

Our Biannual Macro Trends in Anatomic Pathology

Learn about 15 powerful forces reshaping the AP marketplace!

New for 2008!

From the Desk of R. Lewis Dark...

THE DARK REPORT

**RELIABLE BUSINESS INTELLIGENCE, EXCLUSIVELY
FOR MEDICAL LAB CEOs / COOs / CFOs / PATHOLOGISTS**

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COMMENTARY & OPINION by...

R. Lewis Dark
Founder & Publisher



Creative Destruction in Anatomic Pathology

PATHOLOGISTS MAY BE FAMILIAR with the economic theory of “creative destruction.” They are aware of how “creative destruction” is at work transforming and reshaping both the anatomic pathology marketplace and the clinical lab testing marketplace.

Economist Joseph Schumpeter first used the term in his 1942 book *Capitalism, Socialism and Democracy*. He described how constant innovation and entrepreneurial activity continually eroded the market strength of leading companies. This quote from his book captures the concept of creative destruction:

“The opening up of new markets and the organizational development from the craft shop and factory to such concerns as US Steel illustrate the process of industrial mutation that incessantly revolutionizes the economic structure from within, incessantly destroying the old one, incessantly creating a new one ... [The process] must be seen in its role in the perennial gale of creative destruction; it cannot be understood on the hypothesis that there is a perennial lull.”

Economists have recognized the essential truths in Schumpeter’s concept of creative destruction. The incessant innovation he described is why the United States has seen such retailing juggernauts as **Montgomery Ward**, **Kmart**, and **Sears** achieve market dominance, then decline. Currently the retailing champ is **Wal-Mart**, yet innovations and energetic entrepreneurs are already at work creating retail enterprises that will eat away at Wal-Mart’s dominance.

Another feature of creative destruction is that it is painful. Leading companies, as they lose their edge to the up-and-coming innovators, must lay off employees, close facilities, and downsize. Schumpeter observes that this pain is generally short term and is a source of economic vitality for the capitalistic economy, because it means that employees will learn new skills and capital is being redirected toward more productive enterprises.

Why is creative destruction the topic of today’s opinion and commentary? Because, as I read the 15 key trends in anatomic pathology presented on the pages that follow, I can see the forces of creative destruction at work. A growing number of pathologists are experiencing financial pain as the economic position their group practice has enjoyed in recent decades comes under attack from innovators and entrepreneurs entering the anatomic pathology marketplace. Yet it is this incessant innovation that infuses new energy into anatomic pathology and continually raises its value proposition to the healthcare system.

Powerful Trends Reshaping Anatomic Path Profession

➤ **Innovations and a stream of new competitors are speeding the pace of change in pathology**

➤➤ **CEO SUMMARY: THE DARK REPORT presents its newest biannual review of macro trends reshaping the anatomic pathology profession. These macro trends reveal a profession undergoing change and transformation on multiple fronts. New competitors are crowding into the market, payers and accrediting agencies are demanding higher standards of performance, and a host of new technologies are helping pathologists deliver greater value to physicians and patients.**

By Robert L. Michel

THIS BIENNIAL PRESENTATION of macro trends in anatomic pathology delivers several powerful insights to the careful reader. Collectively, these 15 macro trends furnish compelling evidence that pathologists will see plenty of change in coming years.

Every second year, we provide pathologists and lab administrators with our best assessment of the most important strategic drivers in the anatomic pathology (AP) marketplace. 2008 is our fourth list of macro trends. It follows our 2006, 2004, and 2002 lists. (See TDRs, February 6, 2006, January 12, 2004, and January 7, 2002.)

It is no coincidence that this biennial list has expanded into 15 distinct macro trends in anatomic pathology. The

American healthcare system is undergoing rapid transformation. Thus, major shifts in health policy will filter down to influence the pace of change in anatomic pathology.

Our recommendation to pathologists and their practice administrators is that they use this list of anatomic pathology macro trends in a strategic planning session. It provides useful context to evaluate your laboratory's current market position and business strategies against the macro trends presented on the following pages.

In 2006, I concluded this introduction by observing that these trends pointed "to a faster ride in the second half of this decade than in the first." That has proven true and is on track to continue! **TDR**

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THE DARK REPORT Intelligence Briefings for Laboratory CEOs, COOs, CFOs, and Pathologists are sent 17 times per year by The Dark Group, Inc., 21806 Briarcliff Drive, Spicewood, Texas, 78669, Voice 1.800.560.6363, Fax 512.264.0969. (ISSN 1097-2919.)

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SUBSCRIPTION TO THE DARK REPORT INTELLIGENCE SERVICE, which includes THE DARK REPORT plus timely briefings and private teleconferences, is \$13.10 per week in the US, \$13.70 per week in Canada, \$14.85 per week elsewhere (billed semi-annually).

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-state of the pathology profession-

KEY TREND 1

National Anatomic Pathology Firms Capture Growing Share of Market

PATHOLOGY'S FASTEST-GROWING SECTOR involves investor-financed laboratory companies organized to compete for anatomic pathology (AP) specimens nationally. This class of companies emerged in the mid-1990s and has enjoyed sustained success.

This trend can be easily recognized in another way, by looking at those laboratories and pathology group practices enjoying rapid growth in AP case referrals and revenues. During the past decade, the biggest and fastest growing AP providers have been **Laboratory Corporation of America** and **Quest Diagnostics Incorporated**.

The two blood brothers have used three primary strategies to expand their presence in the anatomic pathology market. One strategy is by acquisition (**Dianon Systems** and **US Labs** were purchased by LabCorp and **AmeriPath** was bought by Quest Diagnostics). A second strategy has been to stop outsourcing AP specimens to local pathology groups in different communities around the country and bring these specimens in-house. The third strategy is to encourage their sales reps to increase the number of accounts referring AP specimens.

Since the year 2000, both Quest Diagnostics and LabCorp significantly expanded their share of the national anatomic pathology market. This growth in market share can be illustrated by the number of pathologists employed at the two companies. In 2000, both companies together probably employed an estimated 300 to

400 pathologists. Today, the two blood brothers together employ as many as 1,200 pathologists.

Other national and regional AP companies have also enjoyed this type of steady growth in specimen volume. That's been the case at two publicly traded AP companies, **Clariant, Inc.** of Aliso Viejo, California, and **NeoGenomics, Inc.**, of Fort Myers, Florida. Another pathology company with steady growth is **CBL Path, Inc.**, of Ocala, Florida. Formed in 2002, it now has estimated revenues approaching \$40 million for 2007.

It should be noted that several regional pathology supergroups have posted comparably strong growth rates in case volume and revenues during this decade. But what sets these local pathology practices apart from their peers is that they willingly consolidated into a fairly large size, frequently with more than 20 pathologists in the group. This number gives them the scale to support multiple pathology subspecialty services and at the same time devote considerable resources and money to sales and business development.

The steady growth in the number of regional and national companies offering anatomic pathology services this decade sends a message to smaller pathology group practices, particularly those which serve just one or two community hospitals. Referring physicians are becoming more educated about the AP choices available to them. They are no longer automatically loyal to the pathologists working in their local hospital.

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KEY TREND 2

Specialty Doctors Actively Entering The Anatomic Pathology Business

SPECIALIST PHYSICIANS HAVE DISCOVERED anatomic pathology (AP) as the newest ancillary service gold mine. Across the nation, urologists, gastroenterologists, and other medical specialists are actively establishing in-house anatomic pathology laboratories.

This trend first surfaced around 2003 and has continued to gather momentum with each passing year. Specialist physicians, such as dermatologists, urologists, and gastroenterologists, are a leading source of anatomic pathology case referrals. For that reason, their heightened interest in establishing in-house anatomic pathology laboratories will have a long term effect on the pathology profession.

Back in 2003, the most visible development was the emergence of anatomic pathology laboratory condominiums (pod labs) in 2004. (*See TDR, July 19, 2004.*) However, a negative advisory opinion by the Office of the Inspector General (OIG) in December 2004 dampened the interest of specialist physicians in this type of anatomic pathology arrangement. Since then, establishing an in-clinic pathology laboratory has been the preferred way for specialist physicians to capture revenues from anatomic pathology services generated by their patients.

"There's no question that specialty doctors are doing more and more of these kinds of arrangements," says Joe Plandowski, President of **Lakewood Consulting Group** in Lake Forest, Illinois. "Specialty docs are no

different than pathologists in that they are all under reimbursement pressure. They recognize that doing AP testing in-house is a way to maintain and increase their income."

Plandowski also sees another dimension to this trend. "Certainly revenue is a major reason why specialist physicians decide to invest time and resources into establishing an in-house anatomic pathology service," he observed. "But they quickly identify other benefits to such arrangements. First, they have control over turnaround time for results. Second, it eliminates the hassles of determining which referral lab has which managed care contract. Third, some of these groups quickly grasp that they can improve the consistency and quality of their AP diagnoses."

The trend of specialist physicians establishing in-clinic pathology laboratories will have profound implications for the pathology profession. For example, it changes a long-standing custom of referring pathology specimens to a local pathology group. Now the specialist group engages a pathologist, in some manner, to travel to its office to perform pathology professional services.

Of course, several events can derail or redirect this trend. Medicare officials and private payers are scrutinizing these arrangements and establishing restrictive coverage and reimbursement policies. State by state, pathologists may also be able to encourage scope of practice legislation that constrains physicians from operating an in-clinic AP laboratory.

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KEY TREND 3

Increased Number of Employed Paths May Tip Balance in Pathology Profession

SINCE ITS INCEPTION, the profession of anatomic pathology (AP) has been largely one of private practice pathology groups. The overwhelming majority of pathologists were partners in their groups.

Thus, in what ways will the pathology profession change as the proportion of employed pathologists grows relative to the proportion of private practice pathologists? That question will soon come front and center in policy discussions within the pathology profession.

That's because this decade has seen spectacular growth in the number of employee-pathologists. As noted in AP Trend 1, the number of employee-pathologists at **Laboratory Corporation of America** and **Quest Diagnostics Incorporated** climbed six-fold in the past eight years, now pushing past 1,200 employee-pathologists between the two lab companies. (See page 5.)

There are comparable growth rates in the collective number of employee-pathologists at investor-funded pathology companies launched since 2000. These enterprises use employee-pathologists and, as their sales programs generate greater volumes of specimens, these pathology firms then recruit additional employee-pathologists to perform that work.

There is another phenomenon supporting this gradual shift away from private practice pathology and toward employee-based pathology. Both Generation X and Generation Y pathologists tend to be much more

accepting of employee-based pathology opportunities than were baby boomer pathologists upon graduation from medical school.

As the number of employed pathologists grows relative to the number of private practice pathologists, a tipping point will eventually be reached. The tipping point will mean that the professional goals and concerns of employee pathologists will then compete for attention with the professional goals and concerns of private practice partner pathologists.

When this tipping point is reached, associations such as the **College of American Pathologists** (CAP), **Association of Clinical Pathologists** (ASCP), and others will find themselves needing to be responsive to the different professional concerns of employee pathologists versus private practice partner pathologists. The national agenda of anatomic pathology will need to reflect the specific interests of each group.

Further, as was true in the 1990s, this decade has seen relatively few pathologists become entrepreneurs. This trend represents a marked difference to the 1970s and 1980s, when pathologists regularly banded together to launch clinical laboratory enterprises.

The relative lack of pathologist entrepreneurs in recent years is another sign that the pathology profession may be on an irrevocable path toward a new practice model. The pathology profession may soon find that it is dominated by pathologists working as employees, not as partners in private group practices.

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KEY TREND 4

Ongoing Lab Consolidation Increases Pressure on Small Pathology Providers

IN THE 1990s, THE AMERICAN HEALTHCARE SYSTEM UNDERWENT a transformational period of consolidation. However, one notable holdout from this widespread consolidation was the anatomic pathology profession.

It was widely recognized during the 1990s that private pathology group practices were generally unwilling to form consolidated “super groups” with their colleagues in most cities. In fact, most community hospital-based private pathology practices were emphatic in their resistance to merging their group with one or more pathology groups that also served the local community.

Yet, during the 1990s, almost every sector of healthcare experienced substantial consolidation. This was true of hospitals and independent laboratories. Individual medical specialties regularly came together to create larger practice entities. This was also true of primary care physicians, orthopedic surgeons, ob-gyns, urologists, and gastroenterologists, to name a few specialties.

These providers were reacting to the contracting practices of private payers. During the heyday of the closed-panel, gatekeeper model HMO (health maintenance organization), with its capitated pricing and full-risk utilization, it was sound business strategy for providers to consolidate into larger organizations. Forming larger groups increased their clout during managed care negotiations.

However, unlike physicians in other medical specialties, pathologists

were almost unique in their resistance to the consolidation trend. Today, the pathology profession is seeing the consequences of their resistance to consolidation.

As documented on the pages of THE DARK REPORT for the past 13 years, consolidated “super practices” have important business advantages. Among them are economies of scale, expanded in-house test menu, the ability to support several pathology subspecialties, capital to fund effective sales and marketing programs, along with capital to acquire enriched information technology.

Community hospital-based pathology groups of fewer than five or six pathologists struggle to generate adequate amounts of capital needed to sustain these types of business advantages. Contrast that with the larger consolidated pathology groups that boast 20 or more pathologists. In most cases, these consolidated pathology groups are thriving. They enjoy sustained growth in specimen volume and have enough scale to offset declines in per-case reimbursement—thus preserving the individual incomes of their partner pathologists.

Meanwhile, investor-funded pathology companies are entering the marketplace. Not only are these companies willing to outspend smaller local pathology groups on sales programs, but they continually add pathologists as their specimen volume increases. This is another form of consolidation and is one source of sustained market pressure on local pathology groups.

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KEY TREND 5

Decline and Fall of the Community Hospital-based Pathology Group

MARKET FORCES CURRENTLY IN PLAY will diminish the long-standing dominance of community hospital-based private anatomic pathology (AP) group practices.

In simplest terms, the most dynamic and fastest-growing segments of the anatomic pathology marketplace do not include community hospital-based pathology groups. Over time, faster growth in these other sectors of AP will steadily reduce the existing share of the AP marketplace held by community hospital-based pathology groups.

In recent decades, the overwhelming majority of anatomic pathologists were partners in private group practices. These group practices were typically anchored in a community hospital which generated the lion's share of case referrals.

In fact, coming into the 1990s, community hospital-based pathology groups and academic pathology groups represented nearly all the anatomic service providers in the United States. There were only limited examples of pathology businesses that were not organized around either a community hospital or an academic or tertiary teaching center.

What a difference 18 years has made! Today, a pathologist emerging from medical school has a growing number of pathology business models from which to choose. For example, between them, the two blood brothers are now the largest private employers of anatomic pathologists in the world. **Quest Diagnostics Incorporated** (which acquired **AmeriPath, Inc.** last year) employs upwards of 900 patholo-

gists. **Laboratory Corporation of America** employs more than 300 pathologists. Together, these two companies employ about 9% of the approximately 14,000 board certified pathologists in this country!

Another career opportunity is to work at the steadily growing number of national anatomic pathology companies, also as an employee. These companies range from **Clariant, Inc.** and **CBL Path, Inc.** to **Bostwick Laboratories, GI Partners, Inc.**, and **OUR Laboratories**.

Another fast-growing segment is comprised of specialty pathology companies. Some of these AP firms offer esoteric AP tests regionally. Others are often organized around patent-protected or proprietary diagnostic technology. These companies are posting strong rates of growth in both specimens and revenues. They regularly recruit pathologists to work as employees as they expand their workforce to handle the increasing number of case referrals.

All of these facts support a key point about this trend: the least dynamic sector of the anatomic pathology marketplace is currently that of the community hospital-based private pathology group practice. Without effective business strategies, it appears that community hospital-based pathology group practices will continue to lose market share.

Several factors could offset this trend. In particular, if smaller pathology groups in a community decided to consolidate into a large "super-group," they would enjoy several competitive advantages.

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KEY TREND 6

Patented & Proprietary Test Technology Is Fueling Growth in Specialty Pathology

SPECIALIZED PATHOLOGY TESTING is one of the fastest-growing sectors in anatomic pathology today. Much of this specialized testing is offered in the form of patent-protected or proprietary test technology, which limits access to this technology by most local and regional pathology group practices.

Molecular technologies are the primary fuel for the growth of proprietary diagnostics. Because genomics is in its infancy, this is a pathology trend which is likely to last a long time and be transformational across all of laboratory medicine.

One of the earliest examples of patent-protected diagnostics incorporated genetic technology are the BRCA assays for breast cancer offered by **Myriad Genetics, Inc.** of Salt Lake City. Myriad launched this testing prior to 2000. Today, its diagnostics division is generating revenues of about \$200 million per year.

Since 2000, the number of companies offering patent-protected or proprietary diagnostics has increased steadily. Examples include **Signature Genomics** of Spokane, Washington; **Genomic Health, Inc.**, of Redwood City, California; and, **RedPath Innovative Pathology, Inc.**, of Pittsburgh, Pennsylvania.

For the pathology profession, this trend has an upside and a downside. The upside is that these assays—where they have demonstrated clinical value and are cost-effective—will expand demand for pathology services. The downside for the pathology profession is the restricted access that

most local pathology groups will have to patent-protected or proprietary assays. There are likely to be situations where a patent-protected assay becomes a high demand, gold standard for clinical care, yet that assay can be accessed only through a single laboratory provider or a limited number of licensees.

Some experts predict that proprietary diagnostics are likely to become a major channel for how new lab test technology comes into the clinical marketplace. In the same way that the pharmaceutical industry has used patent-protected therapeutic drugs to build profitable businesses, experts believe this same business model can be successful in clinical diagnostics.

But patented and proprietary tests have historically not comprised a large share of the overall market for laboratory testing. Until recently, laboratories generally had multiple options for setting up and offering a certain type of laboratory test. So the unknown factor in this trend to bring patent-protected and proprietary assays to market is how local laboratories and pathologists react.

Further, both Medicare and private payers are raising the bar on new laboratory tests before establishing coverage guidelines and reimbursement. Thus, it will be up to the test developers to demonstrate significant clinical value for their assays.

Patent-protected and proprietary AP tests represent a new dimension to the AP marketplace. They are likely to further alter long-standing case referral patterns.

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KEY TREND 7

Smaller, Local Pathology Groups Using New Technologies to Expand Services

DIGITAL TECHNOLOGIES ARE FOSTERING a new model of practice that allows pathologists to stay local and take advantage of sophisticated equipment and expertise located offsite.

As a pathology trend, virtual microscopy is one of several developments that give smaller, local pathology groups needed capabilities to compete locally, regionally, and even nationally. Virtual microscopy, along with similar types of technologies, allow local pathology groups to offer state-of-the-art anatomic pathology diagnostic services to their clients.

A number of national pathology companies are developing a collaborative model of practice specifically designed to allow smaller pathology groups to offer their referring clinicians state-of-the-art pathology services. In such arrangements, the local pathology group refers the specimen to a national pathology company, which does the technical component (TC) services. It produces digitized images which are accessed by the referring pathology group, allowing them to provide the professional component (PC) services.

Back in 2001-02, **USLabs** pioneered this collaborative service model as a way to compete against **Impath, Inc.** At that time, Impath performed both the TC and PC services for cancer cases referred to it by pathology groups. By offering to perform the TC and digitizing the results to allow the referring pathologist to perform the PC, USLabs hoped to gain competitive advantage.

At that time, it was the Automated Cellular Imaging System (ACIS) made by **ChromaVision Medical Systems, Inc.** (now made by **Zeiss Microimaging, Inc.**) that USLabs used to digitize the images and make them available to referring pathologists for analysis.

Inspired by how pathologists accepted this TC/PC business arrangement for sophisticated diagnostic technologies, Clariant organized its own national pathology laboratory in 2004 and began offering a TC/PC arrangement. Several other national pathology companies have introduced their own form of TC/PC arrangements.

These developments are significant for several reasons. First, it demonstrates how a local pathology group can use technology to allow it to deliver a full menu of technologically advanced pathology services to its clients. Second, at a time when molecular technologies are requiring pathologists to supplement standard pathology procedures with more advanced diagnostic tests, this intra-pathology TC/PC concept permits smaller pathology groups to provide all the comprehensive diagnostic information needed by the referring physician.

This trend shows how new technologies can change the competitive balance in anatomic pathology. The marketplace is always a moving target and, even as some trends weaken the competitive position of local pathology groups, other trends will provide local pathologists with ways to increase their competitive position.

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KEY TREND 8

Tidal Wave of Genomic and Molecular Technologies Nears Clinical Introduction

GENOMIC MEDICINE WILL TRIGGER a paradigm shift in the anatomic pathology (AP) profession, but in ways that are different than the current popular wisdom.

Progress in molecular diagnostics has been swift since the first complete sequence of the human genome was published in February 2001 in the journal, *Science*. By studying DNA, RNA, and proteins, researchers are discovering pathways and markers for a host of cancers, infectious diseases, and other human maladies.

Since that milestone event, progress in genomic medicine has been swift and continues to accelerate. Each new discovery and insight becomes the basis for another round of discoveries. Modern medicine is in the early stages of an exponential curve in the expansion of knowledge. Laboratory medicine sits at the center of this activity, since lab tests are needed for physicians to understand the DNA, RNA, and proteins of their patients.

One way to understand how different the world of genomic-based diagnostics will be compared with laboratory medicine as it has been practiced is to look at the new language which anticipates and describes the world of genetic medicine. The concepts defined by such terms as personalized medicine, pre-symptomatic diagnosis, genetic pre-disposition, theranostics, and pharmacogenomics are expected to become reality within a few years.

Using these terms as a guide, one outcome of genetic medicine is that pathologists will be more intensely involved in the patient care continuum.

Moreover, as suggested by these terms, tests will need to be conducted to determine whether disease is present and, if so, whether the individual patient is a candidate for specific therapies.

Next, the breakdown of the wall that traditionally defined the clinical laboratory from the anatomic pathology laboratory will continue as the use of genetic technologies expands. One sign of how this will occur is the variety of specimen types that will be used to develop diagnostic knowledge. Recently, multiple research teams have published their findings on how saliva testing can be used to identify several different types of cancer. Similarly, other researchers have identified markers in blood specimens that are good indicators for certain cancers.

Then there is the location at which diagnostic testing occurs. A number of biotech firms are working to develop assays and instrument systems that can be used outside the traditional central laboratory. These assays and instrument systems are also being designed to deliver results in real time.

Add it up! The medical vocabulary is adding terms that require a new type of laboratory medicine. Researchers are finding new markers in specimen types that traditionally did not yield that type of knowledge. And, assays and analyzers using new technologies will take more testing—and very complex testing—out of the central laboratory and nearer to the patient. These are undeniable signs of how anatomic pathology will undergo fairly radical changes in coming years.

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KEY TREND 9

Automation in Histology Will Support New Anatomic Pathology Technologies

HISTOLOGY IS AN AREA that has been slow to change. But now, histology laboratories are struggling to cope with an absolute shortage of trained technical labor, even as they must process a rapidly growing number of cases.

Histology automation is gaining favor and not just because it helps improve the productivity of labor. Histology labs that use automation effectively can reduce overall turnaround (TAT) time, lower costs, and improve quality.

However, none of this could happen if there were no histology automation solutions available. In recent years, manufacturers have stepped up with automated systems that can be used to achieve the goals described above.

One trend catching the interest of pathologists and histology lab managers is the ability to process smaller batches of specimens in shorter periods of time. This type of automation solution is often incorporated by labs using Lean and Six Sigma methods, because small batch and single piece work flow is an essential requirement for success.

"More labs are moving away from the traditional batch system where tissue was placed into the processor at 4 p.m. and not seen again until early the next morning," stated Gilles Lefebvre, VP, Sales Marketing, and Customer Relations for **Sakura Finetek U.S.A., Inc.**, in Torrance, California. "Now, labs can use automated processors which run constantly throughout the day. This is a major change from the previous way of handling tissue."

Histology productivity can increase dramatically with the right automation solution. "A histotechnologist working at peak efficiency can do about 30 to 40 biopsies per hour," noted Lefebvre. "Our Tissue-Tek AutoTEC Automated Embedding System performs at the rate of 120 blocks an hour and it doesn't matter if a lab has loaded a small biopsy or a larger piece of tissue."

Molecular diagnostics is another factor that is increasing the demand for histology automation. The precision of molecular technologies means that standardization of tissue harvesting and tissue processing becomes integral to producing accurate, reliable results than can be reproduced over time.

Automation of histology work processes supports this improved standardization. It also reduces variability, particularly variability that can be attributed to how different histotechnologists process specimens.

Yet the path to full automation in the histology laboratory faces a daunting obstacle. Traditionally, histology has been a labor-intensive service and has not required much capital investment. In order for histology labs to acquire and deploy automated solutions, they will need to convince hospital and health system administrators to invest the required capital.

Thus, the pace of adoption of automation in histology is likely to be slow during the next few years. That will change, once histology labs publish data on the improvements in TAT, quality, labor productivity, and reduced costs attributed to automation.

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KEY TREND 10

Full Digitization of Images and Info Will Transform Anatomic Pathology

NEW DIGITAL technology is changing the way pathologists work. Rather than having to be in the same room with specimens, this technology allows pathologists to work remotely. Viewing digital images allows a pathologist to pan and zoom just as one would do when working with a glass slide under a microscope.

But also, the technology has significant implications for an industry facing a labor shortage because viewing digital images eliminates travel and saves shipping costs. "A pathologist who spends his morning at one hospital and then goes across town to read slides at another facility may not have to make that drive anymore," said Ole Eichhorn, Chief Technology Officer of **Aperio Technologies Inc.**, a company in Vista, California, that specializes in digital pathology. "Pathologists in rural areas who literally spend every day of the week in a different location don't have to do that anymore. It has the potential to have a significant impact on the pathology profession as more pathologists become familiar with it."

One thing that sets this generation of technology apart from earlier telepathology/pathology digitization products is the ability to pull in only the data sets needed by the pathologist. Eichhorn says, "think Google Maps! You start by panning and zooming across a large image in Google maps. You don't have to download the entire dataset of Google maps to find the nearest pizzeria. The same thing happens with digitized pathology images. Pathologists don't need to see the whole image at high resolution. They can pan

the image at lower resolution, then zoom in on areas of interest."

One factor that will drive acceptance of digitized pathology images and information is its use in academic and tertiary care centers for teaching and research purposes. In fact, pathology professors are reporting that some medical school students lack proficiency at using a microscope, because all of their learning is coming from digitized pathology images. The widespread use of digital pathology images in medical school guarantees that newly graduated pathologists will be intimately familiar with working from digitized images and sharing cases with their peers.

This technology trend may also help smaller, local pathology groups. Because the pathologist doesn't have to physically move to a location where the glass slides are located, digitized pathology images can support a "virtual practice." It can allow a pathologist in any locale to read and report out any case that is presented in digital form. Further, full digitization of pathology images makes it possible for a nationally prominent subspecialist pathologist to maintain a successful practice in any geographic location, so long as there is access to the Internet and telecommunications.

This key trend is another example of how technology and clinical practices can evolve in ways that support smaller pathology group practices. To gain advantage, however, such groups will need to invest in the technology needed to incorporate digital pathology images into their practice routine.

*-state of the pathology profession-***KEY TREND 11**

Personalized Medicine Will Require Different Attributes by Pathologists

GENOMIC MEDICINE is a major force now transforming anatomic pathology (AP). As part of this transformation, pathologists will need to utilize different professional attributes in their clinical practice.

In particular, molecular diagnostics and molecular pathology will take many pathologists away from their microscopes. As molecular technologies are used to diagnose a greater range of diseases and medical conditions, pathologists will find themselves required to interact with clinicians in a more active, consultative role.

Further, these interactive consultations are likely to keep the pathologists engaged in the cases of individual patients over an extended period of time. That's because, in the era of personalized medicine, the molecular tests will guide the clinician as to: a) the best therapy for an individual patient; and, b) how well the patient is responding to the chosen therapy.

For these reasons, the arrival of personalized medicine will create the need for pathologists with a different set of skills and attributes. On the skill side, pathologists will obviously need to be expert in genetic testing based on DNA, RNA, and proteomic analysis. On the attribute side, pathologists will need to be more interactive with clinicians, and members of the care team, as well as the patient.

This will be a shift in the long-established attributes that marked successful anatomic pathologists. That is because cell morphology has been the basis for much of the diag-

nostic services delivered by pathologists in recent decades. Anatomic pathologists relied heavily on microscopic analysis of tissue to determine disease and guide clinical decisions.

Typically, the diagnosis could be provided in a narrative report that provided the referring physician with most of the clinical information he or she needed. Thus, productive anatomic pathologists could spend the majority of their day working independently in front of a microscope. They would evaluate samples, prepare reports, and field a limited number of phone calls from physicians seeking to discuss specific cases.

As molecular technologies crowd aside cell morphology as another way to make a diagnosis, anatomic pathologists will find themselves interacting more with the referring physician. In fact, advances in personalized medicine are likely to require pathologists to interact with multiple members of the patient's care team to conduct joint reviews, to discuss the diagnosis, to select appropriate therapies, and to review the patient's progress.

Along with more interaction with other members of the care continuum, anatomic pathologists are likely to assume a role as integrators of a wide range of diagnostic inputs. This is beginning to happen in selected academic and tertiary care center environments. In fact, as healthcare policy encourages more integration of care, pathologists will have the opportunity to apply their knowledge of laboratory medicine in ways that add significant value to physicians and their patients.

*-state of the pathology profession-***KEY TREND 12**

Gen X and Gen Y Pathologists Soon To Move into Path Leadership Roles

TENSION IS GROWING among physicians in many medical specialties as established baby boomer doctors increasingly find themselves practicing with Generation X and Generation Y doctors who have very different career objectives and work habits.

Outside of pathology, this trend is already recognized by many medical specialties. Because of population demographics, it will soon play a greater role in the operational dynamics of pathology group practices.

Many established physician groups are learning that it is challenging to find and attract younger doctors who are willing to work the long hours that baby boomer physicians readily accepted when they graduated from medical school. Younger physicians want regular hours, which means no nights or weekends on call. This is not the same issue for pathology groups as it is for, say ob-gyns, who often exceed 80 hours per week handling professional duties.

Nevertheless, pathologists should be aware that Generation X physicians (born between 1965 and about 1980) and Generation Y physicians (born between 1981 and about 1995) have very different value systems, work ethics, and career goals than the baby boomer physicians (born between 1946 and 1964) who currently hold most of the authority positions in medical group practices.

"Many younger physicians today do not share the priorities of older physicians," said Ronald Watson, J.D., M.Ed., CEO and Managing

Partner of **Medical Search Consultants Unlimited, Inc.** in Cleveland, Ohio. "Younger physicians tend to be more interested in lifestyle, compensation, and flexibility in practice style. They tend not to bring up long-term job security as a priority."

Physician recruiters have said a significant number of older physicians are more concerned with maintaining their income levels while also seeking to pass off the more onerous aspects of working in a practice. In private practices, these older physicians want incoming younger physicians to work long hours. This creates a mismatch in expectations.

"For younger physicians, the key considerations are lifestyle first, compensation second, flexibility in practice style third, and security is often fourth," Watson said. "That list of priorities is somewhat different from the priorities of older physicians. Older physicians started out wanting job security and compensation. Lifestyle and flexibility in style were lesser concerns."

One factor that could complicate the issue is the influx of women into medicine. "Women who practice medicine and start families often want more time off when their children are young, compared with male physicians," noted Watson. "This definitely affects physician productivity and creates its own set of unique issues."

Pathology is at an unusual demographics crossroads. The work habits and career goals of Generation X and Generation Y pathologists are likely to aggravate the supply-demand problems long predicted to occur in the pathology profession as baby boomer pathologists retire in increasing numbers.

-state of the pathology profession-

KEY TREND 13

Medicare Officials Hammer Down On Anatomic Pathology Marketplace

IN RECENT YEARS, perceived abuses in anatomic pathology (AP) referral arrangements seem to have the full attention of federal health regulators. From AP condo/pod labs to TC/PC deals, business practices involving AP specimens are in the gunights of Medicare officials.

Thus, one important trend to watch in 2008 is federal efforts to limit arrangements involving physicians who collect revenue from AP services provided to their patients. The federal **Centers for Medicare & Medicaid Services** (CMS) is taking steps to constrain and control these types of physician referral arrangements.

CMS published a number of physician anti-markup rules in its 2008 Medicare Physician Fee Schedule last fall. Several of the antimarkup rules specifically addressed anatomic pathology arrangements. (*See TDR, November 19, 2007.*) However, during the public comment period, CMS realized that these rules, as written, were likely to create considerable confusion and would have unintended effects that could disrupt long-standing arrangements between hospitals and their pathology groups.

Thus, CMS announced that the scheduled implementation of January 1, 2008 for physician anti-markup rules would be delayed until January 1, 2009—with one exception. Antimarkup provisions that specifically addressed the business model of the off-site anatomic pathology condo (pod) lab were implemented as scheduled.

In response, during January, one of the primary operators of AP condo

laboratory complexes filed a lawsuit in federal court seeking injunctive relief from the anti-markup provisions. That court case will be watched with interest by the pathology profession.

It should be noted that, although pathology has been singled out specifically for the AP condo/pod lab anti-markup regulation, it is not the only medical specialty about which CMS has concerns. Radiology is undergoing similar scrutiny.

In recent years, office-based physicians have established in-house radiology services, along with pathology services. CMS officials believe these types of arrangements can result in higher utilization due to physicians ordering medically unnecessary procedures. Patient care can also suffer if patients do not get the appropriate quality of radiology and pathology professional care from the physicians' in-clinic radiology and/or pathology service.

As the Medicare program takes steps to correct what it perceives to be abuses in how office-based physicians establish and use in-house anatomic pathology services, the pathology profession faces a double-edged sword.

On one edge, it can benefit if Medicare officials get it right and promulgate clear, definitive regulations governing how physicians mark up AP services provided to their patients. On the other edge, pathologists could lose their ability to mark up technical and professional services that have been at the core of specimen referrals between hospitals and other pathology groups. This would be a significant setback for many pathology groups.

*-state of the pathology profession-***KEY TREND 14**

Lean, Six Sigma Management Methods Find Growing Acceptance in Pathology

AS A TREND, USE OF LEAN AND SIX SIGMA METHODS is in its infancy on the anatomic pathology side of the laboratory medicine house. However, in recent years, an ever-growing number of hospitals and pathology groups have taken active steps to introduce these management tools into their operations.

There are at least three primary paths for how Lean and Six Sigma take root within an anatomic pathology setting. First, it is common for the clinical laboratory in a hospital to be the first service to implement Lean and Six Sigma methods into management thinking and work flow redesign.

Since the medical director and laboratory administrator often also have responsibility for histology, their experience with Lean and Six Sigma in the high-volume core lab gives them the perspective to recognize the opportunities for using these same methods in histology and anatomic pathology. The success of Lean/Six Sigma projects in the core laboratory also gives them confidence that they can apply these quality management methods with comparable success in histology and anatomic pathology.

Second, because of sustained pressure on reimbursement, the inadequate supply of technical labor, and rising costs, larger pathology groups are often quick to recognize how quality management systems such as Lean and Six Sigma can help the laboratory operate more efficiently. These pathology groups want to consciously drive ongoing improvement in their work flow and laboratory operations.

The third reason is rooted in the need to deliver high quality outcomes and reduce the rate of errors. Hospitals, reacting to higher performance standards required by accrediting agencies, are measuring many clinical services in greater detail and more frequently than ever before. This often brings new attention to existing error rates in histology and anatomic pathology. Adoption of Lean and Six Sigma methods is one way a pathology laboratory can successfully lower errors and boost quality.

In fact, as Medicare and private payers require that the performance of healthcare providers be made public, including that of anatomic pathology laboratories, there will be ample motivation to use quality management methods to reduce errors, increase quality, and contribute to improved patient outcomes.

Perceptive pathologists already see this coming and are positioning their laboratory organizations to be ahead of this curve. Their strategy of choice is to use quality management systems such as Lean and Six Sigma.

One interesting example is at **Henry Ford Medical Center** in Detroit, Michigan. Led by Richard J. Zarbo, M.D., Senior Vice President for Pathology and Laboratory, there has been substantial progress on reducing work flow errors and other recurring problems in surgical pathology. Because of the demonstrated power of Lean and Six Sigma methods to support world-class performance, pathology groups should be taking active steps to introduce these methods into their laboratories.

-state of the pathology profession-

KEY TREND 15

Challenges from Increased Specialization, Shortages of Pathologists & Tech Labor

THIS TREND ADDRESSES MANPOWER AND HUMAN RESOURCE NEEDS of the anatomic pathology (AP) profession. Impending shortages of pathologists, an existing lack of skilled technologists, and a rapid evolution in AP professional skills are key challenges tied to this trend.

Although pathologists and their practice administrators are well-informed about these issues, they are less aware of the indirect responses other pathology groups are using to address these challenges. Across the nation, these issues are influencing the strategies of pathology group practices.

Specialization is an interesting example. In earlier biannual reviews of anatomic pathology trends, THE DARK REPORT has called attention to the increased demand for pathologists with subspecialist skills. This is a direct reflection of market demand and one sign that the heyday of the generalist pathologist is nearing its end.

On the other hand, subspecialization is a strategy that allows the pathology profession to produce more work from individual pathologists. By being intimately familiar with the case mix generated by urology or gastroenterology, for example, a subspecialist pathologist can be expected to report out a larger number of cases in that specialty than a generalist pathologist.

To cope with the existing shortage of skilled technical staff, such as histotechnologists, the pathology profession has several strategies. One is to use automation in more areas of histology and anatomic pathology. A second strategy is to utilize quality management methods and rapid

process improvement engineering techniques in the work flow in histology and anatomic pathology. Both strategies can improve productivity and quality while reducing the number of trained technical staff required to process that volume of work.

A more challenging issue is how to stay current with the rapid evolution in professional skills required to maintain state-of-the-art pathology diagnoses. The rapid advances in molecular diagnostics illustrate how fast the underlying science can advance. Breast cancer makes a good example of this point. In the past decade, there has been an explosion in understanding of the disease, its different forms and what therapies are indicated for different patients.

Even as it may be challenging for oncologists to stay current with new knowledge, it is equally challenging for a generalist pathologist to keep pace with all the innovations and breakthroughs in breast cancer diagnosis and treatment. This is one reason why pathology subspecialization is becoming widespread.

But it also demonstrates why information integration and smart software is developing at a swift pace. Both the referring physician and the pathologist will benefit from "smart" informatics solutions that can keep them at the cutting edge of medicine.

What these strategies demonstrate is that human resource issues in anatomic pathology will not be solved by training more pathologists. Rather, as noted above, pathologists are already using alternative strategies to deal with these issues.

TDR

INTELLIGENCE

LATE & LATENT

Items too late to print,
too early to report



In an attempt to stop or delay the start of the Medicare Laboratory Competitive Demonstration Project for the San Diego-Carlsbad-San Marcos SMA (statistical metropolitan area), a lawsuit has been filed in federal court by **Internist Laboratory of Carlsbad, Sharp Healthcare** of San Diego, and **Scripps Healthcare** of San Diego. Filed on January 29 in the United States District Court for the Southern District of California, the suit names Michael Leavitt, Secretary of the Department of Health and Human Services, as defendant and seeks to enjoin him from proceeding with the competitive bidding demonstration. Unless changed by the court, February 15 is the date that laboratories wanting to participate in the competitive bidding demonstration must submit their bids.



AP CONDO LAB FIRM SUES TO STOP ANTI-MARKUP RULE

An anatomic pathology condominium (pod) lab company is also suing the federal government. On January 25, **UroPath, LLC** and several

affiliated physician groups filed a lawsuit naming Michael Leavitt, Secretary of the Department of Health and Human Services as defendant. The action was filed in the United States District Court for the District of Columbia. **UroPath** and its co-plaintiffs are seeking an injunction to prevent DHHS from implementing the physician antimarkup rule that affects anatomic pathology services provided in a centralized building. (See *TDR, January 21, 2008.*)



IN VIVO /IN VITRO INTEGRATION AT MOLECULAR SUMMIT

Integration of *in vivo* and *in vitro* testing is a hot topic in molecular imaging and molecular diagnostics. Last week, more than 200 pathologists, radiologists, and executives from biotech, pharma, and healthcare informatics firms crowded into the first annual Molecular Summit, held in Philadelphia by **THE DARK REPORT**. First movers and early adopters from molecular imaging and molecular diagnostics pre-

sented on the early results of their work. One important conclusion to share with clients of **THE DARK REPORT** is that new molecular imaging technologies are providing radiologists with new tools to better identify and characterize tumors and similar structures in the body. However, these technologies still require confirmation by *in vitro* testing before the information is actionable by the patients' physicians.



DARK DAILY UPDATE

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Look for the next briefing on Monday, March 3, 2008.*

Preview #2

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UPCOMING...

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