancer,”—January 2007 and the *Journal of Clinical Oncology*). This guideline reflected a collaborative effort between the CAP and the American Society of Clinical Oncology and focused on the use of HER2 testing in breast cancer, with particular attention to tissue fixation times. In 2008 the Center was officially established as the CAP “home” for the development of evidence-based guideline studies. The idea was to build a center within the CAP where the CAP could collaborate with other specialists in other disciplines to research the best evidence available about emerging medical science and write clear, concrete practice guidelines. Through the Center, input from pathologists and other specialists would generate readily accessible guidelines offering evidence-based content on topics tied to cutting-edge medical science that would be useful for patient care. To date, the Center has partnered or collaborated with more than 20 other pathology and medical societies to produce 16 published laboratory practice guidelines. More are underway.

Under the leadership of Elizabeth Hammond, MD, FCAP, the CAP Center published its

first guideline in 2012. Since then, multiple Evidence-Based Guidelines (EBGs) have been made available to pathologists and non-pathologists in many areas—particularly precision medicine. In 2011 the Institute of Medicine and Science published “Clinical Practice Guidelines We Can Trust,” examining approaches to managing conflicts of interest, establishing transparency, and forming a balanced, qualified multidisciplinary team. Each guideline is the result of extensive and meticulous searches of the literature and iterative review and discussion by the CAP and other experts. From inception of the Guidelines Project, one core goal has been to assist pathologists in assuming new roles in the delivery of medical care to patients. Initially, projects were focused on anatomic and breast pathology. Under the leadership of Elizabeth Wagar, MD, FCAP, and Patrick Fitzgibbons, MD, FCAP, subsequent guideline projects have focused on clinical pathology, with emphasis on biomarkers and immunotherapies, as well as guidelines that can be applied to develop metrics for the CAP Pathologists Quality Registry. Each guideline is posted for public comment to ensure feasibility and practicality. The experience of the Center has been that thousands of comments may be received on a given guideline and each one is carefully considered before the guideline is finalized for approval.

More recently, the Center has added another resource, known as GRADE (Grading of Recommendations Assessment, Development and Evaluation), as an internationally recognized tool to weigh the strength of evidence and create guidelines that are transparent, clear, and consistent. GRADE fosters communication across disciplines and enables the CAP to demonstrate the value of pathology and pathologists in all facets of medical care.

Part of this communication is the intense dissemination effort by which completed guidelines are shared across the CAP. The Council on Accreditation and the



Council on Scientific Affairs reviews final recommendations to identify items for referral to responsible councils and the Checklists Committee. Because the CAP has deeming authority from the Centers for Medicare and Medicaid Services, the CAP is tasked with making sure that all CAP-accredited laboratories comply with CLIA requirements. It takes time to write the Checklists requirements that implement a new guideline, and that cannot begin until the guideline is approved.

### The CAP and SNOMED®

**The following section has been contributed by Raj Dash, MD, FCAP.**

The beginnings of what is now the leading medical-terminology resource in the world, the Systematized Nomenclature of Medicine (SNOMED®), started with a focus on pathology. This history is described in a textbook by Roger Côté, MD, FCAP, covering the first 30 years of SNOMED® (Côté, R. A. *The Evolution of SNOP to SNOMED® International, a 30 Year History*. Secrétariat Francophone International de Nomenclature Médicale (SFINM), 2004). In 1953 the Board appointed a Committee on Nomenclature and Classification of Disease. This committee was charged to help pathologists standardize, organize, and better utilize the information generated in diagnostic

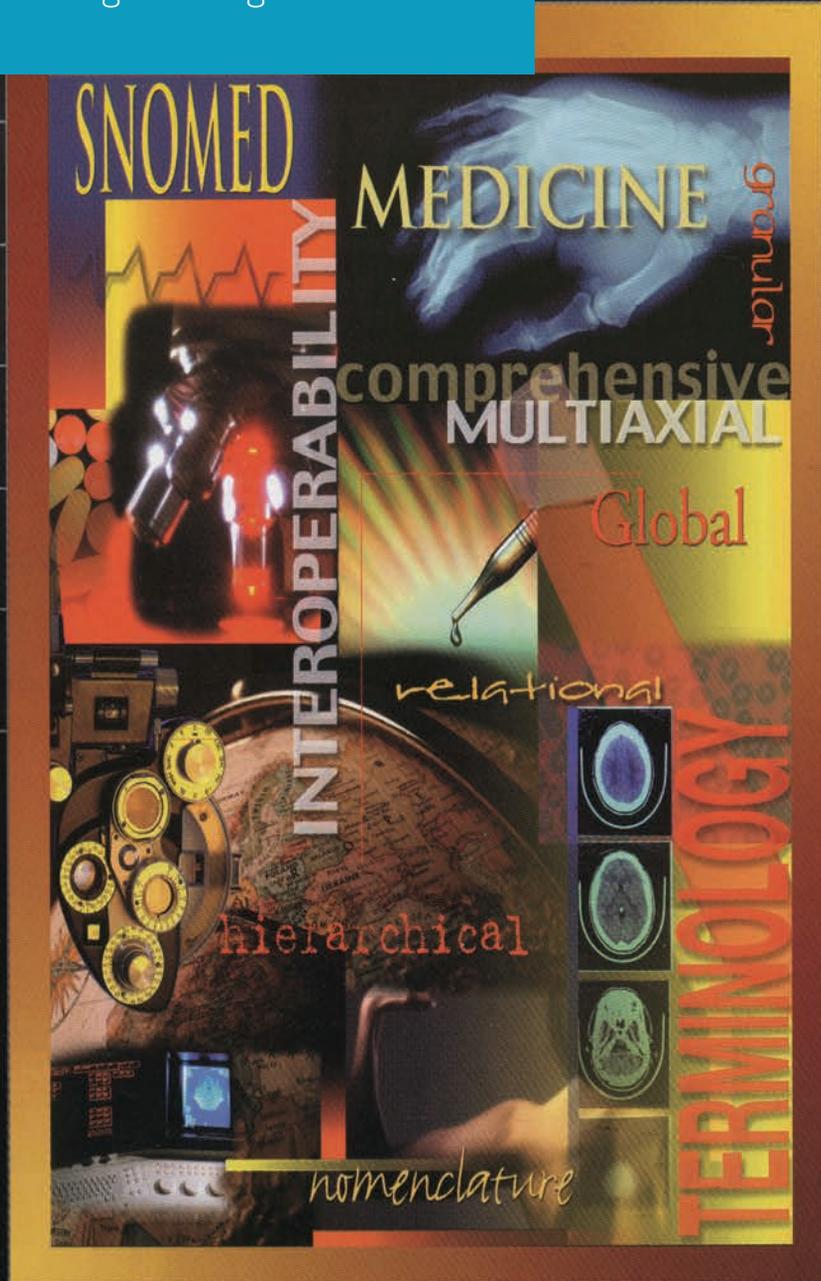
reports. The first systematized nomenclature of pathology (SNOP) was published in 1965 as a work product of this committee. This early initiative focused on getting pathologists up to speed quickly with normalizing the terms used to describe pathology concepts, with a focus on disease of organ. Lowering barriers to manual coding of pathology reports was facilitated by a pin-up chart summarizing the organization of the coding scheme. The value derived from this effort facilitated standardization, statistical reporting, and case finding for teaching, conferences, and research. By the 1970s, SNOMED® was recognized as one of the most successful coding nomenclatures, used both for manual coding and computer program-based encoding of pathologists' diagnoses in natural language.

SNOMED® went through significant evolution over the next three decades. In brief, SNOP evolved from covering primarily anatomic pathology concepts (disease of organ) to laboratory and medical concepts more generally, across additional axes and hierarchies, and was officially published as SNOMED® in 1975. An expanded and more user-friendly publication format, in two volumes, was published as "SNOMED® II" in 1979.

In the 1980s, an effort parallel to SNOMED® developed in the United Kingdom, led by

By the 1970s, SNOMED® was recognized as one of the most successful coding nomenclatures, used both for manual coding and computer program-based encoding of pathologists' diagnoses in natural languages.

*The key to fully implementing a CPR system is a standardized vocabulary.*



**The Global Vocabulary Solution**

Dr. James Read. This effort, dubbed the “Read Codes,” focused on organizing information for the general practitioner rather than the pathologist and was widely implemented within the UK in the 1990s. In the late 1990s, the then most current iteration of SNOMED®, at the time called SNOMED® RT, was combined with the UK Read Codes to form SNOMED® Clinical Terms (CT), and the CAP created a new division dedicated to accelerating the development of SNOMED® CT. SNOMED® CT was published in 2002 with the promise of serving a broader health care community, leveraging the clinical medicine coverage of the Read Codes with the strong pathology and laboratory coverage within SNOMED® RT. SNOMED® CT was made available within the UK by agreement between the CAP and the National Health Service (NHS) and was available outside the UK through licensing by the CAP. The focus changed from expanding the vocabulary to distilling quality from the massive integration of medical concepts across these two large vocabularies. This also represented a turning point for the CAP and the SNOMED® division as the National Library of Medicine (NLM) took a strong interest in having SNOMED® CT serve as the standard vocabulary for the exchange of medical information in the United States as part of its Unified Medical Language System (UMLS). On June 30, 2003, the CAP signed a five-year contract with the NLM, and the next day the Health and Human Services Secretary announced the licensing of SNOMED® as a standard and freely available medical terminology resource for use in the United States.

In subsequent years, SNOMED® CT continued to grow with ongoing support of the NLM well beyond the initial five-year contract. Growing recognition that the value of SNOMED® CT was global but required international support to catapult it into becoming the premier global medical terminology represented another critical inflection point in SNOMED®’s history. Considerable effort was expended to garner support from leaders and health care visionaries of many countries, and in 2007 the CAP successfully shepherded SNOMED®

for future development to a newly formed multinational organization, the International Health Terminology Standards Development Organization (IHTSDO). This new organization, based in Copenhagen, was supported by the following founding member countries: Australia, Canada, Denmark, Lithuania, Sweden, the Netherlands, New Zealand, the United Kingdom, and the United States. Over the next decade the momentum continued to build until today nearly 40 member countries support the international effort to standardize medical concepts across half-a-dozen languages. On December 31, 2016, the IHTSDO adopted a name that had significant global brand recognition, SNOMED® International, and moved its headquarters to London. The CAP continues its strong involvement, particularly to strengthen the efforts of the Pathology and Laboratory Medicine Clinical Reference Group within SNOMED® International.

SNOMED®’s true potential and promise continue to be more fully recognized in an era of growing information overload and pervasive electronic health records. For the CAP, SNOMED® represents a remarkable story of vision, perseverance, altruism, and commitment. The long and successful history of the transition from a pathology-centered vocabulary to the leading international computer-based language reflects the organizational commitment of the CAP and the vision, hard work, and dedication of many members and staff over the years. Amongst the leaders of this effort were CAP members Roger Côté, MD, FCAP, Ronald Beckett, MD, FCAP, Rajesh Dash, MD, FCAP, William H. Donnelly, MD, FCAP, Franklin Elevitch, MD, FCAP, George Gantner, MD, FCAP, Donald Henson, MD, FCAP, John Neff, MD, FCAP, Paul Rastlavicus, MD, FCAP, David Rothwell, MD, FCAP, William D. Sharpe, MD, FCAP, Kent Spackman, MD, FCAP, Thomas Sodeman, MD, FCAP, Arthur H. Wells, MD, FCAP, David Wood, MD, FCAP, and CAP staff members Diane Aschman, Pamela Cramer, and Kevin Donnelly. A remarkable story...and of course, the story remains unfinished.



Chapter Five

CAP ADVOCACY  
FOR THE PROFESSION  
AND FOR PATIENTS

## Chapter Five

*One of the penalties of refusing to participate in politics is that you end up being governed by your inferiors.*

—Gandhi

### **This chapter has been contributed by Donald Karcher, MD, FCAP.**

From the very beginning of the CAP in 1946, advocacy has been at the core of what the CAP does for its members. Advocacy on behalf of the profession and patients remains one of the most important reasons why pathologists join and maintain membership in the CAP. By design, the CAP was originally and continues today to be structured to allow for maximum impact in advocating for pathologists. As the only pathology society set up as a 501(c)(6) organization, the CAP has been able to deploy unlimited resources to lobby Congress, the Executive Branch, and state legislative bodies on issues important to pathology and laboratory practice. The CAP's 501(c)(6) tax status also allowed it to form the CAP's political action committee, PathPAC, in 1992, establishing it as the only PAC making contributions to support candidates for political office sympathetic to the pathologist cause. This unique status as a fully-empowered advocate for pathology has allowed the CAP to lead the entire pathology community for decades in its efforts to ensure a favorable economic and regulatory environment for pathologists and the laboratories they lead. This important work has allowed pathologists and clinical laboratories to have the appropriate financial resources and operational setting to provide the highest possible quality services for their patients.

Advocacy in medicine is focused on policymakers, payers, and regulatory bodies both in government and the private sector and at multiple levels, from national to state to local. Advocacy for pathology typically deals with matters related to the financial well-being of

pathologists and clinical laboratories and the regulatory environment in which pathologists practice and clinical laboratories operate. In this chapter, CAP advocacy activities at both the national and state levels on economic and regulatory issues will be reviewed, with special emphasis on the past 25 years.

Successful advocacy involves effective organizing and messaging to bring policy positions to relevant stakeholders and the general public. The CAP's activities in training and organizing pathologists to serve as advocates and in communicating about the value of pathology and laboratory medicine in the health care system will be illustrated. The status of the CAP as the advocacy leader and representative of the pathology community in the greater house of medicine will also be detailed. As this 25-year period was nearing completion, the COVID-19 pandemic led to major disruptions in health care delivery and the entire world economy. The advocacy activities of the CAP to support widespread COVID-19 laboratory testing and ensure regulatory and financial protections for pathologists, pathology practices, and clinical laboratories will be summarized and also presented in greater detail in Chapter Eight.

During its first 50 years of existence, the CAP's work as an advocate for the pathology profession was extensive and far-reaching. Over the ensuing 25 years, this work has continued to be a major focus of the CAP and has grown into a large enterprise designed to bring policy and legislative experts together as partners with CAP members to advocate for pathologists, clinical laboratories, and ultimately the patients served by the pathology community.



### **Economic Issues for Pathologists and Clinical Laboratories Fee-for-Service Payment: Relative Value, the RUC, Budget Neutrality, LCDs, Private Payers, and the TC Grandfather Clause**

For decades, an argument in health policy has centered on the idea that primary care physicians are underpaid, while specialists and particularly proceduralists are overpaid. This led to a movement in the 1980s that ultimately produced the resource-based relative value scale (RBRVS) designed to reimburse physician services based on the resources required to perform the service. With the advent of RBRVS-based payment, the struggle to maintain fair payment for pathology services began and continues to the present. The group that analyzes the relative value of services on the Physician Fee Schedule and submits recommendations to Medicare is the AMA Specialty Society Relative Value Scale Update Committee, or RUC, which has been in existence since 1991. The CAP is the only pathology organization that is a voting member of this committee.

Over the decades, the CAP has led the efforts on behalf of the entire pathology community to

maintain equitable valuation and payment for pathologists' and related technical laboratory services. Although this work deals first with payments for Medicare patients as determined by the Centers for Medicare and Medicaid Services (CMS), payments by private insurers are typically impacted by the Medicare fee schedule, meaning that advocacy before the RUC and CMS ultimately influences payments for all patients. In addition to providing evidence to support payments for new services, the CAP has successfully defended payment for services identified by CMS for potential revaluation, through the agency's "potentially misvalued code" initiative. Since 2006, over half of pathology services have been earmarked for revaluation, and during this time the CAP's efforts have resulted in a net increase in payments for pathologist services of approximately 51 percent. The move to revalue physician services for Medicare patients was accelerated as a result of multiple laws enacted in recent years, including the Affordable Care Act (ACA) of 2010, the Protecting Access to Medicare Act (PAMA) of 2014, and the Achieving a Better Life Experience (ABLE) Act of 2014, making the work of the CAP in this area that much more challenging.

As the RUC and CMS have together studied and determined the relative values of and payments for all physician services, an equally important process to organize and standardize the definitions of medical services and other medical resources was underway. The AMA's Current Procedural Terminology (CPT) system was developed in the 1960s initially to classify surgical procedures, but over the years came to be the standard nomenclature system for all health care services. The Health Insurance Portability and Accountability Act (HIPAA) of 1996 led to the selection by the US Department of Health & Human Services (HHS) of the CPT system for reporting physician and other medical services and the International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM) for codifying diagnoses (subsequently updated to ICD-10-CM in 2015). As the CPT system gained in importance, the development and maintenance of these codes became of paramount importance. The AMA organized a group called the CPT Editorial Panel to make decisions regarding CPT codes and a second group, the CPT Advisory Committee, to provide assistance and advice to the Panel on these codes. Since the beginning of the CPT Advisory Committee, the CAP has led the review of all pathology and clinical laboratory codes for this important group. In 2003, the CAP partnered with the AMA to create the Pathology Coding Caucus, a group that ensures pathology and laboratory interests are represented to the CPT Editorial Panel on new and revised pathology and clinical laboratory codes. The CAP/AMA partnership continues to the present, as the CAP leads and provides organizational support for the Caucus. The CAP has also been a key member of the Molecular Pathology Advisory Group, a multi-stakeholder organization specializing in advising the CPT Editorial Panel on molecular pathology services. Dr. Mark Synovec and Dr. George Kwass have for decades provided leadership on behalf of the CAP in this critical CPT area.

Another example of the give-and-take between primary care and specialty physicians has dealt with payments for evaluation and management

(E&M) services. Although few pathologists perform E&M services, efforts over the years by CMS to restructure and revalue payments for these services, as part of the continuing push to increase financial support for primary care, have impacted all specialists, including pathologists. The first such attempt by CMS took place in 2007 and payments for specialist services were placed in great jeopardy. A complicating factor was the budget neutrality requirement for aggregate Medicare payments, first introduced as part of the Balanced Budget Act of 1997 (see SGR and Value-Based Payment later in this chapter), which mandates that resource-based rate adjustments of payments for Medicare patients must result in a neutral impact on the federal budget. Based on this requirement, any payment gains by one group of physicians must be offset by losses for other physicians. Strong advocacy by the CAP in 2007 resulted in a significant lessening of the impact on pathology payments, which still saw an aggregate decrease. In 2018, CMS proposed another restructuring of E&M payments, estimated to potentially lead to another 8 percent decrease in payment for pathology services. The CAP engaged in discussions with CMS to lessen the impact of this restructuring on pathologists and, in partnership with other pathology and medical organizations, advocated for removing the budget neutrality requirement as part of the E&M payment adjustments. As of this writing, a proposal was pending to exempt these adjustments from Medicare budget neutrality, as part of financial assistance legislation in response to the COVID-19 pandemic.

Parallel to fighting for fair value and payments for pathology services, the CAP has also fought to maintain appropriate coverage of patient services provided by pathologists. Coverage policy for Medicare patients is sometimes determined nationally, through the national coverage determination (NCD) process, but most coverage decisions are set locally based on local coverage determinations (LCDs) made by regional Medicare intermediaries, more recently called Medicare Administrative Contractors (MACs). The LCD process followed

by the MACs was recognized for some time as being flawed, lacking transparency and providing little opportunity for the latest scientific or medical evidence to be used to support appropriate coverage or to appeal a faulty LCD. Some of these faulty LCDs were ultimately adopted by multiple MACs with minimal debate or review. A notorious example was the LCD pertaining to immunohistochemical stains first developed as part of the MolDX program initiated by the MAC Palmetto GBA. In 2016, the CAP was instrumental in developing federal legislation, the LDC Clarification Act, to address these issues. Strong advocacy by the CAP, with significant grassroots support from many CAP members, ultimately led to the legislation gaining a large number of co-sponsors in both the House and Senate. In late-2018, the bill passed in the House, but had some key provisions removed in committee. In clear response to the legislation, CMS announced that it would reform the LCD process by revising some of its internal rules governing how MACs propose and approve LCDs. As a result, the Senate did not take up the legislation, convinced that the problem had been solved. This was a clear “win” for the CAP, with CMS yielding to the growing support for a legislative fix to the LCD issue.

Although most of the CAP’s advocacy efforts dealing with fee-for-service payments have focused on government payers, many of these efforts have directly or indirectly involved payments by private health care insurers. Advocacy involving private payers is different in many ways from governmental advocacy in that payment policies and practices by private payers are not rules-based or resource-based, and decisions made by private insurers are driven by market forces. Because private health insurance companies deal with private contracts involving both patients and health care providers, anti-trust laws limit the activities organizations such as the CAP can undertake regarding private payment rates and other private contractual matters. That notwithstanding, the CAP has engaged over the years in substantial and sustained advocacy efforts involving private payers and other private entities. These efforts have been focused on ensuring that pathologists and clinical laboratories are paid fairly for services provided to privately-insured patients and that insurance company business practices don’t overburden or otherwise disadvantage pathologists.

A somewhat obscure issue, but one important to many CAP members, dealt with the so-called TC (technical component) Grandfather Clause. The CAP’s advocacy on this issue was in response to actions taken by CMS to eliminate the ability of independent laboratories that performed technical AP services for Medicare hospital patients to bill Medicare directly for these services rather than bill the hospital. CMS issued regulations



Parallel to fighting for fair value and payments for pathology services, the CAP has also fought to maintain appropriate coverage of patient services provided by pathologists.

to eliminate this direct billing and the CAP secured congressional support to pass the TC Grandfather Clause to allow those laboratories that already had such an arrangement as of July 1999 (ie, “grandfathered” by the existing contracts) to continue to directly bill Medicare. This form of payment was viewed as essential to the financial well-being of these laboratories, particularly those located in rural areas. For more than a decade, the CAP strongly supported the TC Grandfather Clause and succeeded in preserving it; however, by 2012 Congress concluded that this payment represented duplication of what was already provided by DRG payments to these “covered” hospitals and decided to not extend the payment provision.

### SGR and Value-Based Payment

The continuing increase in the cost of health care in the US has led to multiple attempts, frequently through legislation, to rein in these costs. The Balanced Budget Act of 1997 represented a major attempt to slow the rise in Medicare payments for physician services. A provision of this law established the so-called Sustainable Growth Rate (SGR), a formula that was to limit the growth in Medicare physician payments based on the previous year’s gross domestic product (GDP) and other factors. It also established a budget neutrality provision requiring any increase in payments to be offset by decreases in payments for other services. From the beginning, the CAP was opposed

to the SGR provisions and, with the AMA and other medical organizations, fought for many years to eliminate or permanently “fix” the SGR formula, but each year Congress chose to postpone action on the SGR and focus instead on other incremental changes to stem the tide of increasing health care related spending. One failed attempt in Congress to repeal the SGR resulted instead in passage of the Protecting Access to Medicare Act (PAMA) of 2014, which included multiple provisions impacting health care costs, including a new method to determine payment rates in the Medicare clinical laboratory fee schedule.

Starting around 2000 and accelerating significantly with the passage of the Affordable Care Act (ACA) in 2010, there was a dramatic increase in a variety of new federal programs and private payer initiatives to slow the increase in health care costs and emphasize quality in health care delivery. In addition to the rapid rise in health care spending in the US as a percentage of the nation’s GDP, publication of two key studies by the Institute of Medicine (now known as the National Academy of Medicine) shined a bright light on the need for a new value-based approach to health care that emphasized both quality and cost: *To Err Is Human* (published in 2000) and *Crossing the Quality Chasm: A New Health System for the Twenty-First Century* (published in 2001). Early value-based models developed during this

From the beginning, the CAP was opposed to the SGR provisions and, with the AMA and other medical organizations, fought for many years to eliminate or permanently “fix” the SGR formula.



period included pay-for-performance (P4P) initiatives and accountable care organizations, both of which were developed by CMS and other agencies as federal programs and by private payers in new contracting models. The CAP worked with Congress and CMS throughout this period to ensure that the newly emerging models would be structured as favorably as possible for pathologists. One P4P program, the Meaningful Use of Health Information Technology program, introduced by the HITECH Act of 2009 and overseen by CMS and the National Coordinator for Health Information Technology, was clearly inappropriate for pathologists, and the CAP led an effort that resulted in pathologists and radiologists being exempted from the requirement to participate. During this period, the CAP organized an ACO Network, made up of pathologists practicing in ACOs, to help understand how pathologists could optimize this model for their practice and also contribute positively to value-based care delivery.

The SGR was finally fully repealed in 2015, as part of the Medicare Access and CHIP Reauthorization Act (MACRA). In place of the SGR formula, MACRA combined the existing value-based initiatives into a single program for payment of health care providers divided into two major tracks: the Merit-Based Incentive Payment System (MIPS) and Alternative Payment Models (APMs). Although the CAP was very much opposed to the SGR, the CAP was also skeptical of the merits of MACRA, a complex system that emphasized primary care and office-based practice and potentially disadvantaged pathologists and other hospital-based (to use the CMS term, “non-patient-facing”) physicians. Since the inception of MACRA, the CAP has worked closely with CMS to minimize the burden for pathologists in complying with MIPS requirements and maximize payment for pathologists under this system. The CAP had already led the pathology community in developing quality measures for pathologists’ use in the earlier P4P programs, such as the Physician Quality Reporting System (PQRS) so the CAP was well-positioned to

quickly provide quality measures for use by pathologists in MIPS. To help pathologists and pathology practices optimize compliance with MIPS, the CAP developed and implemented starting in 2017 a CMS-sanctioned Qualified Clinical Data Registry (QCDR)—the Pathologists Quality Registry. Based on the latest numbers, the CAP’s Pathologists Quality Registry is used by about 100 different pathology practices and more than 1,000 pathologists to improve performance and reimbursement potential under MIPS. The CAP has continued to develop new quality measures for pathologists and work closely with CMS on a range of issues relevant to pathologists in MIPS and APMs.

### **Pod Labs, Direct Billing, and Self-Referral**

With various payment pressures on physicians in the 1990s and 2000s, specialists sought new revenue opportunities to compensate for cuts elsewhere. Some physicians and physician groups responded by marking up anatomic pathology and other laboratory services provided by contracted pathologists and laboratories and paid for through client billing. The CAP confronted these challenges through a multi-pronged lobbying effort at the federal and state levels. In the states, the CAP pursued the enactment of direct billing and anti-markup laws as the CAP affirmed payment for pathology services should be made only to the person or entity that performed or supervised the services. The CAP worked with dozens of state pathology societies to enact laws and change regulations in state capitals across the country. Roughly 75 percent of patients are now covered by direct billing protections.

When markup of pathology and laboratory services was no longer an option, physician groups started opening their own laboratories, including anatomic pathology services, and utilized loopholes in federal self-referral rules (first introduced into federal law in 1988 by Representative Fortney “Pete” Stark of California and known as the “Stark Law”) to circumvent prohibitions against referring anatomic pathology services to their own laboratory. These loopholes, known as the Stark

In-Office Ancillary Services Exception (IOASE), allow certain services to be self-referred as a convenience for patients and to expedite care. These physician-owned laboratories, first called “pod” labs when located at another site and after that was banned by CMS then called “in-office” labs, typically hire a pathologist or contract with a pathology group to provide pathologist services at a deeply discounted rate, and then bill the patient or patient’s insurer full charge for these services. In 2012, the CAP and American Clinical Laboratory Association (ACLA) supported research on the effects of self-referral led by Georgetown University’s Jean Mitchell, PhD, which provided evidence that office-based self-referral of anatomic pathology services is associated with significantly higher numbers of biopsies and a lower percentage of positive diagnoses of cancer. The US Government Accountability Office in 2013 recommended that Congress take action to address the higher use of anatomic pathology services by providers who self-refer. Later that same year, the CAP championed the introduction of the Promoting Integrity in Medicare Act, which would close the self-referral loophole by removing anatomic pathology services from the Stark IOASE. While the CAP worked to gain support on Capitol Hill, significant opposition, including by a majority of physicians in the Doctors Caucus in Congress and others in the house of medicine, stymied the legislation’s progress. After multiple years of lobbying, the CAP was frustrated to find only a small number of representatives and senators willing to co-sponsor the bill, as members of Congress remained reluctant to choose sides between different groups of physicians. Up to the present time, the CAP has continued to look for ways to end the Stark IOASE as a costly provision that ultimately harms patients.

### **Out-of-Network Payment, Surprise Medical Bills, and Network Adequacy**

Another financial challenge has dealt with payment of pathologists for out-of-network services. As the cost of health care has accelerated, private insurers have attempted

to minimize physician payments by developing increasingly narrow provider networks that include only physicians willing to accept their ever lower in-network payment rates. With the increase in narrow networks, fewer in-network physicians have been available to provide care. This situation is problematic enough when a patient is seen in an emergency room and/or admitted for urgent care to a hospital that is out-of-network. But even when the hospital is in-network, because of the narrowness of a patient’s insurer’s network many of the providers, particularly hospital-based physicians, may not be included in the network. As a result, the patient will receive unexpected bills from the out-of-network physicians. In order to protect patients from these surprise bills and also ensure fair payment of pathologists and other physicians for out-of-network services, the CAP has worked with multiple state pathology societies to successfully enact out-of-network billing laws across the country, some of which also have included network adequacy requirements. As part of this multi-state effort, the CAP provided substantial financial support to the state pathology societies to help them hire lobbyists to argue their cases in the state legislatures.

While these laws sought to protect patients from bearing increased financial responsibility for out-of-network care, patients covered by federally regulated health plans were left vulnerable to medical bills not covered by insurance. For this reason, and with strong support from the health insurance industry, the issue was taken up by Congress and the Trump administration in 2019. A number of legislative proposals were introduced, with most setting out-of-network payments at median in-network rates. The CAP strongly opposed in-network rate-setting and proposed as an alternative payments based on independently-determined customary payments for similar services performed in the same jurisdiction. The CAP also supported inclusion of federal network adequacy standards. When the proposed independent customary payment rates failed

to gain traction in Congress, the CAP joined forces with many other physician societies and hospital organizations to support an arbitration process whereby the payment to an out-of-network physician would be determined by baseball-style “best offer” independent dispute resolution between the insurer and the physician. Federal legislation has been passed which encompasses many but not all of the CAP’s recommendations. Enabling regulations are in progress.

### **PAMA and the Clinical Laboratory Fee Schedule**

As noted previously, the Protecting Access to Medicare Act (PAMA) of 2014 contained multiple provisions to control the cost of health care, including a new method to set payment rates in the Medicare clinical laboratory fee schedule (CLFS). Since the CLFS was first introduced in 1984, the rates for most clinical lab services had changed little, with only minor inflation factors used to update the rates. In 2014, Congress decided to push for a more market-based approach to set CLFS rates, with payments by private insurers for the same services used to determine what Medicare would pay through the CLFS. After much controversy and a delay in implementation, the method ultimately used by CMS to calculate these market-based rates excluded private payment data from most clinical laboratories and heavily weighted the data toward very low payments received by large commercial laboratories. In late 2017, the American Clinical Laboratory Association (ACLA) filed suit in federal court against HHS to force reconsideration of the CLFS rates. The CAP filed an amicus brief in support of this suit. When the suit was dismissed in 2018 on jurisdictional grounds, ACLA filed an appeal and CAP filed another amicus brief supporting the appeal. In April of 2019, a federal appellate court ruled in favor of ACLA’s and CAP’s appeal and the case was remanded back to the lower court for consideration. While the suit was being considered, a parallel legislative initiative was also attempting to delay further implementation of the new CLFS and reform the

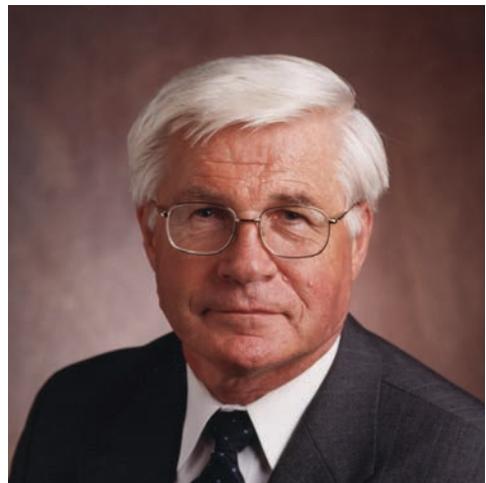
methodology used to set these rates. To protect clinical laboratories from further financial consequences of the COVID-19 pandemic, federal legislation passed to provide economic stimulus, with strong support by the CAP, also included a provision postponing the next round of PAMA-mandated CLFS rate changes and collection of market data.

### **Regulatory Issues for Pathologists and Clinical Laboratories**

#### **CLIA '88**

The regulatory framework for all clinical laboratories in the US is based on the Clinical Laboratory Improvement Act of 1967 (CLIA '67) and subsequent amendments in 1988 (CLIA '88). Since the beginning of CLIA, the CAP has worked closely with the relevant federal agency, formerly the Health Care Financing Administration (HCFA) and more recently CMS, to ensure that the regulations are implemented reasonably and enforced appropriately. The CAP has always been represented by a CAP member on the Clinical Laboratory Improvement Advisory Committee (CLIAC), a body that advises CMS and the HHS Secretary on changes to and new components of the regulations. Although the CLIA '88 provisions have remained largely intact over the years, piecemeal changes have occurred through either rulemaking or additional legislation. Several significant changes in CLIA rules were introduced by CMS in 2003, including revisions to quality control requirements, renaming of test complexity categories, and clarification of personnel requirements.

Starting in 2018, CMS has attempted to make further modifications to certain CLIA '88 provisions, including redefinition of training requirements for laboratory personnel and increased flexibility for PT procedures and enforcement of PT violations. The CAP has provided extensive feedback to CMS regarding these and other proposed CLIA '88 rule changes. Throughout this process, the CAP’s position regarding CLIA '88 revision was and continues to be one of caution in making changes that



could have unintended consequences harmful to pathologists and clinical laboratories. This became a major issue during the debate regarding proposed regulatory oversight of laboratory-developed tests (LDTs) by the FDA (see Laboratory-Developed Tests: FDA vs. CLIA below).

### **Cytopathology Proficiency Testing**

Regulations for cytology Proficiency Testing (PT), created as part of CLIA '88 and originally developed in 1992 but not fully implemented until 2005, were an attempt to address long-unresolved problems with the so-called “Pap mills” of the late 1980s. These rules led to the unprecedented requirement for PT by cytotechnologists and pathologists interpreting Pap tests. Over several years, the CAP and other organizations strongly opposed these requirements and proposed a robust continuing education process as a more appropriate alternative, but failed to have them removed. In an attempt to at least provide a reasonable testing process to fulfill these PT requirements, the CAP in 2006 initiated a cytopathology PT program for both cytotechnologists and pathologists. Also in 2006, the CAP was instrumental in creating and then strongly supporting federal legislation that would replace these regulations with non-punitive requirements for continuing education, but the legislation failed to pass Congress. Since then, the CAP has continued to look for ways to remove the Pap test PT requirement.

### **Congressional Investigation**

In the early 2000s, a tragic crisis involving a midsize urban central hospital laboratory led to hundreds of patients receiving flawed HIV and hepatitis C test results. The crisis forced additional scrutiny of the adequacy of laboratory regulation, as well as all laboratory accreditation programs. The CAP testified at House Oversight Committee hearings and worked with federal officials to ensure proper levels of oversight and safeguards. The CAP’s advocacy played a major role in mitigating risk of the CAP losing its deemed status as an accreditor. The CAP managed

the crisis effectively by making changes to its accreditation program, which drew praise from the representative of the congressional district where the hospital was located.

### **Laboratory-Developed Tests: FDA vs. CLIA**

The history of potential regulatory oversight of laboratory-developed tests (LDTs) by the FDA is long and complex. Although the FDA claimed that it had jurisdiction to oversee LDTs based on statutory language in the Medical Device Amendments of 1976 which amended the Federal Food, Drug, and Cosmetic Act, it chose over many years to exercise “enforcement discretion” regarding this oversight. As LDTs became increasingly complex, the FDA announced in 2010 its intention to regulate development and use of these tests. The CAP initiated advocacy with the FDA around that time to support a risk-based approach to this oversight that would minimize the impact of FDA regulation on clinical laboratories and patient access to LDTs. After much study and discussion, in 2014 the FDA released a Draft Guidance for Oversight of LDTs that quickly became controversial.

The CAP and other organizations accepted the concept of FDA oversight, but expressed a strong preference for the FDA’s role to be limited in scope and involve little or no duplication with existing CLIA regulatory requirements. Debate continued until President Trump’s election, when a purely regulatory approach was abandoned and eventually replaced by a legislative initiative to clarify FDA’s role in LDT oversight. The debate boiled down to whether or not the FDA should have a role in this area and how that role should be balanced with existing CLIA regulations. Two legislative proposals released in 2017 and 2018 (the Diagnostic Accuracy and Improvement Act [DAIA] and the Verifying Accurate, Leading-Edge IVCT Development [VALID] Act) and another in 2020 (the Verified Innovative Testing in American Laboratories [VITAL] Act) were debated as to their merits and potential consequences. Of the three, the VALID Act emerged as the most likely to move forward. Some continued to argue that

the FDA should have no role at all in regulating LDTs and that instead CLIA should be broadly re-opened and “modernized” to allow for better quality verification of these increasingly complex assays. The CAP and other pathology and laboratory organizations continued to be strongly opposed to re-opening CLIA and expressed guarded optimism that the VALID Act was moving in a more positive direction. As of this writing, the issue remains unresolved and the VALID Act has not yet been taken up by Congress.

### **Patient Direct Access to Pathology**

#### **Test Results**

In 2014, HHS issued a final regulation amending CLIA and the Health Insurance Portability and Accountability Act (HIPAA) of 1996 with respect to patient access to laboratory reports. The rule, supported by the CAP, allowed laboratories and pathologists to communicate test results directly to patients upon their request. Around the same time, state laws and regulations impeding pathologists’ ability to confer directly with patients were also modified or repealed by state legislatures, a process driven by state pathology societies with support from the CAP. The changes in law helped ensure pathologists’ status as co-equal physicians in diagnosing patients and not improperly confined to a consultant role to ordering physicians.

#### **PathPAC to PATHNet: Grassroots, Grasstops, and Advocacy Communication**

As noted previously, the CAP’s longstanding status as a 501(c)(6) organization allows it to organize and host a political action committee (PAC). For many years, the CAP avoided forming a PAC, choosing instead to encourage members to support state PACs and to influence legislators through other means, such as the CAP Government Interface Program. In the 1980s and particularly the 1990s, a growing need for grassroots efforts to ensure legislation favorable to pathologists’ needs led to formation in 1992 of the CAP’s PAC—PathPAC. Since then, PathPAC has been a critical political arm of the CAP, allowing members to contribute to efforts

to financially support candidates for Congress sympathetic to pathologists’ positions on a range of issues.

In addition to professional lobbying and support of sympathetic political candidates, one of the most important strengths the CAP has in advocating for pathology is the ability of CAP members to directly bring their message to members of Congress and state legislators as well as federal and state regulators. These grassroots efforts can often tip the scales in getting favorable legislation passed or ensuring good outcomes regarding rulemaking at both the federal and state levels. To facilitate these efforts and help mobilize CAP members’ involvement in grassroots advocacy, PathNET, the CAP’s political action team, was formed in 1999. PathNET members are highly motivated to speak on behalf of the CAP on issues and can be mobilized quickly to send policy messages to Congress and travel to Washington and state capitols to directly advocate on behalf of pathologists. The CAP has also worked with members to help them develop longstanding relationships with legislators and, when needed, to provide so-called “grasstops” advocacy on key issues.

An important part of building and sustaining grassroots and grasstops advocacy involves effective communication with CAP members and a variety of stakeholders important to pathology and clinical laboratory issues. The CAP advocacy newsletter, for many years known as STATLINE, has provided a regular update for CAP members on the major issues of the day. Starting as a paper-based publication, STATLINE evolved over the years into a weekly web-based communication, and in 2019 it was re-named CAP Advocacy Update. Outside of CAP members, communication with policymakers, regulators, and the general public has expanded significantly, with CAP-sponsored print and digital advertising appearing in major national newspapers and other news outlets. In recent years, the CAP has turned to social media channels, such as Twitter, and other digital formats, including podcasts and web-based

webinars, to reach an ever wider audience with important news and information on major issues and policy campaigns.

For decades, the CAP has provided advocacy training for interested CAP members. First called CAP Advocacy School, these efforts brought CAP members to Washington, DC, to learn how to effectively advocate in Congress and other venues. The Advocacy School was eventually replaced in 2010 by the CAP Annual Policy Meeting, where each Spring CAP members would meet in Washington, DC, for an intensive discussion of and instruction on the major issues of the day and then, on the CAP's Hill Day, travel to Capitol Hill to take the CAP message directly to members of Congress and their key aides. Starting in 2020, a new members-only Spring CAP meeting, the Pathologists Leadership Summit (PLS), was organized to take place in Washington, DC. The PLS was designed to bring the CAP House of Delegates together with other CAP members to spend four days learning about advocacy issues and taking multi-track courses on leadership and emerging new trends in technology and pathology practice. The PLS would culminate with the annual CAP Hill Day. Unfortunately, due to COVID-19-related restrictions, the first annual PLS had to be cancelled and replaced with virtual versions of some of the courses planned for the in-person meeting. The PLS

will resume in-person meetings as soon as it is safe to do so.

### **CAP as Advocacy Leader of the Pathology Community**

As the decades-long advocacy leader of the pathology community, the CAP has served for many years as the only pathology representative to key groups, such as the only pathology voting member on the RUC, and has led other important groups, such as the Pathology Coding Caucus (PCC), to support the interests of all pathologists in the US. Since 2007, the CAP has served as the leader and secretariat of the Pathology Section Council of the AMA. Over the years, this group has consisted of representatives of pathology organizations that meet combined organizational and AMA membership criteria. The AMA Pathology Section Council represents the pathology community perspective in deliberations by the greater house of medicine at AMA meetings and has many times moved issues and AMA resolutions in a positive direction for pathologists. Among the more important issues involving the house of medicine, protecting pathologists' scope of practice from infringement by other providers and allied health professionals has involved work with the AMA and its Scope of Practice Partnership and with state medical societies and other specialty organizations.

For decades, the CAP has provided advocacy training for CAP members including junior members.



## **The COVID-19 Pandemic and Its Impact on Pathology and Clinical Laboratories**

This 25-year history of CAP advocacy would not be complete without mention of the impact of the COVID-19 pandemic on the CAP, pathologists, pathology practices, and clinical laboratories, and the actions taken by the CAP in response to this global emergency. As the COVID-19 outbreak spread to the US and throughout the world, grave medical, societal, and economic consequences soon followed. In order to protect both the general public and businesses from financial disaster, Congress passed multiple laws to provide financial relief and monetary stimulus to large segments of the population and the national economy. As these laws were debated and passed, the CAP advocated strongly making sure the legislation allowed pathologists, pathology practices, and clinical laboratories to benefit from loans and grants to help them remain financially viable throughout and beyond the pandemic. As of this writing, the CAP continues to support these efforts both in Washington and in the states. For a more detailed discussion of the many ways in which the CAP responded to the challenges of the Coronavirus pandemic, please see Chapter Eight.

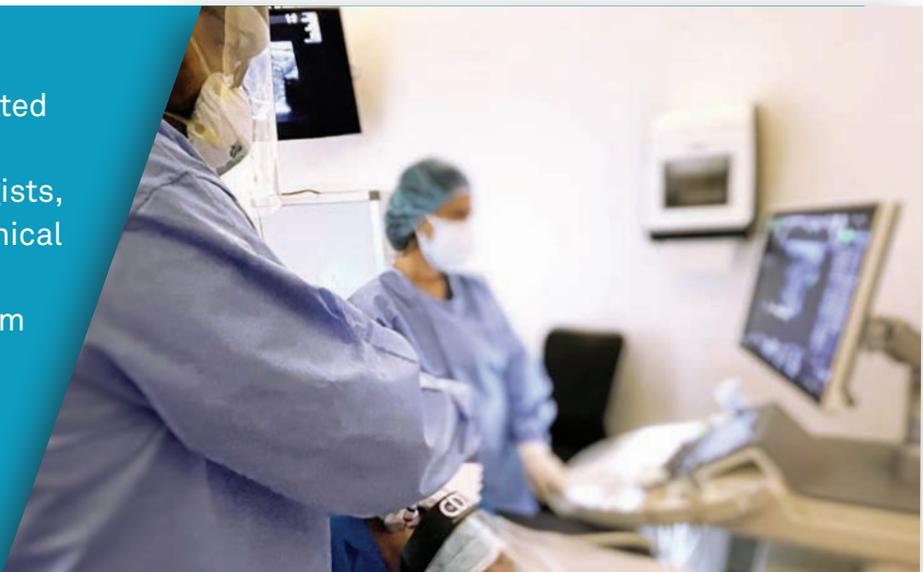
## **The CAP Council on Government and Professional Affairs and the CAP Washington Office**

The group within the CAP charged with overseeing the advocacy efforts of the organization has taken different forms and been known by multiple names over the years. The CAP Legislative Committee was formed in the early 1950s and was divided into separate groups and subsequently reunited and renamed more than once. In 1983, the council took on its current name of Council on Government and Professional Affairs (CGPA).

Over the years, the CGPA has been organized to involve multiple committees reporting to it with charges focused on governmental affairs at both the federal and state levels, economic affairs, and professional affairs. By 2012, the current structure of the CGPA committees into three main groups was finalized. The Federal and State Affairs Committee, Economic Affairs Committee, and PathPAC currently represent the main areas of the CGPA's work. In 2012, the CGPA Policy Roundtable was formed as a combined member and staff group to collect data and provide analyses to inform the development of CAP advocacy positions and campaigns. Along with other work, the Policy Roundtable has fielded and analyzed the results of the periodic Practice Characteristics Survey and Pathology Group Leader Survey.

The CAP Washington, DC, office has a similarly interesting history. Although professional staff members were hired in 1965 to assist

As these laws were debated and passed, the CAP advocated strongly, making sure the legislation allowed pathologists, pathology practices, and clinical laboratories to benefit from loans and grants to help them remain financially viable throughout and beyond the pandemic.





## 2020 FACTS AND STATS

the legislative efforts of CAP members, the CAP Board first approved a Washington office in 1969. In 1970, Alfred S. Ecolano was hired as director of the new CAP Washington office. Mr. Ecolano was a highly effective director, leading the office in achieving many legislative victories and other important accomplishments during his tenure, and remained in his position for 21 years, until his retirement in 1991. His successor was Jayne Hart Chambers, who presided over a growing staff and oversaw significant changes in the CAP's advocacy division, including the formation of PathPAC, an expanded legislative lobbying effort, and increasing advocacy on economic and payment issues within the AMA CPT and RUC panels. In 1998, John Scott became the third person to lead the division of advocacy for the CAP. During Mr. Scott's tenure, a team of highly effective staff, working closely with CAP physician leaders, has been assembled to address the multitude of issues outlined in this chapter. Critical programs and resources have been developed during this period, such as PathNET, the state legislative affairs program, the Policy Roundtable, the annual CAP Hill Day, and the Pathologists Quality Registry. Over the years, the CAP Washington office has grown in direct proportion to the expanding financial and

regulatory challenges being faced by CAP members and the entire pathology and clinical laboratory community.

### CAP Advocacy into the Future

As is clear from the history of the CAP as the advocacy leader of the pathology community over the past 75 years, standing up for the interests of pathologists and clinical laboratories has been and continues to be an intrinsic part of the mission and culture of the CAP. Throughout this period, the CAP has effectively protected the value of pathologists as key medical practitioners in the health care system and guarded pathologists and clinical laboratories from economic and regulatory challenges. In the end, these efforts have allowed pathologists and clinical laboratories to maintain the highest practice standards and provide the best possible quality services to individual patients and the public at-large. Medical advocacy is difficult and costly, and not all of the CAP's work in this area over the years has been equally successful, but when CAP members and staff work together on behalf of pathologists and patients, great things can be accomplished. Into the future, advocacy will continue to be a major focus of the CAP and a primary value of CAP membership for pathologists.



Chapter Six

EDUCATION—  
THE GROWTH  
OF A MISSION

### *An Investment in Knowledge Pays the Best Interest. —Benjamin Franklin*

#### **For many years the CAP's primary missions focused on laboratory improvement and advocacy for pathologists and the profession.**

Although many educational programs were developed, they often were designed to enhance and support laboratory improvement programs such as Proficiency Testing and accreditation. Subsequently, however, education as a CAP core mission emerged as a distinct member service in and of itself, apart from program support. This started in 2002 with the Board's approval of an education business plan, and was followed in 2010 and 2015 with learning strategy initiatives. The Education Committee initially oversaw the implementation of the business plan. To ensure the plan's strategic evolution, the Board created in 2007 a Council on Education. Since establishment, a number of committees and working groups have reported to the council, including CME, Archives Editorial, Curriculum, Clinical Pathology Education, Graduate Medical Education, and Publications. Experts from other areas of the CAP, including accreditation, genomics, and informatics, continue to provide the council with critical representation and continuity in priority education focus areas.

Concurrent with this process and to support education as a center of excellence, the CAP recruited additional professional staff comprised of experts in needs assessment and test development, instructional design, delivery, learning technology, evaluation, and content acquisition. Partnership amongst staff, members, and faculty experts remains key to the CAP's success in developing several new programs. These have included a patient safety course, which meets the ABPath's (American

Board of Pathology) Continuing Certification requirements, as well as the award-winning Advanced Practical Pathology Programs and Learning Series, which focuses on emerging areas of science and technology where no recognized specialty designations are yet available. And in the near future, the CAP will launch its new destination CME conference that offers intermediate-to advanced-level education focused on high priority topics frequently encountered in pathology practice. As these new initiatives have been implemented, educational efforts supporting traditional lab improvement programs have continued, including the development of several web-based programs and webinars devoted to accreditation and Proficiency Testing issues. Some such programs offer very detailed, online courses for LAP inspectors and team leaders.

In order to meet the needs of the academic community, programs dealing with pathology training were bolstered by the creation of a Graduate Medical Education Committee (GMEC) and collaborative programs with the Association of Pathology Chairs. The GMEC focuses much of its work on research initiatives exploring the training gaps between new-in-practice pathologists and the needs of hiring practices. The committee has championed professionalism training for residents with research to understand professionalism attitudes and behaviors; publication of an educational approach; and sessions held at the APC/PRODS and CAP Annual Meetings. The committee published recommendations on professional activities (EPA) for pathology training; a joint CAP-APC EPA working group also was formed to partner on a national pilot study. The Pathology Informatics Essentials

for Residents (PIER)—a collaboration between the CAP, APC (Association of Pathology Chairs), and API (Association for Pathology Informatics)—was released in 2014 and presents training topics and resource options for program directors and faculty to effectively provide informatics training to their residents and meet ACGME informatics milestone requirements. Another joint project, the Test Utilization Program, emphasizes the importance and principles of appropriate test utilization practices and helps residents achieve these Accreditation Council for Graduate Medical Education (ACGME) milestones.

In providing accredited CME to its members, the CAP has not only met the standards of the Accreditation Council on Continuing Medical Education (ACCME) but also achieved its highest status of the six-year Accreditation with Commendation, in both 2008 and 2014. The states of Florida and California also recognize the CAP as a continuing education provider for laboratory professionals. The CAP supports the education activities of pathology and clinical laboratory organizations at the local level by awarding CME credit through its Joint Providership Program, a program that continues to grow year after year.

When the Maintenance of Certification requirements of the American Board of Medical Specialties and the American Board of Pathology were received with considerable confusion by affected members, the CAP responded with initiatives including CAP's approval as a CME, Self-Assessment Module (SAM), and Part IV (improvement in medical practice) provider. The CAP implemented technology improvements to facilitate automatic reporting of completion data to ACCME/ABPath on behalf of diplomates holding time-limited board certificates. Additionally, the CAP offered expanded opportunities for educating attendees to earn SAM credits without completing a scored post-test, as was previously required.

In 2002, a significant change took place in the organization and structure of the annual meeting of the CAP. The joint meeting of the CAP and the American Society of Clinical Pathologists (ASCP), which had been collaborative ventures by the two organizations for many years, was discontinued. The decision was difficult for both organizations and resulted in considerable questioning by members, many of whom belonged to both the CAP and the ASCP. The separation resulted from a number of factors including differences about financing and programming. In addition, at the time of the separation, there were policy differences between the two organizations concerning federal regulatory and advocacy positions. A National Meeting Planning Committee was convened to organize a new annual meeting structure and curriculum with emphasis on developing content of specific relevance to CAP members and programming by faculty with specific content and presentation expertise. In subsequent years, the annual meeting strategy has undergone periodic review, resulting in extremely successful presentations of content in new and innovative ways that meet the needs of a membership with an increasingly broad spectrum and variety of interests and priorities.

Since 2002, the CAP has grown its physician-focused education program in numbers of courses, breadth of content, and overall satisfaction. The CAP offered almost 500 courses in 50 specialty areas in 2019, more than four-times the number in 2002, and increasingly presents across a variety of learning formats (in-person, online, and virtual live) that meet members' learning needs and preferences. To-date, more than 61,000 physicians have completed CAP education activities, with 93 percent of all courses receiving high overall value ratings (4.2 or greater on a 5.0 scale).



Chapter Seven

MEMBER SERVICES,  
INVOLVEMENT, AND  
MEMBER-STAFF  
COLLABORATION

# Chapter Seven

*No One Cares How Much You Know, Until They Know  
How Much You Care.* —Theodore Roosevelt

## **High member engagement and strong collaboration with staff distinguish the CAP from other medical professional organizations.**

In the past 25 years this partnership has grown in tandem with the 90 percent growth of the CAP professional staff. The rapid rise of laboratory improvement programs and new strategic initiatives demanded the expertise of an increasingly large, highly skilled staff. The significant increases in program revenues (from just under \$60 million in 1997 to \$225 million in 2020) reflect the CAP's staff development in conjunction with the rewarding collaboration between CAP members and staff.

During this period, substantial growth occurred in the volume and number of Surveys offered, as well as the number of CAP-accredited labs in the US and internationally. Such growth has been accompanied by increases in the complexity and rigor of the accreditation program, most notably subsequent to the identification of problems in the execution of the inspection process (previously discussed in Chapter Four).

New strategic functions included capabilities in instructional design, assessment, and professional learning in support of education activities. Additionally and due to increased competitive pressure, the CAP developed more robust marketing and sales capabilities for laboratory improvement programs and in 2014 created an overarching brand strategy covering the entire organization, including a reinvigorated logo. Increasing stress on pathologists' reimbursement and scope of practice led to additional advocacy resources in Washington and more sophisticated and

proactive communications abilities.

A renewed emphasis on grassroots membership enabled the commitment of increased resources to support the House of Delegates and Residents Forum. The CAP Foundation implemented the See, Test, and Treat program with additional staff support for the Foundation from the CAP. Investment in updating CAP information systems led to increased capability in project management, systems architecture, and sourcing.

In parallel to these initiatives, member-staff partnership has evolved to best leverage increasing professional staff capabilities. CAP member leaders continue to establish priorities based on their broad knowledge of the profession and to develop programs and services according to their deep understanding of the practice of pathology and laboratory medicine. Professional staff provide input and implement programs and services based on their experience responding to competitive markets. The unique blending of CAP member leadership in the science and medicine of pathology and professional staff expertise across a broad range of functional areas combines to advance pathologists and pathology as well as support the CAP's powerful presence in laboratory medicine around the world.

To maximize the member-staff interaction, the CAP Board authorized the creation of a council with specific responsibilities for membership-related activities. After a number of name changes, a newly-named Council on Membership and Professional Development was charged in 2006 with specific responsibilities for delivering services and benefits for pathologists,



residents, and fellows, and for raising the image of the profession by becoming the source of information to the public on pathology related health issues.

The CAP holds a unique place in American medicine because of its role in promoting excellence in the practice of pathology and laboratory medicine. This role is sustained by an outstanding staff of professionals. However, the enormous support provided to CAP laboratory improvement, advocacy, and educational programs by CAP members lies at the heart of this success. The countless hours of voluntary commitment by CAP members is extraordinary. Their devotion is critical to the CAP's accreditation inspections, committee work and meetings, as well as many other CAP-related activities. All the hours CAP members dedicate represent time taken away from compensated work and from their families.

In the remainder of this chapter, five important services to members will be discussed in some detail: Information Services, the House of Delegates, the Residents Forum, the CAP Foundation, and CAP publications.

### **CAP Information Services from 1985 to 2020: Growth and Complexity**

An operational foundation of all CAP

activities including membership services is Information Services (IS). There is no area of CAP functioning that does not depend to a critical degree on IS support. All pathologists live in a relatively new world of Electronic Health Records, Hospital Information Systems, and Laboratory Information Systems. The presence of information technology in all aspects of our professional lives has led to an increasing dependence of all CAP activities on an information technology service of growing complexity and functionality. All of the CAP missions—laboratory improvement, education, member services, and advocacy—rely heavily on IS functions. Over the past decades, the growth, complexity, and cost of CAP IS services have increased significantly.

Beginning in 1985 the CAP made incremental improvements to its infrastructure and application systems. Custom applications that supported the Surveys (Proficiency Testing) order processing and PT response-processing functions were either upgraded or replaced with newer-generation technologies, as were the applications that supported the Quality Assurance Service. In 1989 the CAP moved all computer operations from Traverse City, Michigan, to Northfield, Illinois.



Additionally, new functionality needed to aggregate and report laboratory performance to federal regulators was developed.

Between 1990 and 1994 the CAP invested heavily in system modifications required to comply with new CLIA '88 Regulations. These new regulatory requirements increased data volumes and conflicted with some of the design assumptions made during the construction of the previous PT-Response-processing applications. Additionally, new functionality needed to aggregate and report laboratory performance to federal regulators was developed. During this time period, the mainframe-based custom PT order-processing application was replaced by a microcomputer-based application. This change was required to handle the increase in order-management demand that was created by the CLIA '88 regulations.

While the CAP successfully modified the Surveys data-processing system to comply with CLIA '88 regulations, the result was neither ideal nor suited to support the high levels of customer service expected by our members. The CAP created a member-staff Surveys Quality Management Team, which developed recommendations to the Board for investments in improving and replacing the mainframe-based custom system. The Board accepted these recommendations, and then engaged a consulting firm to design and build a replacement Proficiency Testing system.

During the years 1995–1999 the CAP developed a new application system called SCORES to serve the data-processing requirements of the Proficiency Testing service. The transfer of PT operations to this new system meant that the on-premises mainframe was underutilized, since it was principally supporting just the Laboratory Accreditation operational processes. Consequently, the CAP extended the SCORES system to support LAP operations as well. These extensions were implemented during 1999. During the latter half of this period, the CAP hired a consulting firm to assist with the development of an information systems strategic plan. The Board approved this plan and made investments to replace aging systems and to deploy new functionality, including the CAP's financial system, the association-management system, and the principal infrastructure technologies. By the end of the decade, the CAP's operational dependence on its mainframe had been eliminated, and it was decommissioned.

The invention of the World Wide Web in 1989 was soon followed by the popularization of graphical browsers, which rapidly changed global information sharing. During 1995, several CAP committees explored and developed proposals to establish a CAP website. The website was seen as a member service that could electronically connect pathologists and the

public to CAP resources. The Board of Governors approved the development of the CAP's first homepage at its November 1995 meeting and initiated a pilot project to introduce the site in the autumn of 1996 at the CAP annual meeting. Initially, the informational website focused on a public audience with limited transactional capabilities, but the site did offer some content limited to members only. Subsequently, there was an increased focus on the development of functionality to enable Proficiency Testing and accreditation customers to utilize the web as an optional channel for interacting with the CAP. Consequently, the CAP website has evolved into a significant benefit to our members and to the public, although access to certain functions remains limited to members. Over the years, member requests have led to many revisions of the website in an effort to make it more user-friendly. These efforts continue today as the content and complexity of the site increases.

Between 2005 and 2009, website investments continued with the deployment of new education/learning capabilities, such as Competency Assessment Service, the integration of a Learning Management System for online courses delivering pathologist-focused content, and the development of the "Contact the CAP" application. Investments were made in automation to support the transfer of some administrative functions from LAP Commissioner offices to the CAP central office, such as inspection-team assignment, staff inspector assignment and scheduling, and the management of the LAP Checklists. The CAP also developed its Cytopathology Proficiency Testing Programs during this period, which required major investments in support of operational processes and automated outputs.

In the years between 2010 and 2014 many of the information-technology investments were focused on the re-installation and expansion of its Enterprise Resource Planning (ERP) front office/back office application system, as a foundational component of information services strategy. Website capabilities continued to be expanded during this period with the deployment of new program-

specific capabilities, such as the Fields of View service and the DigitalScope™ virtual-microscopy service. Member services also further developed with an Online Learning Portal, assisting in the planning and delivery of personalized educational curricula, along with new integration tools affording the option to automate parts of the submission of laboratory observations to the Proficiency Testing service.

From 2015 to 2020 investments in the web continued, with the development of a mechanism for laboratory managers to reapply online for accreditation. The online PT Results-Form application achieved improvements in performance and stability. CAP staff worked with the Board to revise the strategic plan in order to take advantage of advances in the growing maturity of cloud-based services. Member leaders continue to guide the CAP in the expansion of its service portfolio, with information technology services remaining a critical component.

### The House of Delegates

**The following section has been contributed by Katherine Knight, MD, FCAP, Speaker of the House of Delegates (2018-2022).**

Philosopher and poet George Santayana famously said, "Those who cannot remember the past are condemned to repeat it." Condemnation is perhaps too strong a word, but certainly the history of the CAP House of Delegates (HOD) demonstrates a definite repetitive pattern in its search for identity.

The CAP was founded in 1946, with an Assembly (the HOD predecessor) approved by the Board of Governors in 1957 to ensure broad-based grassroots representation for CAP membership to the leaders of the organization. The constitution of that Assembly was geographically focused, essentially identical to that of today, with one elected delegate for every 50 Fellows of the CAP in each state, with additional representation from the District of Columbia, United States territories, Canada, and the United States Armed Forces. The stated purposes were:



House of Delegates



1. Improve communication between the Board and membership
2. Identify members for leadership development
3. Involve more Fellows in CAP activities
4. Strengthen regional educational programs

What was missing in this process was a well-defined, legitimized role for the HOD within CAP policy process and operations. This resulted in what over the coming decades would become an often-antagonistic relationship between the House and the CAP officers and Board. These growing pains are clearly outlined in “A Brief History of the Formation and Transformation of the College of American Pathologists House of Delegates” by Drs. John Milam and James Carson, published in the *Archives of Pathology & Laboratory Medicine*, December 2008. This existential dilemma ebbed and flowed until 1970, when the Assembly was converted to a House of Delegates with a policy-generating function, to act as a legislative body of the CAP. This was to include initiating business; considering reports of the officers, councils, and committees; as well as passing on resolutions and recommendations to the Board. Despite that most resolutions and recommendations submitted to the Board were favorably received, the HOD’s new title and function lacked teeth. Essentially all actual policy-making authority continued to rest solely with the Board.

The Speaker and Vice-Speaker of the HOD attended Board meetings as guests, with the Speaker becoming an ex-officio BOG member in 1972 in an attempt to increase communications with CAP membership. Voting rights for the Speaker, however, were not granted until 1984, and it was not until 1989 when the Vice-Speaker was also granted ex-officio status. This inclusion of House leadership at the Board table was one of the first steps toward recognition of the House’s function as the grassroots voice of pathologists.

Even with greater Board involvement of House leadership, identity issues continued and in fact worsened during the 1980s and 1990s.

A true mission for the HOD remained lacking, membership lagged, and the actual need for the House as a part of the CAP was put into question. In 2003, concern for the viability of the House prompted CAP President Paul Raslavicus, MD, FCAP, to present a series of proposals that were incorporated into a House Steering Committee document entitled “Strategic Tactics for Revitalization.” This prompted a drive toward reform of the House, with changes in rules that included returning the House to an all-elected body. Consequently, the 2005 HOD meeting saw record attendance, and in 2006 four core functions for the House of Delegates were determined by its members as most important for the success of this body. Ironically, these new functions echoed the old functions from 1957:

1. To serve as a “sounding board” of the general membership
2. To serve as a mechanism for two-way communication with leadership
3. To identify issues outside the council/committee structure of importance to membership
4. To create a forum to develop CAP leaders

Nevertheless, tensions remained between CAP leadership and the House, due in large part to the continuing lack of a well-defined role for the HOD within the broader CAP, as well as the HOD’s actual relationship with the Board. In 2007 the Board and HOD leadership held a retreat to attempt to work through these issues. Also in 2007 the format of the House meetings began to change, allowing for more interactive and less formal sessions, including round-table discussions and an open question and answer session with the House leadership. An ad hoc committee was established to focus on improving member communications. And in the next few years, House members were informed about and contributed to issues as varied as increasing medical student interest in the practice of pathology, the importance of CAP advocacy, education, accreditation, and scientific affairs.

Despite this positive momentum, the House in many ways remained an enigma, a potentially tremendous resource for the CAP but as yet not fully tapped. Hampered by its label as a legislative body but without true policy making authority, the HOD needed transformation to become truly relevant. David Novis, MD, FCAP, was elected Speaker in 2010, with Rebecca Johnson, MD, FCAP, and subsequently James E. Richard, DO, FCAP, serving with him as Vice-Speaker through 2014. Under their leadership, the HOD moved from a fairly nebulous legislative body to one that functioned as the “customer” of the larger CAP. This move promoted heightened engagement of House members in the operation of the CAP and engagement of the Board in partnering with the HOD. At last, the mission of the House was clearly defined as representing the voice of the CAP membership, conveying the needs of the members to the CAP Officers and Board, and in turn providing feedback as to the success of CAP leadership in meeting those needs. The vision of the HOD established at that time was “One College” composed of the House, the Councils and Committees, and the Board working together for the good of CAP membership. This period saw formation of Action Groups composed of HOD members designed to address needs of membership, distribution of surveys to membership to identify issues of importance, and the institution of CAP Officer and Board of Governors candidate forums at the HOD Spring meeting. The impact of these efforts soon became evident in a steady increase in HOD membership and satisfaction.

Dr. Richard assumed the position of Speaker in 2014, with Kathryn Knight, MD, FCAP, as Vice-Speaker. The mission and vision established during the prior four years served as the foundation for the next four, with continued emphasis on the need for the House to have a truly essential role within the overall structure of the CAP. Establishing an effective communications network remained an ongoing effort, as did work toward elevating the stature of the HOD and its leadership, including that of

House Delegation Chairs. Individual members of the HOD Steering Committee were successfully appointed as liaisons with each of the five CAP Councils, to assist those Councils in identifying ways that the HOD might assist them and their Committees in their work. This resulted in the productive involvement of House membership in reviewing and influencing CAP products and direction. The Officers and Board of Governors were actively involved in House meetings, fielding questions from the House floor. And the House maintained its trajectory of increasing membership and member satisfaction.

Today the House of Delegates continues to evolve and build upon these successes. In 2018, Dr. Knight was elected Speaker, with Sang Wu, MD, FCAP, as Vice-Speaker. In continuing to focus on the mission and vision of the HOD, during the last year and a half the House has tackled numerous important member needs, including:

1. Diversity within the CAP, particularly at the leadership level, with a resultant BOG initiative to address the critical importance of this issue within our organization
2. Resilience, wellness, and burnout
3. CAP advocacy, including engaging House members to respond to Action Alerts from our CAP DC office
4. Strengthening state pathology societies to include interaction between Delegation Chairs and state society presidents
5. Promoting increased involvement with the Residents Forum to ensure that our young leaders have access to mentors and understand future opportunities

The year 2020 presented global challenges that threatened the ability of organizations to merely maintain existing obligations to memberships, let alone to grow, strengthen, and thrive. Where is the House of Delegates today? The House is the largest, most diverse organized body under the umbrella of the College of American Pathologists. Boasting almost 500 members strong at the outset of 2020, the diversity of the House is its most vital asset. With younger



members who care about pathology practice and future directions in the profession, the HOD can and should nurture and develop CAP future leaders. Antagonism between the House of Delegates and the Board of Governors seems to be a thing of the past. Satisfaction survey assessments of members' opinions of the effectiveness of the House and the BOG are at an all-time high. And as the election for members of the Steering Committee for 2020-2022 unfolds, an unprecedented 18 House members submitted their applications for seven positions, reflecting the increased energy and engagement of the HOD membership.

It would seem now that the House and the Board have well-learned from history. To continue applying those lessons toward positive results, the two bodies must continue to evolve and remain relevant. The House of Delegates is a microcosm of the larger CAP, a true representation of membership, and a tremendous resource for positive impact not only within the CAP but throughout the specialty of pathology.

### **The Residents Forum**

**The following section has been contributed by Adam Booth, MD, FCAP, Past Chair of the Residents Forum (2018-2020).**

The Residents Forum (RF) was formed in 1988. A residents section had been first suggested in 1973, but the concept remained dormant until 1987 when a residents section was again explored. The Forum was established to interest pathologists in CAP activities at an earlier stage of their careers, and to identify younger individuals for leadership roles in the organization.

Following the establishment of the Residents Forum, the Board voted to budget for the addition of a Junior Member position on most CAP committees. This allowed residents to associate with experts in various subspecialties of pathology, thereby enhancing their careers and encouraging residents to make distinctive contributions to the functions of the respective committees. In 1998 the Residents Forum was

realigned to report directly to the Council on Practice and Education and the Forum reports today into that Council's current iteration, the Council on Membership and Professional Development.

For many years the Residents Forum operated in the same format as the House of Delegates, meeting on Saturdays during the spring and fall meetings. The RF adopted resolutions, which were 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.

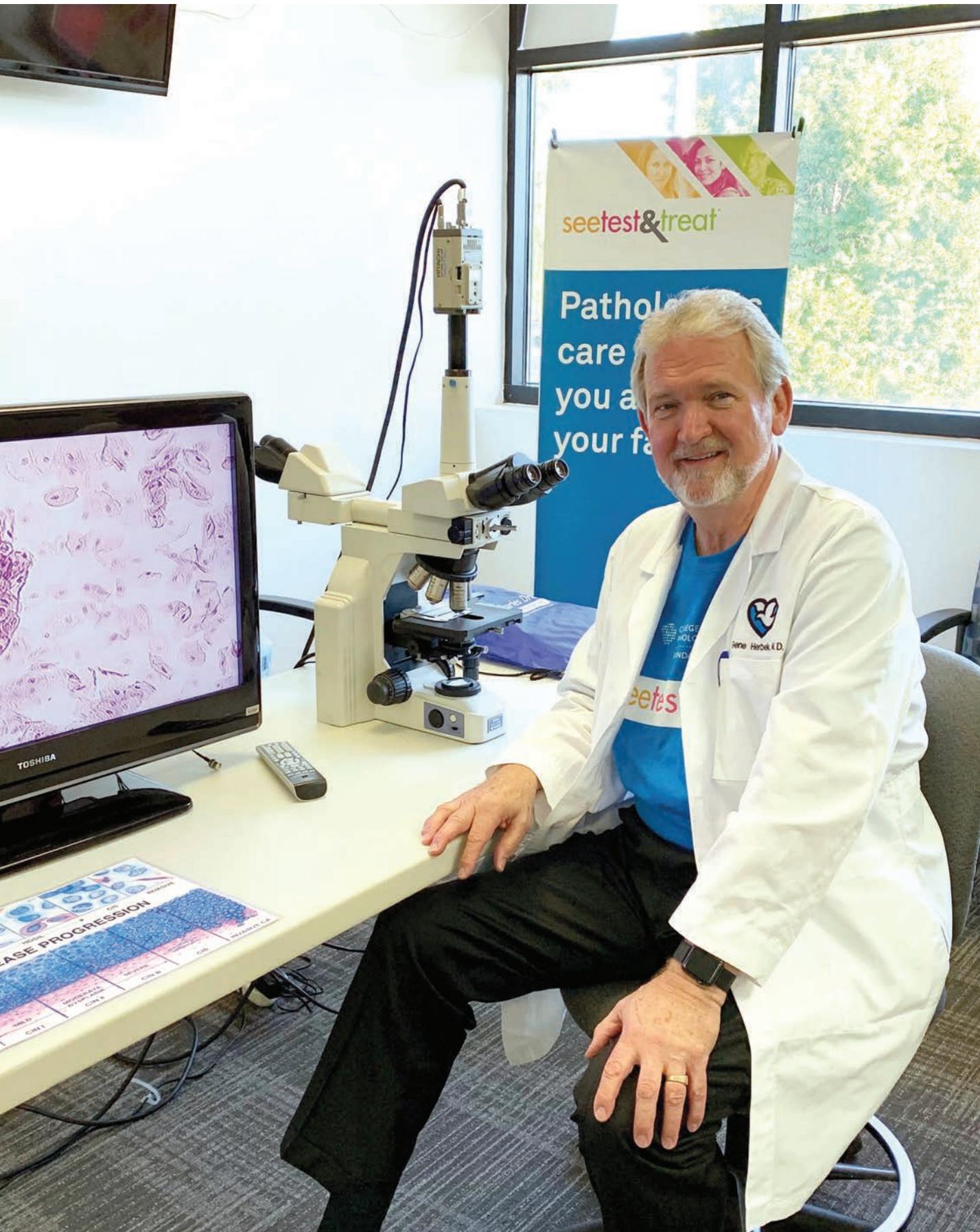
More recently, meetings have transitioned from a predominance of reports by liaisons, committee junior members, and resolutions to more directly pertinent and engaging topics such as financial planning and professional development. However, updates on the workforce and preparation for practice sessions have endured as mainstays on the agenda. The advent of digital pathology, informatics, and artificial/augmented intelligence has steadily led to presentations and panels to keep trainees attuned to future practice changes.

While the agendas and trainees have changed throughout the past 25 years, the Residents Forum continues to represent the voice and needs of the CAP junior members. The RF championed with success the CAP Standardized Fellowship application. And most recently, growing concern over the pathology pipeline of medical students led the Residents Forum Executive Committee to revitalize the Medical Student Forum in 2019.

### **The CAP Foundation**

The CAP Foundation was established in 1963 as a tax-exempt 501(c)(3) corporation. The CAP Board provided initial funding, and as the Foundation has grown it has received continued CAP support as well as tax-deductible contributions from members and others. The Foundation in its early years primarily funded research grants and sponsored speakers





at the CAP fall meetings, but in recent years it has presented national invitational conferences concerning problems in the practice of pathology. Other programs have been the CAP Foundation Scholars program supporting research projects in pathology, as well as various memorial funds supporting young pathologists. These programs include the Geraldine Colby Zeiler Professorship in Cytopathology, the Herbert Lansky Award, and the John H. Rippey Memorial Fund for Laboratory Quality Assurance.

Over the past 25 years a major emphasis of the Foundation has been preparing pathologists for the future. In pursuit of this goal a number of initiatives have been undertaken including the Futurescape conferences (2007, 2008, 2009, and 2011) designed to create a dialogue among forward-thinking medical, corporate, and financial decision makers. The theme of the first conference was an examination of methodologies expected to dominate anatomic pathology practice in the digital age.

The Foundation has established relationships with diagnostic companies offering innovative grants to medical students for informatics studies and for attendance at the CAP annual meeting. One such grant-recipient commented, "The CAP Annual Meeting provided a wonderful experience for me to engage with pathologists from all parts of the country, listen to talks by leaders in the field, and to meet my future peers. It was very enlightening to hear from various program directors and residents about the strengths of their programs, their individual interests within pathology, and ways that I may better myself as a future applicant. In addition, these contacts serve as valuable continuing resources when it comes time to apply for residency."

The Foundation has consistently supported learning and training opportunities for young pathologists, including the Translational Diagnostics Advanced Training Award (supported by Ventana). This grant offers CAP junior members hands-on exposure in the development of novel histopathology-based

diagnostic assays. Grant recipients tailor their experience to explore R&D innovation, digital pathology and whole slide imaging, platform and instrumentation development, and tissue sample management.

The Gerald R. Hanson, MD, FCAP, Global Pathology Fund was established in 2019 to expand the reach of pathologists in globally underserved areas to support international-pathology-focused programs in the areas of training, education, leadership, patient care, quality, and research.

The CAP Foundation See, Test & Treat® (STT) was initiated by a grant from Gene and Jean Herbek; Dr. Herbek served as CAP President from 2013-2015. Dr. Herbek hosted the first event at Standing Rock Indian Reservation in 2001. STT has become one of the Foundation's most acclaimed and nationally recognized programs, earning top honors in 2017 from the American Association of Association Executives. The program brings the lifesaving skills of pathologists to medically underserved communities by providing a comprehensive cancer-screening program that connects women in need to the life-saving diagnostic skills of a pathologist and the services of a volunteer team of health care professionals assembled for their care. The program serves to foster partnerships between pathologists and their clinical colleagues, and to educate the public about the important role that pathologists play on the patient-care team. This pathologist-led program offers medically underserved women, those with little or no access to preventive care, those without health insurance (uninsured or underinsured), and those facing barriers to care (language, cultural, financial, transportation) free cervical and breast cancer screenings, education, same-day results, and a connection to follow-up care in a one-day, single visit model. In 2011, the Gene and Jean Herbek Humanitarian Award was established to recognize pathologist leaders who have made innovative and unique contributions to advance the See, Test & Treat® program.

Despite the COVID-19 pandemic, the CAP Foundation planned to offer eight STT programs in 2020. Each program is also tailored to include additional services that respond to the unique needs of its community. During the program, additional services that improve health status and quality of life are often offered, including HIV testing, blood sugar testing, dental and vision screenings, healthy cooking classes, vaccines, financial counseling, and health insurance counseling. Health insurance navigators assist uninsured individuals explore their health insurance options.

Upon this review of the accomplishments of the Foundation since its inception in 1963, it is evident that it has consistently supported education and training in pathology and laboratory medicine with an emphasis on facilitating new technologies that underline the central role of pathologists in medicine as well as supporting young pathologists in advancing their careers. Through its conferences, awards, grants, and patient-serving endeavors such as See, Test & Treat®, the CAP Foundation has earned its place as one of the important programs of the CAP and highlights the commitment of pathologists to patient care and the advance of our specialty.

### **CAP Publications—Developments and Milestones Since 1997**

**The Archives of Pathology & Laboratory Medicine and CAP TODAY® are both widely-read and respected publications of the CAP. The following passages have been contributed by Robert McGonnagle, the publisher for many years of both publications.**

As the 1990s wound down to the new millennium, *CAP TODAY*® and the *Archives of Pathology & Laboratory Medicine* settled into a period of steady growth and development. Already by 1995, *CAP TODAY*® enjoyed the widest readership among the clinical laboratory's most important decision-makers for products and services. A strong commitment to independent, third-party readership and

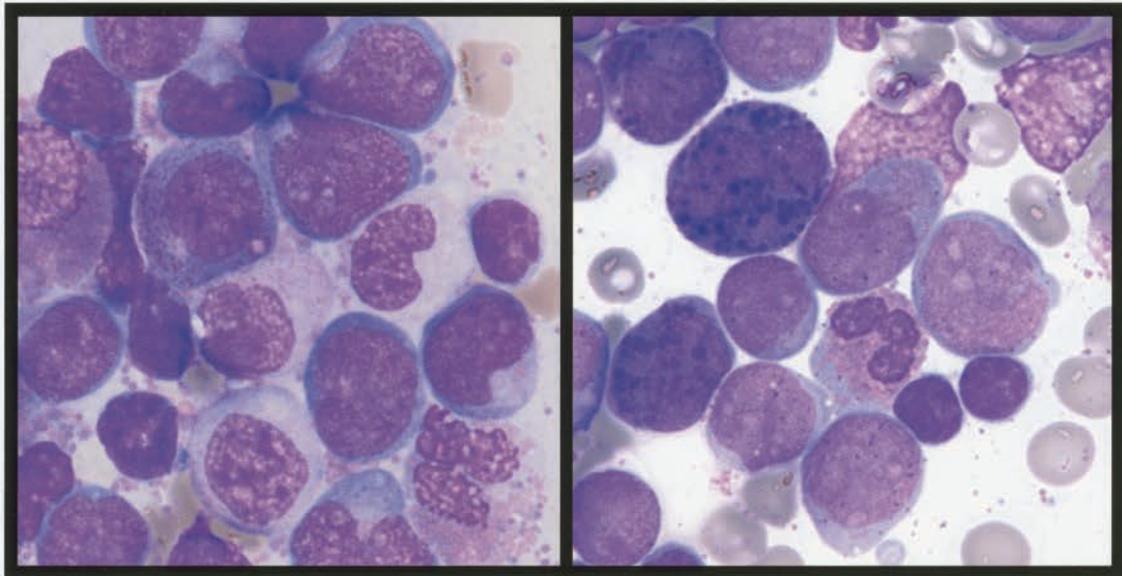
market research provided a foundation for advertising sales efforts that propelled the magazine to the first-place position in ad pages, dollars, total number of advertisers, and recognized best advertising value. Importantly, this represented the first time an association title could claim such leadership in this specialty field.

Just as the CAP's laboratory programs grew in reach and importance throughout these years, so too did its magazine, *CAP TODAY*®, which offered crucial updates on those very programs while also mining the wide-ranging expertise of the CAP's many committees, as each committee addressed the new technologies, business practices, and scientific advances affecting all disciplines of the specialty. The in-depth editorial treatment of new and hot topics, using multiple sources and professional writers, created an editorial product rich in appeal. This approach remains to the current day, as does the policy of asking all sources to review article drafts to confirm accuracy and sharpen discussion. Frequent updates on hot topics bring focus to the development of consensus in the field and the consolidation of best practices.

Sherrie Rice, the founding editor, still remains in place, providing each monthly issue with unwavering care and attention. Her infinite tact and uncompromising standards are well-known among the magazine's staff and the members of the editorial board. Many sections of the magazine such as Selected Abstracts, Q&A, and Newsbytes were overseen by CAP members who shared in the desire to create a first-rate and up-to-date source of information for their colleagues and for laboratories. While many members and writers contributed over the years, others have joined in to help produce the monthly issues. And all CAP presidents since initial publication have each in turn produced a monthly column, in their own voice, throughout the duration of their two-year terms. This column has been well read and respected, including by the many non-pathologists who receive and read *CAP TODAY*®. It is the quality

# ARCHIVES

of Pathology & Laboratory Medicine



Acute Myeloid Leukemia With  $t(8;21)$  Translocation Showing Blasts With Perinuclear Hofs and Very Fine Auer Rods (left), and AML With  $inv(16)$  and Blasts With Monocytic Features and Abnormal Eosinophils With Basophilic Granulation (right)

October 2015

Special Section—2014 New Frontiers in Pathology



COLLEGE of AMERICAN  
PATHOLOGISTS

of content of all the features, departments, and editorial choices that has built and sustained the title for 35 years, and counting.

In January 1995, a collaborative effort between the CAP and the AMA—the *Archives of Pathology & Laboratory Medicine* (hereafter, *Archives*)—was launched under the sole aegis of the CAP. The editor during the previous joint CAP/AMA sponsorship, William W. McLendon, MD, FCAP, of the University of North Carolina in Chapel Hill, remained in that role under the new arrangement, with Jean Wright providing indispensable editorial assistant on-site in the offices of the UNC medical school and hospital. Ties with the AMA were reflected in that the AMA logo ran on the journal's cover along with that of the CAP. The AMA preserved a role in overseeing editorial quality and advising on many elements.

Dr. McLendon decided to step down as editor in 1997. This was significant because the journal had been housed at UNC dating back to the editorship of Kenneth Brinkhous, MD, which began in 1974. Dr. Brinkhous was succeeded by Dr. McLendon in 1984. After residing at UNC for 23 years, the CAP faced a new future with a new editor for its newly acquired journal.

After a careful solicitation for candidates and extensive vetting, review, and personal interviews, a search committee recommended to the Board for its approval, Kenneth D. McClatchey, MD, FCAP. Dr. McClatchey, who had recently become the chair of pathology at Loyola University Chicago, moved into his new role and established the editorial office at Loyola and brought in Patrick Kearns and Katie Giesen as paid editorial assistants. Both are still the backbone of the journal's operations, as executive managing editor and managing editor, respectively, though they are now housed at CAP headquarters as full CAP staff.

Dr. McClatchey paid great attention to resident affairs in the journal and established a popular journal CME offering. He also began the enduring *Archives* reception at the annual USCAP meeting, welcoming all and honoring

*Archives* authors and reviewers. This singular event raised the profile of the journal among so many important pathologists over the years who have become stalwart contributors.

Dr. McClatchey died at age 61 in December 2003, after a short illness. In the meantime, Gregorio Chejfec, MD, FCAP, of the University of Illinois at Chicago, Department of Pathology, stepped in as the interim editor. After a year's effort, the search committee and the Board approved Philip T. Cagle, MD, FCAP, as the new editor of *Archives*, starting his stewardship in January 2005. Dr. Cagle immediately set out on the mission to improve the reputation of the journal while strengthening its usefulness to practicing pathologists.

Dr. Cagle inaugurated an online submission and review system. He also launched a masthead of unprecedented proportions, detailing the various section editors and editorial board members overseeing the many subspecialties of pathology as well as important topics of interest. His goal was to provide the highest level of genuine peer review for myriad varied journal submissions. The dual mission—raising reputation and usefulness—required such attention. The *Archives* flourished as never before, entering the top tier of comparable journals and achieving recent all-time highs in impact factor.

It is fitting that Dr. Cagle was serving as editor in 2009 when *Archives* was the only pathology journal voted among the top 100 most influential journals of the past 100 years. This recognition from the Biomedical and Life Sciences Division of the Special Libraries Association remains a pinnacle of pride in the life of *Archives*. The recognition underscores the enduring value of the journal. In the meantime, regular studies of readership have continued to demonstrate that *Archives* is the journal most widely distributed to and read by North American pathologists. After 15 years, in December 2019 Dr. Cagle retired as editor, with Donna E. Hansel, MD, PhD, FCAP, professor and chair of Pathology at Oregon Health & Science University, serving as interim editor. In 2020 the

CAP appointed Alain C. Borczuk, MD, FCAP, chief of thoracic pathology and professor of pathology at Weill Cornell Medicine in New York, to serve as editor-in-chief.

Meanwhile, the manuscript submission and review system was only the first of many advances in the digital, online age for both *CAP TODAY*<sup>®</sup> and *Archives*. *CAP TODAY*<sup>®</sup> staff studied such developments keenly, and gradually the staff initiated a project aimed at a rich online offering. In 2009 the magazine launched a digital edition, which was soon followed by a website, [captodayonline.com](http://captodayonline.com). These digital advertising offerings have made the magazine the leading digital advertising presence in the laboratory/pathology marketplace. The extraordinary development and success of *CAP TODAY*<sup>®</sup>'s digital efforts are almost entirely owing to Mary Lindsay, a staff member who has consistently excelled at this purpose for almost a dozen years. *Archives* also is online with full text and images

and a healthy web offering of marketing options for advertisers. Kantar Media of New York, the leading evaluator and research tracker of health care publications online and in print, has noted that the CAP has the most robust percentage of online advertising revenue of any major association publisher it tracks. Since 2014, the *CAP TODAY*<sup>®</sup> webinar series has received glowing reception from participants and well-subscribed grants from many sponsors. This has helped all concerned in reaching the multidisciplinary dialogue now a routine expectation for precision medicine in the diagnostic and therapeutic arenas of modern pathology and oncology practice.

The CAP publications—the *Archives of Pathology & Laboratory Medicine* and *CAP TODAY*<sup>®</sup>—will continue to chronicle the evolving story of the specialty of pathology and laboratory medicine for many years to come.



Chapter Eight

THE CAP RESPONSE  
TO THE COVID-19  
PANDEMIC

## Chapter Eight

*Pitted against microbial genes, we have mainly our wits.*

—Joshua Lederberg

**This chapter has been contributed by Nancy Johnson, MBA, Senior Manager, Brand Communications and Writing (CAP Staff and Senior Management Committees).**

### **Pathologists Led Testing for COVID-19**

The world faced in 2020 the greatest health crisis in a century—COVID-19. The fast-moving pandemic claimed hundreds of thousands of lives, devastated economies, and tested the health care system. New cases emerged every day and pathologists played a critical role in the race to control the coronavirus outbreak. Pathologists worked on the front lines designing the tests for the virus, validating those tests, and making sure they were accurate. For patients in hospitals suffering from COVID-19, pathologists supported testing and performed all necessary laboratory work. When patients died, pathologists conducted autopsies to help understand the pathophysiology of the disease and its impact on the human body. This crisis made it more apparent than ever that the laboratory is central to high-quality health care and the pathologist is essential to making a diagnosis.

More than 1,000 CAP-accredited laboratories provided COVID-19 diagnostic services, even when instruments, reagents, and other necessary supplies were difficult to acquire. Pathologists and laboratorians provided diagnoses and test results to more than 100,000 patients every day. They had to get creative with how they collected specimens. While some institutions made homemade swabs using 3D laser printers, pathologists understood that the quality of the specimen would determine the accuracy of the results. That's why they

insisted upon rigorous validation of those products. "We can't just buy a test off the shelf and start doing it in our laboratories," said Christina M. Wojewoda, MD, FCAP. "We have to make sure that we can detect positive patients and make sure that the negative patients are truly negative." Pathologists understood that bad data was worse than no data, and so they turned to quality control and Proficiency Testing protocols to ensure that COVID-19 results produced in their laboratories were as reliable as possible.

"Our job as pathologists and as physicians in the laboratory is to make sure that those tests give us the best possible answer," said Timothy C. Allen, MD, FCAP. He understood the consequences of making the wrong decisions based upon faulty test results. "Then people are going to be in the public spreading the virus or people may be hunkered down at home when they could otherwise be out, but they don't know if they're positive or negative. We want to avoid that."

While the medical community fought COVID-19, some patients battling other diseases like cancer delayed care because of delayed surgeries and fear of exposure to the virus. "Unfortunately, cancer doesn't know that we're having a pandemic," said Leilani Valdes, MD, FCAP. "Cancer is happening and being diagnosed every day, even with the conservation of unnecessary procedures and screening procedures. We cannot let those patients stay at home and not have their chemotherapy and not have their radiation therapy or not get the cancer resected because there's too much at risk." The CAP recognized the issue of delayed treatment and was able to convince the Centers for Medicare & Medicaid Services (CMS) to



loosen regulations that interfered with efficient patient care. These included a temporary moratorium on CLIA-driven lab inspections and allowing pathologists to sign-out cases from remote locations. Other interventions by the CAP are detailed below.

### **The CAP Secured Relief for Patients, Pathologists, and Laboratories**

As many Americans faced extreme economic hardship during this health crisis, the CAP supported funding provisions in the Families First Coronavirus Response Act. The act ensured that all testing for COVID-19 would be covered without patients having to share the costs and it also included \$1 billion to pay for tests for patients without health insurance. The new law also required Medicare, Medicare Advantage, Medicaid, and private health plans to provide free coverage for COVID-19 diagnostic testing.

The pandemic dealt a swift, damaging financial blow to many pathologists and their practices. A CAP member survey revealed that 70 percent of pathologists and laboratory professionals reported reduced work hours and pay as well as increased burnout. The median decrease in anatomic pathology testing was 69 percent, representing a significant revenue cut.

The Coronavirus Aid, Relief, and Economic Security (CARES) Act created more than \$350 billion in emergency aid for small businesses during the economic downturn. The CAP urged Congress to provide further financial and economic assistance to pathology practices. This included clarifying insurance coverage for all diagnostic tests for COVID-19, suspending scheduled Medicare cuts to clinical laboratory services in 2021, and providing billions of dollars in relief. The CAP made a concerted effort to provide information to members on how to access small-business assistance loans as part of the Paycheck Protection Program (PPP). With the cancellation of elective surgeries and a decrease in specimen volume, Matthew Foster, MD, FCAP, reduced staff hours in his practice to avoid furloughs. His initial application for PPP funding was unsuccessful but his practice received financial relief on the second round. “We brought our employees back full time and had a positive cash flow which was a welcome relief for us,” he said. “It allowed us to be prepared for the next surge, whenever that might come.”

One month later, Congress responded to advocacy from the CAP and others and agreed

to a \$484 billion spending package to replenish a depleted small-business loan program and cover necessary expenses to expand capacity for COVID-19 tests. The law required the Trump administration to create a national strategy to provide assistance to states for testing and increased testing capacity. The legislation provided \$100 billion to support hospitals, physicians, and other providers. In addition, the CAP offered practice management tools and resources for pathologists and their practices outlining various financial programs developed to provide economic relief during the COVID-19 crisis.

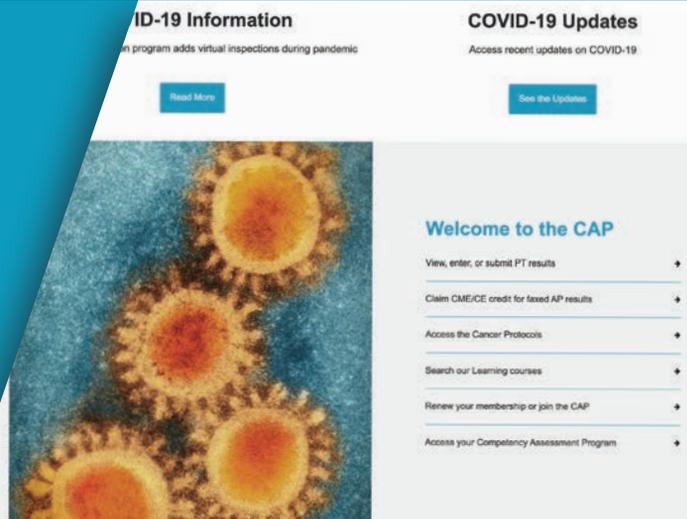
As the pandemic continued and the demand for diagnostic testing grew, the CAP sought to improve reimbursement for COVID-19 testing to ensure that laboratories were compensated fairly and that payment reflected the labor, equipment, reagents, and supplies needed to perform the COVID-19 diagnostic assay. The CAP asked the CMS to increase payment for unique CPT code 87635 for reporting laboratory testing services that diagnose the presence of the novel coronavirus.

To equip pathologists and their laboratories with testing supplies needed to diagnose patients, the CAP lobbied the federal government to further assist laboratories with solving chronic shortages and supply chain issues as more

than a half million patients received COVID-19 tests every day. CAP President Patrick Godbey, MD, FCAP, spoke directly with officials from the CDC about persistent shortages and asked for guidance on how states could obtain testing supplies and personal protective equipment for laboratories. The CAP partnered with a group of associations representing the laboratory community to write a letter to Vice President Mike Pence asking the administration to address obstacles to performing diagnostic tests for COVID-19. Survey data collected by the CAP showed laboratories had increased their testing capacity, but they could do more if testing supply shortages were fixed and they had the necessary supplies. For example, 64 percent of laboratory directors responding to the survey reported difficulty in acquiring reagents for platforms and test kits to conduct testing for the virus.

During the COVID-19 crisis, the requirement for pathologists to travel to work and unnecessarily expose themselves to the virus put them, their families, and their colleagues at risk for a potentially deadly illness. It also jeopardized patient health because of delayed care if pathologists could not perform their duties in the traditional workplace due to illness or quarantine. The CAP lobbied government officials for regulatory relief. It called on CMS to relax certain CLIA requirements and others

Within the first month of launch, approximately 25,000 people visited the page and devoted an average of five minutes engaging with the content.



believed to be unnecessary impediments to laboratory operations during the pandemic. In a significant move to relieve the burden on pathologists, the CAP persuaded the federal government to issue a waiver allowing pathologists to work remotely during this national emergency.

### **The CAP Kept Members and Customers Informed and Responded to Their Needs**

In this unprecedented crisis, members turned to the CAP for helpful, reliable information. The organization launched its COVID-19 section of the website to meet the evolving needs of members and customers looking for answers to pandemic-related questions. Within the first month of launch, approximately 25,000 people visited the page and devoted an average of five minutes engaging with the content. The site included a question and answer section addressing topics of interest to members and customers including availability of testing, accreditation, test method validation and verification, quality control, molecular-based testing, anatomic pathology, and clinical pathology. The CAP also held a series of virtual all-member town hall meetings to share data on laboratory challenges presented by the pandemic and discuss accreditation issues as well as the development of COVID-related Proficiency Testing. The Council on Accreditation and the Council on Scientific Affairs collaborated on questions and answers to topics such as the use of COVID-19 convalescent plasma and how to use serological tests that detect antibodies to the virus.

Education remained a valuable, coveted resource and the CAP made more than 60 online CME and SAM courses available to its members for free. In addition, the CAP offered a daily virtual lecture series for residents, a successful offering with more than 7,000 registrants and an average daily attendance of more than 800. The CAP presented its COVID-19 response to state pathology society presidents, HOD delegation chairs, and CAP councils and committees.

### **The CAP Secured Regulatory Relief**

The pandemic upended normal laboratory quality activities and the CAP quickly stepped in to guide laboratories through the many changes. CAP staff was successful in getting a response from CMS that called for suspension of all routine inspections except for immediate jeopardy complaint investigations. An e-Alert went out to all accredited laboratories with details on how to efficiently resume inspections in the future. A staff cross-divisional team assembled to identify and triage issues related to both domestic and international PT shipments. A logistics SWAT team met regularly to help mitigate disruptions due to international shipping restrictions and temporary laboratory closures.

With the support of the Microbiology Committee, a cross-functional team comprised of staff from various departments launched a PT program for laboratories that use nucleic acid amplification methods to detect SARS-CoV-2. This happened in an accelerated timeframe to meet the urgent need for a quality assurance product for members and their laboratories. Another staff team in collaboration with the Diagnostic Immunology and Flow Cytometry and Microbiology committees began the process of developing a serology PT program for COVID-19.

### **The CAP Communicated**

When the pandemic began, CAP staff transitioned to a virtual mode with business operations continuing largely uninterrupted. Members were featured in COVID-19 news stories close to 4,000 times in online, print, and broadcast media, reaching an audience of more than 500 million. Pathologists offered their expertise to journalists on topics ranging from delays and shortages in coronavirus testing to laboratory workers being the unseen warriors in the fight against COVID-19. Meanwhile, a parallel digital advertising campaign targeting the patient/public audience highlighted the pivotal role pathologists played in the health crisis. The video ads featured interviews with members and reached millions of people in



targeted geographic areas. The CAP joined the national *#inthistogether* social media campaign to recognize and acknowledge the work of pathologists and laboratory professionals during the pandemic.

### Heroes Emerged in the Pandemic

Many pathologists working on the front lines during the coronavirus outbreak shunned the label of hero. They continued giving their best to save lives, make people healthier, and better understand this deadly virus. Mary Fowkes, MD, PhD, FCAP, directed the autopsy service at Mount Sinai Hospital in New York City, the first epicenter of the pandemic in the United States. She and her colleagues performed autopsies on more than 100 deceased COVID-19 patients. During the brain removal procedure, Dr. Fowkes wore an enclosed positive pressure suit to protect herself from aerosolized virus. Still, she feared contracting the virus. “It’s been a lot of long weeks,” she said. “I have grown children, but I want to see them grow older. My biggest fear was that I would leave them without a mom.” Sadly, Dr. Fowkes died unexpectedly of causes unrelated to the Coronavirus on November 15, 2020. Dr. Fowkes was a member of the CAP Board of Governors and her passing came as a shock and a great loss to her family, many friends, and colleagues.

When New York Governor Andrew Cuomo put out the call for all medical professionals to help wherever needed, Justin Snow, MD, FCAP, a cytopathology fellow at NYU Langone Health, responded. Pathology was slowing down with fewer specimens since non-essential surgeries had been delayed or canceled. “I didn’t think I’d

be joining a clinical ward in my fellowship, but it’s something I’m happy to do working on a ward with cardiology patients,” he said. “Since our health provider friends needed help, I decided to do it.”

Jonathan Lai, MD, a first-year resident at McGill University Medical Center in Montreal, Canada, was in the first wave of pathologists to be deployed to COVID-19 patient floors. “I didn’t have much clinical experience. So I went on rounds with attending physicians to understand the patient needs, and I cleared out small tasks like restarting meds, writing discharge and admissions forms.” Dr. Lai also spent time talking with family members of COVID-19 patients. On his last shift, he communicated with the grown daughter of an elderly woman who was dying from the virus. “I said I followed your mother for four days and she’s very comfortable right now. They can’t come in to see their parents which is sad, so it helps when the medical workers keep in touch with the families.” In the near future, Dr. Lai will choose a pathology specialty and he said this pandemic experience will influence his approach to medicine. “As a pathologist, we need to have the skills to talk with patients and their families, and I will carry that on with me.”

The writing of this chapter concluded in December of 2020, coincident with the “Emergency Use Authorization” approval by the FDA of two vaccines. The eagerly-awaited vaccines are game changers and the pathology community as well as all physicians, healthcare workers and the public anticipate the control of this pandemic.



Chapter Nine

# PATHOLOGY TODAY AND TOMORROW

# Chapter Nine

*If you do not think about your future,  
you cannot have one.*

*—John Galsworthy*

**In 1948, the US Secretary of State, General George Marshall, stated that the world had the means to eradicate infectious diseases from the earth.**

Seven decades later the mistake of this prediction is obvious as we suffer through the COVID-19 pandemic and the recent epidemics of SARS, MERS, ZIKA, and H1N1 influenza as well as the persistence of HIV/AIDS, tuberculosis, and malaria as worldwide causes of significant morbidity and mortality. Previous chapters focused on the present and the past; this last chapter looks ahead and addresses several new technologies that are transforming medicine, highlighting changes in the social, economic, and regulatory environments that will affect the CAP, pathologists, and pathology practice in the coming years.

This chapter will discuss technologies that are currently changing the practice of pathology and laboratory medicine as well as the practice of medicine. The issues concerning molecular and genetic pathology, the biome, digital pathology, artificial intelligence, and social media will be briefly summarized as well as evolving applications by drawing on the expertise of CAP members who are experts in these disciplines.

The chapter will begin by exploring the potential impact on pathology, the CAP, and its members of significant changes in the societal, political, economic, and regulatory environments. These “predictions” are made in full recognition of the wise words of Niels Bohr, a Noble Laureate in 1922, that “it is difficult to predict, especially the future.” Hopefully the comments may stimulate discussion. The specifics will undoubtedly prove to be less than perfect but are intended to raise questions about the immediate future and to

underscore that all pathologists need to be aware that the world of medicine, pathology, and the laboratory are undergoing substantial change.

## **Social, Economic, Political, and Regulatory Changes in a Post-COVID Environment**

The world, of course including the United States and the societal, political, economic, and regulatory environments of medicine as well as pathology and the laboratory will be different after COVID. Trends that were happening before the pandemic will, in all likelihood, be accelerated in some cases and changed in others. The COVID-19 pandemic has significantly impacted pathologists and the laboratory workforce, with many practices experiencing a tremendous human burden along with decreases in anatomic pathology and clinical pathology testing volumes and other financial strains. What are the questions—and perhaps the answers—that the CAP and its members need to be considering?

Societal and economic trends have changed and are continuing to impact the pathology and laboratory practice environment. Even before COVID, critical changes included the move to vertical integration of health care, consolidation and centralization of hospitals, and the emergence of vast health systems employing large numbers of physicians. Pathologists and pathology groups have been part of this centralization process and in many cases have lost elements of practice autonomy. Challenges to payment for pathology and laboratory services have taken place in both the private insurance and government sectors. These challenges are confronted—and will continue to be—by the CAP at both the national and state



levels, the latter with the collaboration of state pathology societies. For example, as of August 2020, The Centers for Medicare & Medicaid Services (CMS) plans to implement significant payment cuts to pathologists in 2021. The reduction, which the CAP has strongly opposed for more than a year, is a result of budget neutrality requirements that offset the cost of major changes to evaluation and management (E&M) services set to take effect next year. Without intervention, pathologists will see an overall decrease in Medicare payment of nine percent to fund increases in payment for E&M services.

The success of challenges to these negative changes will be dependent on the continuing engagement of individual pathologists and their support of the efforts of the CAP. Above all, in an increasingly competitive environment, the continuing viability of pathology will depend on the ability of the CAP, our state societies, and our members to demonstrate to our clinical colleagues, to administrators, to patients, to regulators, and to legislators the critical importance of pathology to the efficient delivery of high-quality patient care.

Political and economic developments have

always impacted the medical environment. Given the current intensity of political divisions in the US, future legislative events impacting our profession will be very significant but difficult to predict. The extent to which health insurance remains partially employment-based or becomes more government-based will certainly impact the way in which medicine and pathology are financed, as well as how they are practiced. The momentum to move from fee-for-service payment to systems more reliant on quality measures will continue. This will impact the role and compensation of pathologists and will require pathologists to take very assertive steps to identify and make public the great contribution to quality in patient care provided by pathologists. Although “federalese” terminology describes pathologists as “non-patient-facing,” all pathologists will need to demonstrate the critical role that the right test at the right time with the right result plays in ensuring the appropriate care of patients. The CAP will continue to help pathologists deal with these changes in many ways, including initiatives such as the Washington office’s efforts coupled with member advocacy, PathPAC, PathNET, and the CAP Pathologists Quality Registry platform.

Significant changes in the location of laboratory testing and types of testing platforms are driven by the centralization of the sites of delivery of health care, as well as by the increasing costs of new and complex technology. A different, rising trend may be seen, however, in the development of discrete “point-of-care” technologies and their deployment in alternative locations such as national-chain pharmacies. The impetus for rapid, easy, “on-site” technology was clearly demonstrated in the response to the COVID pandemic, perhaps most notably in the demand for rapid testing for the virus and related antibodies. It is a matter of speculation whether the “internet of things” will facilitate remote monitoring of physiologic and laboratory data captured by smart phones and smart watches.

The role of the autopsy continues to be a source of some discussion and controversy within pathology as well as in the broader context of medical practice. Although still a major component of pathology residency training, the number of required autopsies has recently been reduced and the rates of autopsy performance are decreasing nationally. However, during pandemics (HIV, COVID), autopsy findings continue to contribute significantly to the clinical and pathophysiologic knowledge base.

Pathologists are slightly less than two percent of all US physicians, yet all physicians recognize the critical importance of correct pathology diagnoses and accurate laboratory results. Despite this, there is concern about the

decreasing percentage of US medical school graduates choosing pathology as a specialty. Many explanations for this trend have been suggested, including economic uncertainty supported by largely unsubstantiated concerns about the future of pathology practice. The CAP has recognized that one factor contributing to the trend is the marginalization of the teaching of pathology in medical schools. This phenomenon is a result of the move towards unitary and organ-system-based curricula with pathology departments no longer providing individual pathology courses or electives. Medical students are, therefore, no longer exposed in a meaningful way to pathologists who participate in the routine delivery of patient care. Also, the question has been raised as to how the increasing complexity of pathology and laboratory medicine will affect the proportion of generalist to specialty pathologists. Will there be a shift of specialty expertise to centralized locations?

A related issue that is likely to receive increasing attention is that of diversity of the medical and pathology workforce. Currently, the national pathology workforce may be one of the most diverse in American medicine, with many female and international medical graduates but with a small number of pathologists of color. The CAP Board implemented a Board Diversity Project Team committed to exploring ways in which the CAP can support efforts to increase diversity in the profession as well as in the membership

The role of the autopsy continues to be a source of some discussion and controversy within pathology as well as in the broader context of medical practice.



and leadership of the CAP. Recommendations have included changes in the committee appointment process, enforcement of term limits for committee members, and changes in the Board election process. Further attention to this issue is to be expected and will be vital.

“Scope of Practice Creep” has been identified (Allen, *Archives of Pathology & Laboratory Medicine*, April 2020) as a potential threat to pathology as well as to other specialty areas. For many years, pathologists have worked routinely in a collegial manner with a variety of other professionals—medical technologists, pathology assistants, histotechnologists and cytotechnologists, and doctoral-level scientists. However, economic pressures, consolidation, and a potential scarcity of pathologists may contribute to attempts by others, including non-physician medical personnel and non-pathologist physicians, to render services traditionally performed by pathologists. The related issue of the size and adequacy of the pathology workforce continues to be the subject of study and statistical analysis. A paper in the April 2020 issue of *Archives of Pathology & Laboratory Medicine* concluded that “the demand for pathologists is strong,” although the study did not directly address the question of whether projected pathologist workforce size is adequate for anticipated needs. Another CAP workforce analysis study (Robboy et al, *Archives of Pathology & Laboratory Medicine*, December 2013) demonstrated that an anticipated substantial “retirement cliff” would begin in 2015 and that more pathologists will retire from the specialty than will enter from training programs. The COVID-19 pandemic has had a significant impact on the pathologist and laboratory workforce, with many practices experiencing a tremendous human burden along with decreases in anatomic pathology and clinical pathology testing volumes and other financial strains. A recent survey of CAP-accredited laboratories reported a median drop of 69 percent in anatomic pathology testing and 46 percent in clinical pathology testing, regardless of whether or not they were performing COVID-19 testing.

Pathology and laboratory medicine are highly regulated professions and the CAP plays a major role in the regulatory sphere through the Accreditation and Surveys programs. The requirements of the CLIA statute are pervasive and the reality of mandatory assessment of pathologist competency exists in cytopathology. It is not farfetched to suggest that in the future requirements for competency assessment will extend to other areas of pathology practice. This will raise serious issues about the intrusion of government into the practice of medicine and will require pathologists and the CAP to align with other pathology organizations and the House of Medicine.

Finally, there is an increasing emphasis in the medical literature as well as public media on the social determinants of disease and health, with such determinants including poverty, diet, health care access, environment, education, and housing. A related concern has been the demonstration of striking discrepancies in the impact of disease on people of color. This issue has been highlighted by statistics on the higher rates of morbidity and mortality from COVID-19 in people of color. Parallel discussions have also emerged about “race-based” algorithms (eGFR) and reference ranges for transgender populations. While it is very difficult to predict how the evolution of these issues and changes in the social, economic, and political arenas will change medical care, it is very likely that some practices of pathology and laboratory medicine will be impacted.

### **Molecular and Genetic Pathology and Other Emerging Technologies.**

Personalized Medicine has been defined by the National Cancer Institute as a “form of medicine that uses information about a person’s own genes or proteins to prevent, diagnose, or treat disease.” The ability to help link exome or genome sequencing results to clinically-useful information will be both a challenge and an opportunity for pathologists to assist in the genotypic-phenotypic correlation in patients found to have disease-associated genetic variants. The capability of pathologists to



The role of the pathologist in the era of molecular medicine is unchanged from the role that we have always played as laboratory leaders and patient advocates.

correlate clinical, laboratory testing, morphologic, and imaging studies with genetic findings is a natural area of expertise for pathologists. Five CAP members, most of whom are chairs of CAP committees engaged in molecular testing, were asked to give their opinion as to the future of molecular and genomic testing with particular attention to the impact on pathologists and the care of patients as well as how pathologists can continue to play a significant role in molecular and genomic testing. Three CAP member experts have provided comments about other emerging and transformative technologies. Their responses, in their own words, are as follows:

—**Michael Datto, MD, PhD, FCAP; Chair, Accreditation Committee**

The role of the pathologist in the era of molecular medicine is unchanged from the role that we have always played as laboratory leaders and patient advocates. We must continue to be scientific and critical in our evaluation of new technologies to ensure that they provide accurate results, that these results are actionable and provide value in the care of our patients. Of course, we must do this with the best interest of our patients in our minds for the tests that we offer in our own laboratories; but our responsibility does not end there. Through our work with the CAP and other private and governmental regulatory agencies, we will continue to help laboratories around the country and around the world provide high-quality, high-value molecular testing.

Molecular medicine will continue to expand and evolve. Comprehensive genomic profiling of every patient with use of this data through the course of their lifelong care is on the near horizon. Comprehensive genomic profiling on every tumor is already a reality. The field has already become too large and too complex for our clinician colleagues to manage the integration of molecular data into the care of their patients. Our role is to guide our clinician colleagues to the right tests at the right time and to serve as the subject-matter experts on both the use of the technologies and the results that they provide. Finally, pathologists are in a unique position to see how this data can be structured in our EMR and how it should flow through our electronic systems to allow electronic physician decision support.

—**Chad McCall, MD, PhD, FCAP; Laboratory Director, Carolinas Pathology group and Atrium Health, Charlotte, NC**

Over the next 5-10 years, I predict that molecular and genomic testing will become a daily part of the jobs of most pathologists. Even if we are not all interpreting the actual molecular tests, we will be ordering them to help us subclassify most of the cancers we diagnose. I wonder if the day will come when morphology

becomes a screen to direct molecular testing, which actually will make the diagnosis. After we make the diagnosis, we will also be performing more molecular studies to help direct therapy. As targeted therapies become more numerous, so will the tests required to use them. We will still be the “doctor’s doctor” for years to come, but our jobs will change.

—**Joel Todd Moncur, MD, PhD, FCAP; Chair, Molecular Oncology Committee**

Molecular diagnostics is such a dynamic area that it is somewhat challenging to predict with any certainty the future of the field. Nevertheless, some themes are emerging. First, I think the regulatory framework for molecular testing will likely be resolved within the next 5-10 years. My best guess: Laboratory developed tests will likely undergo some type of review before clinical implementation and the level of that review will depend upon the risk associated with the test. I believe the CAP will play an important role in that preclinical assessment and review. Second, I think lab utilization is going to become increasingly important in molecular diagnostics. There is much work to do in order to bridge the divide between pathologists and treating providers. I believe pathologists are critical to helping the medical community to become more proficient with the utilization of molecular tests. Third, there are numerous advances in technology and laboratory performance that we can expect in the next 5-10 years. The performance and utility of cell free tumor DNA, tumor mutational burden, and RNA sequencing will become further solidified in coming years. Mutational signatures associated with various tumors may very well enter clinical practice. These comments are focused on molecular oncology, but similar advances in germline testing (including pharmacogenomics) and infectious microorganism testing will also occur. Lastly, I think that standardization is going to be of the utmost importance over the next 5-10 years. The molecular community has done a wonderful job establishing a framework for so many aspects of molecular testing, such as the use of tiers

for reporting germline and somatic variants. That work will continue and will even extend to the standardization of pre- and post-analytical variables that are so important for quality. The CAP has been at the center of all these advances and I know it will continue to be. The committees and members of the CAP provide a rich environment for making progress on all these fronts.

—**Ann Moyer, MD, PhD, FCAP; chair, CAP/ACMG Biochemical and Molecular Genetics Committee**

The cost to perform molecular genetic testing has drastically decreased in recent years due to advances in technology. This has allowed for increased research, leading to new findings that are applicable to patient care for an expanding variety of indications, along with increased access to testing for patients. As more patients undergo genetic testing for hereditary disorders, more genetic variants are identified, including some that are very rare or private to the individual or family. These rare variants can be difficult to interpret. In addition to clinical correlation with the patient’s phenotype, genetic test results may be best used when also interpreted in conjunction with other diagnostic laboratory findings, as well as gross and histologic findings when applicable. Therefore, the pathologist is uniquely positioned to take a lead in integration of molecular genetic testing with other modalities to facilitate patient care. There is growing enthusiasm for the use of augmented human intelligence (AHI) in health care settings, and perhaps this could be leveraged to aid the pathologist and clinician in integrating genetic testing results with other clinical, laboratory, and pathologic findings. It would be exciting to be able to provide more integrated reports to aid the clinicians in their daily work. Molecular genetic testing is an exciting field in 2020, but we remain limited in our understanding of complex, multifactorial disorders. The future will be exciting as genetic testing expands from evaluation of the coding region of the genome to non-coding regions, epigenetics, and beyond.

—**Sophia Louise Yohe, MD, FCAP; Chair,  
Personalized Health Care Committee**

My answer prior to COVID I think would have been different. Prior to COVID-19, I would have focused on the expanding role of genomic testing in oncology, genetic risk score, and on artificial intelligence/machine learning. I still think those things are important but now I must add the role of laboratory developed tests for molecular testing.

First, in regard to genetic testing in oncology, the predicted shift to testing of larger next generation sequencing panels is occurring, with reimbursement for testing being the main limitation. There are many roles for pathologists in this testing from assessing adequacy and tumor percentage of the sample, to interpreting the results, to participating in tumor boards and making recommendations regarding therapeutic indications. The latter role is uncomfortable for many pathologists, but I think is important for us to embrace this role to provide the best care for patients and to demonstrate the importance of pathologists in patient treatment and management.

Second, using genetic risk scores is most familiar to pathologists in the triple test or quad test used for fetal aneuploidy screening. Although, this use of a risk score is being supplanted by circulating fetal DNA tests; genetic risk scores follow a similar idea but are based on many more data inputs. A few risk scores have been published and are being offered, and I think the CAP has an important role to play in ensuring the quality of these risk scores from the technical testing to the bioinformatics algorithms used to calculate risk to reporting.

One could write a book on artificial intelligence and machine learning (AI/ML), but I will restrict my comments to their use in molecular diagnosis and testing, which I foresee mainly being the way large genomic data sets will be used. Many have said that pathologists need to become masters of data, and that is definitely true for molecular genomics. Bioinformatics algorithms that filter and sort based on certain

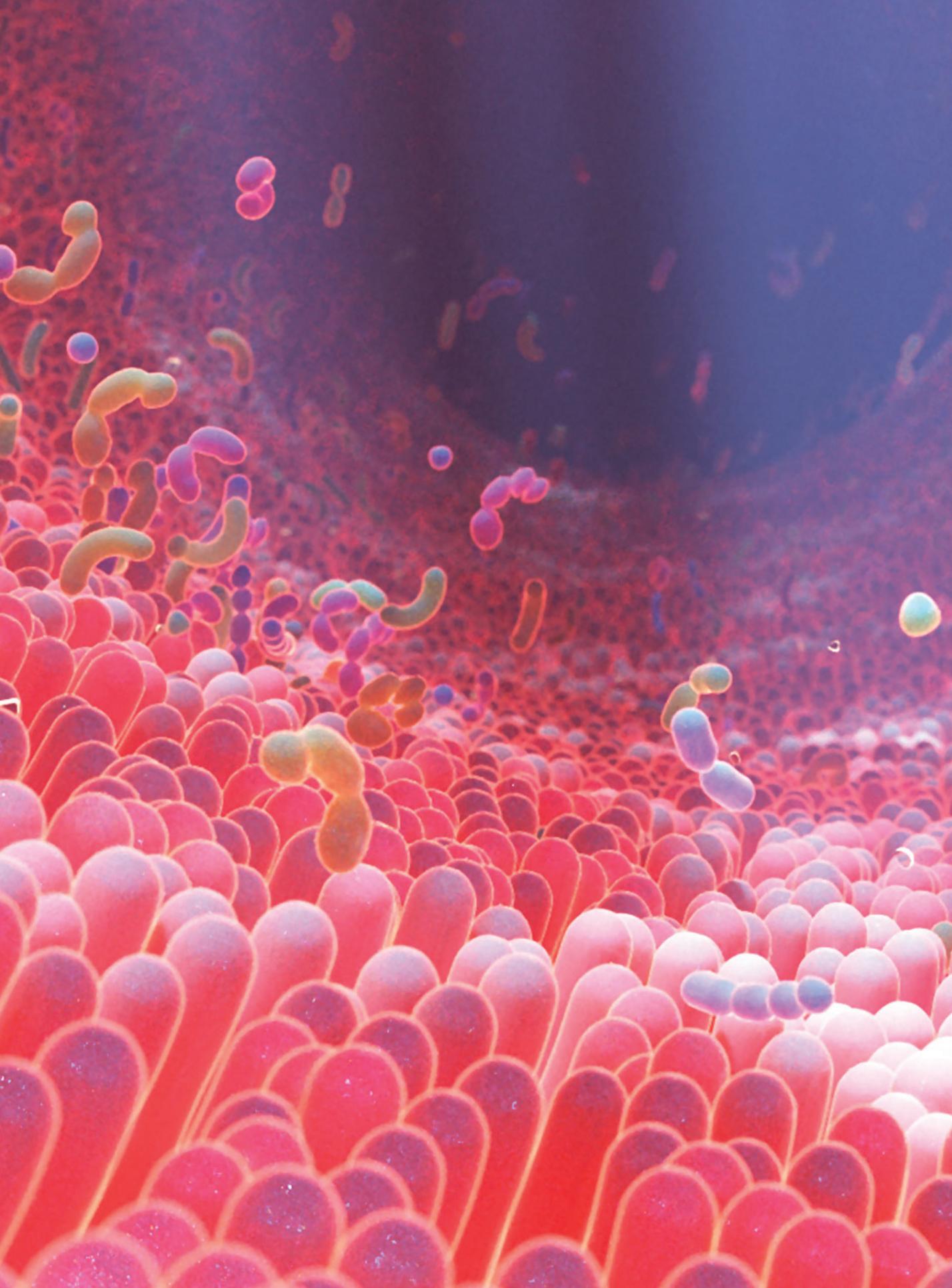
data fields or a combination of data fields certainly fit some definitions of AI and are already in use for interpreting NGS data and, as mentioned previously, for genetic risk scores. I imagine machine learning will be applied to these same areas. Combining molecular genetic data sets with other types of data sets (for example, digital imaging of a tumor and genetic testing of that tumor) is achievable and may improve the diagnostic and therapeutic information gleaned from a specimen.

I am a staunch believer in the value of laboratory developed tests (LDTs), especially in the wake of the COVID pandemic. In many states LDTs have been critical to expand and maintain testing volumes in the face of shortages from “black box” instruments and kits. Scientific knowledge and standard of care advance constantly and sometimes quickly, and as such the flexibility allowed by LDTs is so important in the world of diagnostic and therapeutic testing. I understand that the LDT process can allow unscrupulous, careless, or just mistaken developers to market tests with inadequate performance, and that regulation would catch some (but not all) of these; nevertheless, I think the benefits outweigh the risks and that the CAP could play a role ensuring that LDTs are good quality. CAP does this already with PT testing, although a separate more proactive approach might prove useful.

### **Pathology and the Human Microbiome**

**The following section has been contributed by  
James Versalovic, MD, PhD, FCAP.**

Since the inception of the Human Microbiome Project (HMP) as a multidisciplinary effort in 2007, the specialty of pathology has been an integral part of translating advances in microbiome science into the practice of medicine. The early planning efforts in 2007 and 2008 with the National Institutes of Health (NIH) and centers in Cambridge, MA, St Louis, MO, and Houston, TX, included pathologists and pathology personnel to devise human body sampling protocols and procedures for obtaining specimens from different body sites. In order to generate a meaningful map of the



biogeography of human-associated microbial communities, it was clear that expertise in pathology for human specimen collection would be pivotal in this effort. Initial efforts focused on sampling of sources as diverse as the oral cavity, nares, skin, vagina, and stool in healthy human adults. The first comprehensive reports of the healthy adult human microbiome were published widely in 2012. Initial studies were rapidly expanded to include the respiratory tract and other body sites in neonates, children, and adult populations globally with collaborative efforts such as the International Human Microbiome Consortium (IHMC). By 2012, the stage was set to explore the possible contributions of the human microbiome to disease diagnosis and management, and so potentially extending the role of the pathologist and the clinical laboratory to stratifying human disease and understanding disease mechanisms.

The first true application of the human microbiome in disease diagnosis and management was the example of recurrent *C. difficile* infection with antimicrobial treatment for various infections long established as the major contributor to *C. difficile* infection. Such disorders of microbial ecology provided fertile ground for new therapies such as fecal microbiota transplantation (FMT). Pathologists participated in different medical centers by providing guidance on stool collection and associated DNA sequencing studies to evaluate microbial composition following antimicrobial therapy. Microbial dysbiosis based on 16S rRNA gene sequencing allowed the gastroenterologist or treating physician to distinguish patients in critical need of FMT when established treatments failed. Another example was that of patients who had undergone peripheral stem cell or bone marrow transplantation and were at risk for enterococcal bacteremia. By detecting potential opportunistic infections in advance by stool-based DNA sequencing of the microbiome, pathologists and clinical microbiologists can identify patients at risk for drug-resistant bloodstream infections. Beyond the diagnosis and treatment of infectious diseases, advances

in biomedical research have identified microbes and associated metabolites that are associated with chronic diseases such as diabetes, cardiovascular disease, colorectal cancer, and metabolic disorders.

Pathologists and clinical laboratories will continue to recognize the presence of microbes and microbial metabolites in the human body. The future of pathology will partly depend on a holistic world view of contributing mechanisms of human disease and how pathologists harvest this information to improve diagnosis and stratification of patients, ultimately refining treatment and management strategies. Diseases like irritable bowel syndrome that were not addressed by pathologists and clinical labs previously now enter the realm of possibilities for enhanced diagnosis due to advances in human microbiome science and pathology. Pathology must leverage the “other half” (more than 50 percent of cells in the human body are microbial!) in order to advance our understanding of disease mechanisms and to apply these lessons to refinements in patient care in the 21st century.

### **Digital Pathology and Artificial Intelligence: Challenge and Promise**

**The following section has been contributed by Eric Glassy, MD, FCAP.**

Consider the invention of the sphygmomanometer. The blood pressure cuff first appeared in US medical practice in the early-1900s and it generated concern and debate among physicians. Some doctors thought that it could not possibly be as accurate as they were in palpating patients' pulses. A machine could never replace a human. It took more than 50 years before blood pressure cuffs were used routinely in hospitals. The adoption of digital pathology and artificial intelligence (AI) have followed a similar path. The digital revolution that is transforming every industry has come slowly to pathology. But not all pathologists are yet prepared to embrace it.

Digital pathology involves the acquisition, management, and distribution of pathology

and clinical laboratory digital images and their associated data. Gross and microscopic static images and live-view telepathology are part of digital pathology, but the term is primarily associated with the creation of virtual glass slides, so-called whole slide images (WSI).

The first WSI system was created more than 25 years ago and it took a full day to encode a single slide. The field has rapidly evolved, with scans now done in less than a minute. Adoption has been slow but steady, primarily in niche uses such as consultations, tumor boards, virtual IHC stains, quality assurance, image sharing, frozen sections, education, insourcing of cases from outside the United States, and more recently, AI and image analysis. As well, of course, the COVID-19 pandemic has also been a driver as pathologists needed to perform primary diagnosis from the safety of their own homes.

There are notable barriers to implementing digital pathology, including hardware costs, IT integration, workflow adjustments, and regulatory issues, but the strongest wave overcoming these concerns and driving adoption is the tsunami of AI and machine learning. A host of algorithms are under development that count, measure, diagnose, prognosticate, and streamline workflow.

By 1950, medical knowledge had been doubling every 50 years. By 2020, the doubling time

had become 73 days. AI is needed to keep up. Our choice to embrace this transformative technology will extend the longevity and relevance of our specialty. There has never been a time of greater promise, or one of greater potential peril. But the peril is not the advance of algorithms. AI will not replace pathologists. Rather, pathologists who adopt AI will replace those who don't.

Traditional analog, linear thinking is a recipe for obsolescence. Pathologists must think strategically about the forces of disruption and innovation shaping their future. Pathologists will become interpreters and integrators of a wide range of data—next generation sequencing, omics, molecular data, and virtual images. A paradigm shift is coming and computer-assisted digital pathology will make us more valuable to patients, providers, and payers. Digitally-enhanced diagnostics, driven by artificial intelligence, will allow those results to be delivered more quickly and accurately than ever before and will be a key component of precision medicine. The CAP plans to continue to be a partner in that exciting new world. The following paragraphs will describe what the CAP has achieved in these two areas during the past decade.

### The Start of Digital Pathology

Anatomic pathology is a visual discipline. The earliest practitioners were also artists, who

Today, the term “digital pathology” usually refers to whole slide images—virtual glass slides.



put pen to paper and illustrated gross and microscopic findings. Drawings gave way to film and other analog solutions. Eventually, pathology imaging went digital. Today, the term “digital pathology” usually refers to whole slide images—virtual glass slides. The evolution from still images to virtual slides was not smooth. A host of technologies were developed, from “camera-on-a-stick” static image capture to robotic scopes and analog video cameras for telepathology, and finally diagnostic-quality digital slides.

The ability to digitize an entire pathology glass slide, thereby creating a whole slide image (WSI), has proven transformational and created many clinical, educational, and research applications. The CAP embraced digital pathology technology starting with the first commercial slide scanner, called the BLISS system, designed by James W. Bacus, PhD, in 1994. This technology changed medical student teaching of histology and introductory pathology. Prior to the introduction of WSI virtual microscopy, collections of glass slides were used with individual student microscopes. With virtual microscopy, all students could see the same high-quality specimen, appropriately annotated. As enhanced and improved technologies became available, the CAP partnered with DigitalScope™ in 2010 to offer state of the art cloud-based WSIs to support the CAP’s educational programs worldwide.

### **Regulatory Barriers and Advocacy**

Whole slide imaging usage continued to grow but there were roadblocks, including regulatory issues. A 2009 FDA public hearing regarding whole slide imaging resulted unfortunately in a Class III designation. Undeterred, CAP members and other organizations worked in support of digital pathology. At a CLIAC meeting on digital pathology, an overview of the pathologist’s perspective on digital pathology was well received. The CAP worked with the Digital Pathology Association (DPA) to improve interoperability and standards. Eventually the FDA allowed a de novo classification pathway for primary diagnosis, and as of this

writing there are two FDA-approved digital pathology systems.

More recent advocacy by the CAP has focused on COVID-19 and remote sign-out of whole slide images. The Digital Pathology and Informatics committees created a white paper which was used to lobby for regulatory relief within CLIA licensing and FDA approval of digital systems. Once again, the CAP’s advocacy efforts prevailed and the CMS agreed to exercise regulatory discretion, temporarily waiving CLIA regulations required for making diagnoses remotely at non-CLIA licensed locations.

### **Digital Pathology Workgroups**

The Council on Scientific Affairs (CSA) approved the creation of a series of work groups tasked with identifying the key digital and other technologies and applications that were projected to significantly impact pathologists and the practice of pathology in the next decade. The technologies identified were in vivo microscopy, next generation sequencing, and digital pathology. The workgroups identified a number of areas that should be considered when developing the scope and parameters of digital pathology. These topics included:

- Clinical applications for digital tools
- New test development
- International insourcing
- Standards for interoperability
- Medical and residency education
- CAP education/Proficiency Testing/publications

The strong efforts of the working groups coupled with the increased importance of WSI in pathology led to the formal transition to a CAP Committee in 2014. The charge of the Digital Pathology Committee (DPC) was to support the development by various CAP committees of programs, products, and requirements that contain digital pathology applications and will serve as a resource for the CAP public position on digital pathology applications and practice tools.

## Publications

Two publishing efforts by the CAP have helped to advance digital pathology. The first is the *Digital Pathology Resource Guide* (published in 2012). It is the resource book of choice on digital pathology for practicing pathologists who want to understand the field of digital pathology or are considering applying it in their practice. The guide is updated every 18 months and is free to CAP members. It is organized into eight sections: introduction, how to setup a digital pathology laboratory, lessons learned from subject matter experts, clinical applications, CAP resources and guidelines, regulatory resources, other educational resources, and insights from digital pathology adopters who are outside the United States. Each section begins with a discussion followed by journal articles summarized in abstract format.

The second CAP piece influential in advancing digital pathology was a pivotal paper published in 2013 in the *Archives of Pathology & Laboratory Medicine*, by the CAP Center. The paper provided 13 guidelines to assist the pathology community with validating WSI for clinical diagnostic use. Validation of WSI is a regulatory necessity to ensure that a pathologist using this technique to view digitized glass slides can consistently make the same clinical interpretation as they would from viewing the glass slides using a

traditional bright field microscope. A digital pathology resource page on the CAP website links to these publications and other activities.

## Standards and Accreditation

One of the roles of the DPC is to promote standards. To that end, the CAP serves as secretariat to the Digital Imaging and Communications in Medicine (DICOM) Standards Committee Working Group 26, whose goal is to promote DICOM standards to allow for interoperability between vendor systems. The CAP Digital Pathology Committee has created inspection checklists to reflect good laboratory practices. The checklists have undergone several revisions and now include items on validation, image analysis, virtual slide record retention, security, and patient confidentiality.

## DigitalScope™ Software

Because of the increasing importance of digital pathology, the CAP partnered with Imqis (International Medical Quality Improvement Systems) in 2011 to create digital pathology software called DigitalScope™. This state-of-the-art software is used to view whole slide digital images over the Internet in real-time. The CAP adopted the technology for continuing education and performance evaluation. The Hematology and Clinical Microscopy Resource Committee instituted peripheral blood virtual

Because of the increasing importance of digital pathology, the CAP partnered with Imqis (International Medical Quality Improvement Systems) in 2011 to create digital pathology software called DigitalScope™.



slide Proficiency Testing (PT) challenges in 2011. This was an attempt to more closely mimic the real world where peripheral blood and bone marrow cellular morphology are directly assessed using stained glass slides. The virtual smears have the advantage of allowing cells to be viewed in context—the entire feather edge of a glass slide is available for examination. White cell differential counts can now be performed virtually as can red blood cell morphology assessments. The program proved to be very successful and the DigitalScope™ software is now integral to many virtual educational and performance assessment programs, including surgical pathology, dermatopathology, Pap tests, non-GYN cytology, bone marrow, body fluids, parasitology, bacteriology, and sperm morphology. The software is also used for eLearning and the CAP's Case of the Month. Virtual images viewable with DigitalScope™ were incorporated into *Archives of Pathology & Laboratory Medicine* articles in 2012 and also extensively showcased in the second edition of the Color Atlas of Hematology.

## Artificial Intelligence and Machine Learning

Few phrases in the health care information technology world conjure up quite as much excitement and apprehension as “artificial intelligence” (AI); it has become a dramatic force throughout the health care industry. The CAP is anticipating these changes and helping to prepare members for this new, disruptive digital reality. There are now four groups within the CAP working on artificial intelligence, machine learning, and computational pathology.

The first is the Information Technology Leadership Committee (ITLC) that directly reports to the Board of Governors. The ITLC is structured to be agile in responding to the shifting landscape of various informatics and web-based activities, including artificial intelligence. AI has the potential to touch activities throughout the CAP, and the ITLC is intended to be the cross-council glue for coordinating, prioritizing, and aligning initiatives that benefit both the business of pathology as

well as the advancement of its members. A special AI/machine-learning project team was approved by the Board that will help develop mid-level strategy around how AI is created and leveraged to the greatest benefit of patient care. In addition, the project team will coordinate involvement with other non-CAP organizations such as the American College of Radiology, the Digital Pathology Association, and the Alliance for Digital Pathology, as well as AIMed to ensure that the CAP becomes and remains influential in AI activities affecting pathologists.

The second group is the Digital Pathology Committee which was renamed the Digital and Computational Pathology Committee in 2019 to reflect the increasing importance of big data and artificial intelligence. This committee focuses on digital pathology algorithms. It also has created a new quality improvement program for whole slide images (HQWSI). Participating laboratories submit stained and cover slipped glass slides and also upload their scanned whole slide images. An expert panel of committee pathologists evaluates whole slide image scans for quality.

The third group is the Artificial Intelligence/Anatomic Pathology Project Team, established in April 2019 by the CSA. Its role is to advise the CSA and the CAP generally about artificial intelligence/machine learning within anatomic pathology (AP). Its purpose is to delineate AI use cases in AP that are likely to arise in the near future, help develop AI validation standards, and potentially assist with federal regulatory activities of AI in AP.

Lastly, the Informatics Committee Machine Learning Working Group is writing an educational white paper on machine learning and developing a catalog of issues and problems that should be considered by a pathologist when implementing AI systems.

In 2019, the group hosted a meeting in Washington, DC. Participants included members from other CAP committees and work groups as well as representatives from the American College of Radiology and from the FDA.

The creation of these entities clearly shows the CAP's commitment to the exciting and challenging new world of artificial intelligence. It is hoped and expected that these initiatives will help to prepare the CAP and its membership for the new world of digital pathology and artificial intelligence.

### Social Media and Pathology

**The following section has been contributed by Jerad Gardner, MD, FCAP.**

I started actively using social media for pathology education in 2013. Back then, very few pathologists were using these platforms professionally. When I began, it was mostly a hobby; now, it is a significant part of my daily life and career. Over the past seven years, I have watched the global pathology community on social media grow and evolve in ways I never imagined. Pathologists who have never met “in real life” interact on Facebook like old friends and conduct research together despite living on different continents. Pathology residents and medical students interested in pathology can now have numerous practicing pathologist mentors, both private and academic, from many different institutions thanks to Twitter (at the time of this writing in 2020, there are over 6,000 pathologists on Twitter by my count). Twitter journal clubs like #pathJC allow pathologists from multiple countries to meet and discuss the peer reviewed medical literature. YouTube allows pathology educators to teach 24/7 by continually sharing the teaching videos they create for free globally even while pathologists care for their own patients, spend time with their families, or sleep. Even the most junior pathology resident can learn from and converse with some of the top pathology experts in the world using only their computer or smartphone. Social media has leveled the playing field by allowing all pathologists to have a voice and to hear the voices of others without paywalls, institutional hierarchies, or geopolitical boundaries. I view this democratization of pathology, medicine, and education as a positive innovation overall, but it may also be a disruptive one. The academic institutions, medical societies and organizations, research journals, and other activities we participate in will have to adapt to and accommodate this or risk becoming obsolete.

Social media is not a trend. Yes, Twitter or Facebook or YouTube could possibly be supplanted by new platforms in the future, but the actual heart of social media—the ability to share content with others online and to respond to the shared content—that is here to stay. For good or for bad, I do not believe we can go back to a world before social media now that people are used to interacting in this way. On the contrary, I foresee social media becoming so embedded into all of our daily activities to the extent that, in the not-so-distant future, social media will no longer be



Few phrases in the health care information technology world conjure up quite as much excitement and apprehension as “artificial intelligence” (AI); it has become a dramatic force throughout the health care industry.

New technologies will come and many will go, but it must forever be the people who are at the center of pathology.



considered a distinct, separate, novel thing. For many people, it is already viewed that way today. Just as physicians have had to adapt to using computers, email, internet, and smartphones in our personal and professional lives, so we must also adapt to using social media. It is a powerful tool that can be used for great good or great evil. Our students and residents will use social media, especially those “digital natives” of the coming generation who have never known a world without Wi-Fi, touchscreens, tablets, and smartphones. It is our responsibility to instruct them in the ethical and professional use of social media in ways that protect patient privacy and benefit society. If we as educators and mentors do not use social media ourselves, how can we possibly model the proper use of it for our mentees?

New immunostains, new molecular tests, whole slide imaging/digital pathology, artificial intelligence—all represent novel technologies that have reshaped our field dramatically over the years and will continue to do so in

the future. Social media may have potential for unofficial consultation particularly from underdeveloped countries. It is not likely that formal official consultation will take place in the developed world for legal, regulatory, and financial reasons.

New technologies will come and many will go, but it must forever be the people who are at the center of pathology. The joy and strength of pathology as a field revolves largely around our strong sense of community, our support of each other, our desire to push the boundaries of diagnostic medicine, and our eternal commitment to offering the highest quality of patient care. Social media does not replace face-to-face teaching or other traditional modes of interaction between us, but rather complements and enhances them dramatically. Whatever we are trying to accomplish in our own careers and in the field of pathology as a whole, I believe social media will allow us to do it bigger, better, faster, and stronger than ever before.



# EPILOGUE

## *Touching upon significant developments during the last quarter of 2020 and the first quarter of 2021*

### **The US faced many public health threats in 2020 and 2021: COVID-19, public violence, and racism.**

Battling a pandemic that claimed lives and livelihoods as well as systemic injustice reflected in morbidity and mortality statistics presented unique challenges to medicine and its practitioners. As a result of these challenges, new initiatives arose. This Epilogue will show how the CAP faced specific threats to the profession and in partnership with its members is laying the groundwork in several areas to support pathologists, customers, and most importantly, patients, for now and in the future.

### **Advocating for Pathologists During a Pandemic**

- The CAP launched another sustained lobbying campaign that is saving pathologists \$85 million in proposed Medicare cuts. When Medicare increased codes for physician office visits, codes for other areas—including pathology services—were proposed to get cut due to budget neutrality provisions. The CAP fought to mitigate those cuts, and now Congress has added \$3 billion to the 2021 Medicare fee schedule. CAP members were mobilized to delay the Medicare cuts that would have burdened pathologists and other physicians who are on the front lines of the pandemic. Because of CAP advocacy along with support from the American Medical Association (AMA) and other medical professional groups, Congress finalized bipartisan legislation that partially mitigated the proposed 9 percent cut to pathologist Medicare payments until the end of 2021. Over 400 pathologists sent 1,408 messages through the CAP Action Center to more than

300 members of Congress in support of this legislation. President Joe Biden signed the bill into law, offering critical relief to pathologists. The legislation also delayed implementation of a new evaluation and management add-on code for three years which accounted for 3 percent of the proposed 9 percent cut.

- The Biden White House outlined its national strategy for the COVID-19 response and pandemic preparedness. Representing pathologists who are at the forefront of diagnostic testing, the CAP engaged with the Biden administration on priorities for pathology and laboratory medicine. The CAP raised issues of problems with obtaining testing supplies, continued access to services, and the financial implications of the pandemic on laboratories. The CAP also responded to the new administration's public health efforts on health care disparities and global health security. Further, the CAP made the case for having a seat at the table to engage with administration officials and help inform health care policy decisions.

### **Leading in the Response to COVID-19**

- A new CAP Quality Cross Check program—SARS-CoV-2 Antigen (COVAQ) has been released and added to the existing COVID-19 programs. Many laboratories are performing SARS-CoV-2 antigen testing across multiple platforms—and, in some instances, multiple locations—due to volume of testing as well as severe shortages of staffing and availability of reagents and supplies. The Quality Cross Check—SARS-CoV-2 Antigen program enables laboratories to monitor performance of up to three assays at once, allowing them

to identify potential issues before they affect patient results. Moreover, this ensures the accuracy of all laboratories' COVID-19 tests for antigen detection—while conforming with CLIA regulations.

- CAP Regulatory Relief: The CAP was instrumental in successfully advocating for regulatory relief during the pandemic. Significant areas of relief included the ability for remote sign out by pathologists, allowing for accreditation inspection delays and virtual inspections, and for significant reduction in onerous laboratory result reporting requirements.

### **Social Justice, Racism, and Violence**

- During 2020 and 2021, the nation faced an unprecedented assault on democracy, continued racial injustice, and acts of violence against people of color and Asian-Americans as well as continuing evidence of anti-Semitism and discrimination against the LGBTQ community. Understanding that there are no easy, quick answers to some of these problems that have existed for centuries, the CAP took a stand with public statements of support for communities of color and in opposition to violence. Subsequent to the murder of George Floyd and other racially-motivated assaults on people of color and of Asian-Pacific Island origin, Dr. Patrick Godbey, the President of the CAP, wrote and issued the following statement: “The College of American Pathologists condemns racism, injustice, and discrimination in all their forms. We stand united against these despicable things. We are committed to diversity, equity, and inclusion. We are committed to mutual respect, listening, and understanding. As physicians, we work for the betterment of all people no matter their race, socioeconomic status, religion, gender, sexual orientation, or place of birth.”
- The CAP formed the first-ever Diversity, Equity, Inclusion (DEI) Committee to

support the visibility and participation of underrepresented pathologists, pathologists new-in-practice, and pathologists-in-training. The work of this committee involves the development of a pathology pipeline to build leadership in the CAP that reflects the rich diversity of our members. The ultimate goal is to ensure that the CAP is more diverse and equitable, enhancing a culture of inclusion where pathologists from underrepresented groups can fully contribute and thrive. Diversity in the profession fosters greater trust by patients-of-color and of diverse backgrounds, while also improving health care.

- Following mob violence and the insurrection at the US Capitol, 147 members of Congress voted to decertify the 2020 presidential election results. After exhaustive deliberation, the PathPAC Board made the decision to pause, indefinitely, its campaign contributions to those lawmakers. PathPAC has had and will continue a long tradition of bipartisanship in its support of candidates; however, PathPAC believes that in addition to being good stewards of the donations from CAP members, PathPAC also must reflect the values of the CAP. Those values represent a commitment to the democratic process as provided for in the US Constitution, including the peaceful transfer of power, which has been observed for over 200 years. In recognition of this, it was clearly affirmed that the College of American Pathologists abhors mob violence at any time and in any place.

### **Ensuring the Future of the Profession**

- Over the last ten years, there has been a significant drop in the number of US senior medical students and graduates applying for and matching in pathology residency programs. Declining interest in pathology as a specialty prompted the need for a strategy to address this potential risk to the profession. To encourage US medical students to choose

pathology as a specialty, the CAP has initiated the following:

- o Influencing adoption of new medical school curricula which introduces pathology earlier and gives exposure to pathologists and pathology practice
- o Proactively identifying and mentoring medical students with an interest in and/or aptitude for pathology
- o Establishing an annual CAP Pathology Award in medical schools to raise the visibility and stature of pathology among medical students and faculty

### **Keeping Members at the Forefront of New Technologies**

- Changes in technology and their impact on pathology and laboratory medicine are

constant. The CAP vigilantly tracks, prepares, and educates CAP members regarding ever-changing technology. To do so, CAP members in leadership and committee roles assess the best way to share information broadly and design resources to aid the pathology and laboratory medicine community. Several committees of the Council on Scientific Affairs as well as the Information Technology Leadership Committee and the newly created (2021) Artificial Intelligence Committee, serve as the intellectual hub to keep the CAP at the forefront of new and emerging technologies. One such current, and vital, instance of applying cutting-edge technologies: The CAP website and related learning initiatives continue to provide members with innovative educational programs related to COVID testing.





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COLLEGE of AMERICAN  
PATHOLOGISTS



### **Our Mission**

The College of American Pathologists (CAP), the leading organization of board-certified pathologists, serves patients, pathologists, and the public by fostering and advocating excellence in the practice of pathology and laboratory medicine worldwide.

### **Our Vision**

People are healthier because of excellence in the practice of pathology and laboratory medicine.