[*This summary has been generated from PathLogix notes taken during a presentation delivered December 3, 2008 to a session of the California Society of Pathologists' Annual Meeting—California Seminars in Pathology—held in Los Angeles. Mr. Michel is editor and publisher of The Dark Report, which its website touts as "Reliable Business Intelligence about Laboratories, Pathology, and Diagnostics." PathLogix has no affiliation or arrangement with Mr. Michel, The Dark Report or its other principals. PathLogix does not purport that this summary is exhaustive of Mr. Michel's presentation, nor that every figure and/or idea presented here is wholly accurate, but that the summary does fairly represent the above-mentioned presentation.*]

Mr. Michel's presentation can probably be divided into three parts: The current and future healthcare demographic environment in the U.S., prevailing forces in the anatomic pathology field, and growth opportunities and challenges for pathologists and groups. (He didn't outline the presentation in this way—it was a stream of PowerPoint slides—but it did seem to break down along these lines.)

THE HEALTHCARE DEMOGRAPHIC ENVIRONMENT

Mr. Michel sees the current healthcare market as having four distinct sources of change:

- Healthcare choices will become more consumer-driven, especially with the advent and increasing presence of Health Savings Accounts. He noted during Q&A that HSAs make revenue collection tougher because there is more payment-dependency directed toward patients rather than insurers.
- Health-data sharing will increase significantly, driven by Medicare incentives, hospital-based initiatives, the HHS push for EMR adoption by 2014 (a date likely to move farther into the future,) and consumer demands for have more access to and control of their health information. All of this will have to occur within the constraints of HIPAA.
- New diagnostic and laboratory technology will push turnaround times and diagnostic accuracy to new levels. There will be an increase in diagnostic speed and quality.
- Introduction and use of Deming-based quality management methods. CAP was cited as one entity already employing Deming or Deming-like QA (Six Sigma, etc.)

Mr. Michel elaborated, principally, on the consumer element in the environment and the kind of impact the consumer will have in the marketplace:

- The consumer as more-involved payer will mean more performance/price-driven emphasis than previously.
- The availability of healthcare information in general and a consumer's individual health records will make patients more sophisticated.
    - Of note: there are currently (2007, latest data) 9.8M people in Health Savings Accounts. That number was double the previous year, and was expected to double again (or greater) over the next year.

- For pathologists, the consumer becomes a bigger part of the pathologists' revenue stream. Several HSAs are setting up processes that facilitate lab work payment, or at least partial or base payment, at the point of care.

The consumer and the future.

US POPULATION **303,000,000**
BABY BOOMERS (b. 1946 through 1964) **80,000,000 (26% of population)**

People are living longer, are healthier, and are more technology-savvy and demanding because of their access to information. Never in the history of the United States has there been such a large group of people approaching retirement, and at a time when life expectancy gains are measured in years compared to where life expectancy was a quarter century ago. Mr. Michel referred to the Baby Boomers as the "Silver Tsunami" because they are approaching or have already entered (in some cases) retirement. The "tsunami's" impact in one area alone shows how dramatically this will affect lab activity.

Aging and Lab Tests:

- ✓ People under 65 average two (2) lab tests per year
- ✓ People 65 and older average nine (9) lab tests per year
- ✓ The number of people 65 and older will increase significantly in the next few years, and will double in 10-15 years.

While Boomers as a group tend to be healthier at a comparable age to their parents, they will still have the aging issues that are part of living. Also, new data is showing that, again at comparable ages, Boomers are healthier than their children. Healthcare needs will pivot upward not just because of an aging population but also because of health issues that post-Boomers and GenX-ers, and their younger siblings, will witness. The main reason, Mr. Michel contends, is obesity.

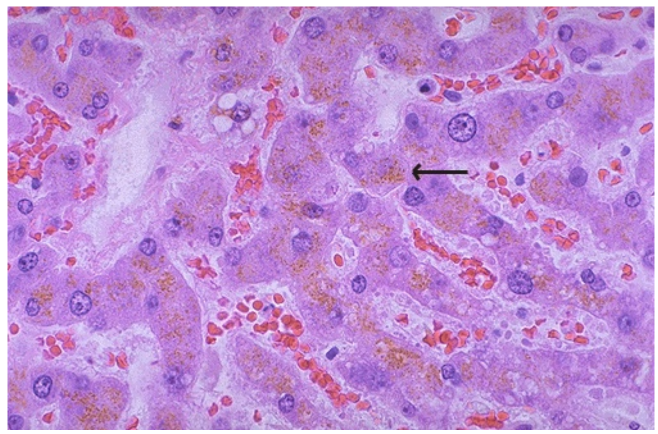
[Here he went through a series of slides from the Centers for Disease Control which showed, state by state, the increasing rates of obesity in the U.S. over a 20-year period. The increase is dramatic. Refer to the CDC website for more info.]

THE CURRENT LABORATORY ENVIRONMENT

Mr. Michel touched on some of the more prominent aspects of the pathology laboratory's changing environment by looking first at the activity of Quest and LabCorp and their highly-acquisitive natures.

- ~13,000 pathologists in the U.S.
- ~900 pathologists in some manner of association with Quest
- ~500 " " " " " " " " LabCorp
- A number of larger lab groups (Dianon, UroCor, US Labs, Ameripath) have been consumed by one or the other giant.

But there is promise.



A number of smaller pathology groups are finding a healthier business climate by either leaving hospitals altogether and starting group practices, or developing groups that are hybrid hospital/outpatient/clinic-oriented.

Importantly, specialization has been a key for survival and success among a number of those that have branched out. This is especially true, according to Mr. Michel, among paths who have focused on urology and gastroenterology. These have developed clinic or facility-based histology labs. They have found they don't have to be very large to hold their own and gain a level of security.

Pathology Groups, nationwide - 3,300
60% of pathology groups - 6 > doctors

The most successful groups have not only found a specialty, but have also developed new techniques or specialized testing to enhance their positions.

- RedPath
- Signature Genomics
- PhenoPath
- Access Genetics

All described as "strong, growing companies."

Mr. Michel quoted a former CEO of LabCorp, Thomas McMahon, as being prescient four or five years ago in an article in the Dark Report. Mr. McMahon noted that outpatient procedures were increasing and would continue to increase dramatically compared with inpatient. Mr. McMahon also pointed to "molecular diagnostics" as being part of the leading edge of technology.

With that notation, Mr. Michel argued that more molecular and genetic tests are coming into regular lab use daily. He also sees an evolution in fully-digital anatomic pathology. (He cited Aperio and BioImagene as two leaders in that area.) Mr. Michel sees a need for greater integration and interoperability between systems as the move to EMR picks up speed. He emphasized digital connectivity and digital (immediate) delivery.

GROWTH OPPORTUNITIES AND CHALLENGES

As Mr. Michel sees it, growth will be dependent on several factors:

- Developing and/or emphasizing a specialty (GI, prostate)
- Having a well-funded marketing program
- Installing and using advanced and sophisticated informatics
- Reinvesting in their businesses

Being local matters in a positive way if there is consolidation (working closely with other specialists) and range (GI, breast, urology, derm,) a hospital/outreach hybrid, and personal pathologist-clinician relationships.

Molecular instruments will change histology significantly in a year or two.

A consolidation or team approach to patient care will become more prominent, especially between pathologists and radiologists, but also involving cardiologists and other specialists.

Mr. Michel offered one caution for groups, not because it threatens their markets but because of what it means to the industry overall: Big Pharma.

- Ventana had a market valuation of $290M. It was purchased by Roche for $3.4B. Ventana had an array of products and techniques which held no significance for Roche, except….Ventana had developed a library of biomarkers that matched up with a number of drugs Roche now has (or at the time had) in trial. A tissue-testing rep told me later just what this means: a biomarker that helps signal certain drug therapy as a first-stage application is worth, for example, $5,000/mo./patient to a drug company. Or $50,000 a month. $120,000 a month.

Finally, he advised all pathologists to get organized about their business, to think through where they want to be in five years, or ten, and to become collegial within the broader healthcare landscape in new ways and with new associations.