

# IMPLEMENTATION OF DAY-TO- DAY DIGITAL PATHOLOGY IN THE US MARKET

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# DIGITAL PATHOLOGY MARKET IN THE USA

- IS IT REAL?
  - ARE THERE CLINICAL IMPLEMENTATION SCENARIOS, OR IS IT MOSTLY A “BIGFOOT”?
  - EVERYONE TALKS ABOUT IT, BUT NO ONE HAS SEEN IT ....



# DIGITAL PATHOLOGY MARKET IN THE USA

- ACADEMIC SECTOR
- CORPORATE SECTOR
- GOVERNMENT SECTOR
- SMALL PRIVATE PRACTICE SECTOR
- RESEARCH SECTOR (NOT COVERED HERE)



# ACADEMIC SECTOR

- POSSIBLY THE MOST UNIQUE
- NEEDS IMPLEMENTATION OF HIGH-SPEED, HIGH-VOLUME SCANNERS,
- IMPLEMENTED OVER THE ROBUST NETWORKS
- SEAMLESS DIGITAL SLIDE SHARING AND ADVANCED STORAGE.
- RVU'S
- PATHOLOGISTS ARE NOT REALLY INCENTIVIZED ON THE VOLUME OF CASES INTERPRETED/DIAGNOSED
- SALARIED SECTOR
  - MIXED NEEDS WITH TEACHING AND RESEARCH
- ENHANCED STORAGE AND SHARING NEEDS



# ACADEMIC SECTOR

- CENTRAL HISTOLOGY LABORATORY
  - CENTRAL SLIDE DISTRIBUTION
  - UNIFORM SLIDE PROCESSING
- EASE OF SCANNING
  - THE NEED OF A HIGH THROUGHPUT SCANNER
  - THE NEED FOR A “DIGITAL PATHOLOGY SPECIALIST”
- COMBINED NEEDS WITH RESEARCH
- EVEN IN THIS SCENARIO IT IS HARD TO IMPLEMENT DIGITAL IHC SCORING



# DIGITAL PATHOLOGY SPECIALIST

- UNIQUE SITUATION:
  - WE HAVE HISTOTECHOLOGISTS AND HISTOLOGISTS
  - WE DO NOT HAVE “DIGITAL PATHOLOGY SPECIALISTS”
- “WHO ARE WE DEPENDING UPON TO SCAN OUR GLASS SLIDES INTO DIGITAL”
  - THE PERSON WHO FILES THE SLIDES IN EACH PATHOLOGY DEPARTMENT IS THE PERSON WHO “UNDERPERFORMED” IN ALL OF THE OTHER DUTIES IN THE LABORATORY
  - WE WILL NOW TRUST THE QUALITY ASSURANCE AND OPERATION OF 1/2 MILLION DOLLAR DEVICE TO A PERSON WHO HAS A 9-5 JOB AND MANAGES TO MIX UP SPECIMENS DURING THE ACCESSIONING



# DIGITAL PATHOLOGY SPECIALIST

- UNIQUE POSITION
  - PROBABLY HIGHER COMPLEXITY (OR EQUAL COMPLEXITY) TO PATHOLOGISTS ASSISTANT POSITION
  - NEEDS TO OVERSEE THE ENTIRE PROCESS OF DIGITAL SLIDE CREATION, DISTRIBUTION, AND TROUBLESHOOTING
- HYBRID IT, HISTOLOGY AND PATHOLOGY POSITION



# ACADEMIC PATHOLOGY

- FURTHER ADVANTAGES:
  - SLIDE FILING
    - NO NEED TO DEPEND ON THE GLASS SLIDE FILE
    - EASE OF ACCESS
  - ABILITY TO INSTANTLY SHARE THE SLIDE IN QUESTION/INTEREST
    - IT HAS ADVANTAGES ONLY IN THE CASE OF DISPERSED DEPARTMENT
    - CUTS DOWN ON INTERRUPTIONS
      - THE INTERRUPTIONS ARE RATHER ANNOYING
  - VIRTUAL QA CONFERENCE IS A POSSIBILITY



# ACADEMIC PATHOLOGY

- AS STATED, THIS IS POSSIBLY THE MOST UNIQUE SECTOR;
  - IT NEEDS IMPLEMENTATION OF HIGH-SPEED, HIGH-VOLUME SCANNERS,
  - THEY NEED TO BE IMPLEMENTED OVER THE ROBUST NETWORKS,
  - IT IS ALLOWING FOR SEAMLESS DIGITAL SLIDE SHARING AND ADVANCED STORAGE.
  - HIGH AND EASY VENDOR COLLABORATION; LIKELY TO CAVE IN TO VENDOR DEMANDS AND EXCUSES
- ONLY ONE SECTOR IS SIMILAR TO THIS
  - WE NEED TO UNDERSTAND THAT THE OTHER 2 SECTORS HAVE DISSIMILAR NEEDS



# CORPORATE PRACTICES

- QUEST, LABCORP, AURORA, CLARIENT,
  - NEEDS SIMILAR TO THE ACADEMIA, BUT EVEN MORE SPREAD GEOGRAPHICALLY
  - INTENSE TURNAROUND TIME REQUIREMENTS
  - 24/7 LABORATORY (HISTOLOGY) OPERATIONS
    - SEAMLESS SLIDE SCANNING (NO BATCHING)
- PATHOLOGISTS ARE IN GENERAL NOT IN CHARGE

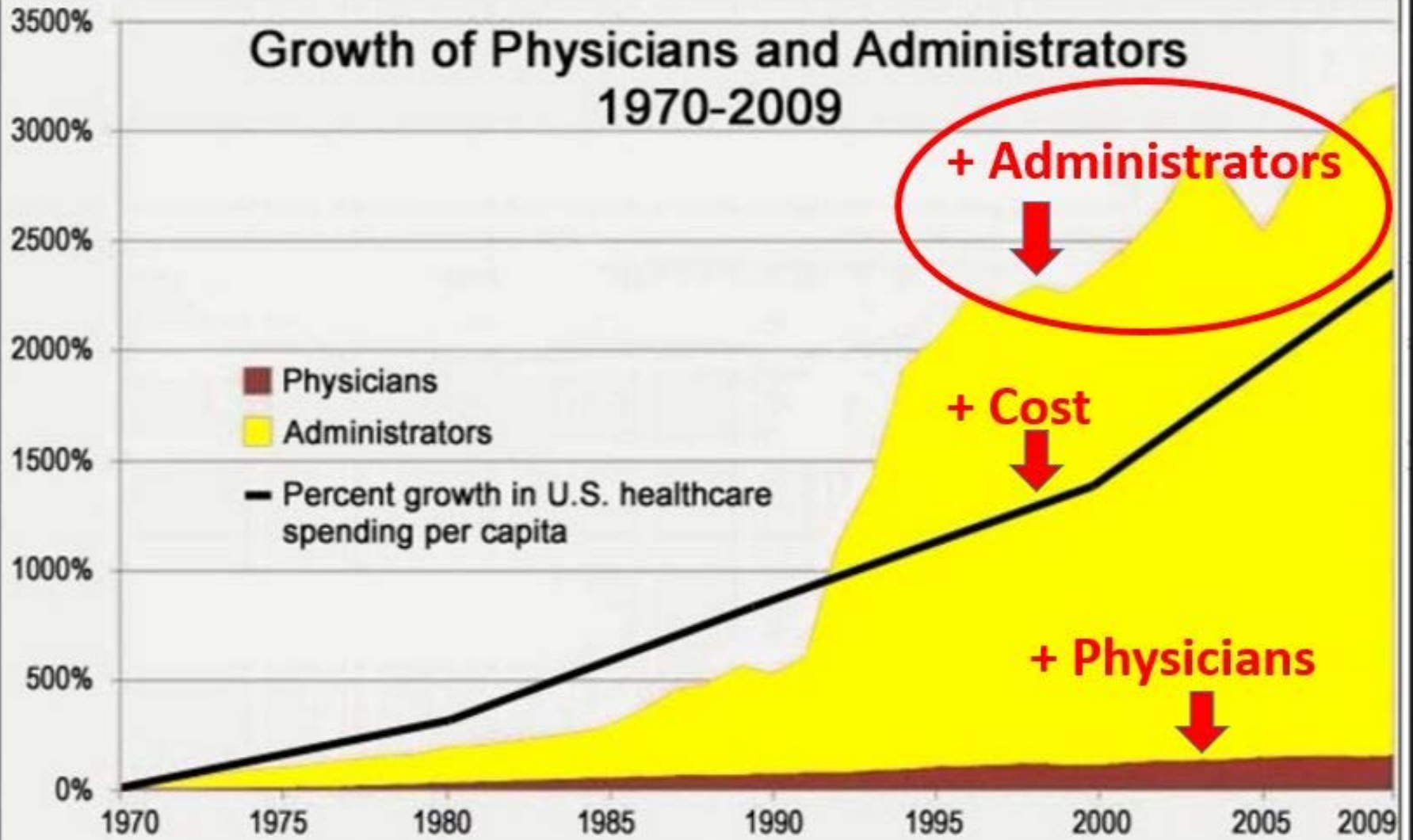


# CORPORATE PRACTICES

- LEAST LIKELY TO CAVE TO THE VENDOR DEMANDS AND EXCUSES
- THEY EVEN FORMED THEIR OWN PATHOLOGY SOCIETY
  - AMERICAN CLINICAL LABORATORY ASSOCIATION
    - MOTTO: ACLA IS THE CLINICAL LABORATORY INDUSTRY'S LEADING ADVOCATE PROVIDING EFFECTIVE COMMUNICATION WITH CONGRESS, REGULATORY BODIES, OTHER HEALTH CARE ORGANIZATIONS AND THE PUBLIC.
  - UNAWARE OF ANY OTHER MEDICAL BRANCH WHERE THE MEDICAL PROFESSIONAL SOCIETY (COLLEGE OF AMERICAN PATHOLOGISTS) ALLOWED TO BE PUSHED AROUND BY THE CORPORATE SOCIETY
    - THEY DO DRIVE A LOT OF REIMBURSEMENT BATTLES AND NEED TO BE CONSULTED TO SET THE DIGITAL PATHOLOGY REIMBURSEMENT RATES



# Growth of Physicians and Administrators 1970-2009



Source: Bureau of Labor Statistics; NCHS; and Himmelstein/Woolhandler analysis of CPS



# CORPORATE PRACTICES

- FROSTY (FROZEN SECTION) VANS
  - SINGLE OR DUAL SLIDE SCANNER FOR FROZEN SECTION VANS
  - NEEDS TO BE VIBRATION RESISTANT AND HAVE HIGH THROUGHPUT SCANNING AND 20 X (OR 10 X WITH POINT OF INTEREST EITHER BEING LIVE OR SCAN ON DEMAND)
    - GROSS CAMERAS (LIVE) ALSO NEEDED
    - NOT A HYBRID BUT A SEPARATE SYSTEMS
  - AGAIN, BOTH AN EXPERIENCED HISTOTECHNOLOGIST OR A PA AND A DIGITAL SLIDE SPECIALIST NEED TO BE INVOLVED
    - CROSS TRAINING A POSSIBILITY
  - 4G OR 5G MOBILE NETWORK
    - SECURE CONNECTIONS



# CORPORATE PRACTICES

- WORKLOAD DISTRIBUTION
  - SIMILAR SUBSPECIALTY EXPERTS ARE NOT NECESSARILY IN THE SAME TOWN OR EVEN REGION OR STATE
- FEDEx IS THE ONLY WAY OF DISTRIBUTING RIGHT NOW
  - ALSO COURIER SERVICES FOR SHORTER DISTANCES
- IN ADDITION TO PRESERVING THE LUCRATIVE INSURANCE CONTRACTS (THE CASES NEED TO BE PROCESSED AND DIAGNOSED AT THE ORIGINATION POINT), SOME CUSTOMERS WANT TO STAY LOCAL
- SOME PRACTICES STILL MAINTAIN THE ILLUSION THAT THE TISSUE IS PROCESSED AND DIAGNOSED LOCALLY
  - MEDICARE AND, MEDICAID HAVE SPECIFIC SET OF REQUIREMENTS



# CORPORATE PRACTICES

- INTENSE TURNAROUND TIME PRESSURE
  - PATHOLOGISTS ARE AT LEAST PARTIALLY INCENTIVIZED
    - FOR COVERAGE, ETC, THEY COULD TAKE ADDITIONAL WORLOAD
  - ALSO PENALIZED FOR UNDERPERFORMANCE
    - I AM NOT PRIVVY TO THE EXACT INFORMATION
- IN ESSENCE – SPOKE AND WHEEL MODEL WITH “SPOKE” CHANGING AS PER SPECIALTY



# GOVERNMENT BASED ANATOMIC PATHOLOGY LABS

- SOME GOVERNMENT PRACTICES (I.E. NIH) MIMIC ACADEMIA
- VETERANS' ADMINISTRATION AND ARMED FORCES
- MIXED DP NEEDS OF ALL OF THE SCENARIOS ABOVE
- COVERAGE



# GOVERNMENT BASED ANATOMIC PATHOLOGY LABS

- SOME GOVERNMENT PRACTICES (I.E. NIH) MIMIC ACADEMIA
- VETERANS' ADMINISTRATION AND ARMED FORCES
  - THE AFIP SYNDROME (JOINT PATHOLOGY CENTER)
  - HEAVY USE OF SECOND OPINION
  - THE CULTURE DID NOT CHANGE SINCE 60s
    - HIGH "CASE SHOW" RATE
    - NO TRUNAROUND TIME PRESSURE (WHATSOEVER)
  - CASE MIGHT BE LOOKED @ BY A NUMBER OF PEOPLE OVER THE SPAN OF SEVERAL DAYS
    - EASE OF SHARING – VASARE ORGANIZED IN VISNS
    - NO NEED FOR MULTIPLE LICENSES



# GOVERNMENT BASED ANATOMIC PATHOLOGY LABS

- VA HAS LESS PRONOUNCED COVERAGE NEEDS, DEPENDING ON ACTUAL NUMBER OF PATHOLOGISTS PER HOSPITAL
  - COVERAGE NEEDS ARISE DURING LONG TERM SICKNESS, MATERNITY LEAVE, ETC
  - SUBSPECIALTY COVERAGE IS A REAL ISSUE
    - MOST OF THE STAFF ARE GENERALISTS
- THE ONLY LIVABLE CONTRACT WITH VA IS APOLLO TELEPATHOLOGY



# GOVERNMENT BASED ANATOMIC PATHOLOGY LABS

- ARMED FORCES LABORATORIES
  - IN GENERAL, SMALL NUMBER OF PATHOLOGISTS
    - WOULD BENEFIT FROM BEING ABLE TO COVER IN REAL TIME
  - NO NEED FOR HIGH THROUGHPUT SCANNERS; NEED FOR LIMITED NUMBER OF SCANNERS
  - MEDIUM THROUGHPUT, POSSIBLY MOVEABLE
  - MOVEABLE DIGITAL PATHOLOGY SPECIALIST
  - DISSIMILAR TO FROSTY VANS – THE IMPLEMENTATIONS COULD BE PLANNED IN ADVANCE
  - IMPLEMENTATION UNITS COULD BE UTILIZED ACROSS THE SEAS ETC



# SMALL ANATOMIC PATHOLOGY PRACTICES

- THE COSTS THAT ARE EASILY BORNE BY THE OTHER 3 PLAYERS ARE VIRTUALLY IMPOSSIBLE TO BE UNDERTAKEN BY THE SMALL LABORATORIES
- IT IS NOT CLEAR THAT VENDORS COMPREHEND THIS ISSUE
- NEED POINT-TO-POINT CASE SHARING (CONSULTATIONS) AND STORING OF THE DIGITAL SLIDES IN LIEU OF THE ACTUAL GLASS SLIDES THAT LEAVE THE PRACTICE
- PATHOLOGISTS ARE PAID EITHER PER CPT CODE OR INCENTIVIZED PER OUTPUT



# SMALL ANATOMIC PATHOLOGY PRACTICES

- NEED POINT-TO-POINT CASE SHARING (CONSULTATIONS)
  - THE SMALL PRACTICES CLASSICALLY HAVE BETWEEN 1 AND 3 PATHOLOGISTS
  - THE SUBSPECIALTY EXPERTISE IS NOT HIGH
- STORING OF THE DIGITAL SLIDES IN LIEU OF THE ACTUAL GLASS SLIDES THAT LEAVE THE PRACTICE
  - LARGE DEMANDS ON THE PRACTICES FOR SLIDE SENDOUTS
  - 99 % OF DIAGNOSES ARE JUST RETYPED.
  - LARGE PART OF REIMBURSEMENT FOR THE TREATING FACILITY
  - ORIGINATION POINT DICTATES THE PROCESS



# SMALL ANATOMIC PATHOLOGY PRACTICES

- NEED POINT-TO-POINT CASE SHARING (CONSULTATIONS) AND STORING OF THE DIGITAL SLIDES IN LIEU OF THE ACTUAL GLASS SLIDES THAT LEAVE THE PRACTICE
- THIS IS NOT A LARGE SCANNER HIGH THROUGHPUT SYSTEM SITUATION



# PARTNERS IN IMPLEMENTATION

- RADIOLOGISTS
- SURGEONS
- DERMATOLOGISTS
- OPHTHALMOLOGISTS
- DENTISTS



# SOME TAKE HOME MESSAGES

THE MARKET IS NOT ONE SIZE FITS ALL SOLUTION

SCANNERS CANNOT BE \$250K PLUS IF THEY WILL BE ADOPTED BY SMALL PATHOLOGY PRACTICES

OMNYX STORY - 10 YEARS IS TOO LONG



# SOME TAKE HOME MESSAGES

WE CANNOT EXPECT THE PATHOLOGISTS TO ADOPT THE TOOLS THEY ARE NOT COMFORTABLE WITH

THERE IS VIRTUALLY NO DIGITAL PATHOLOGY TRAINING IN RESIDENCY

SOME OLDER PATHOLOGISTS STILL QUESTION THE UTILITY OF IHC AND CLAIM MORPHOLOGY IS THE MASTER, NOT TO MENTION MOLECULAR PATHOLOGY

EXTENSIVE PROSPECTIVE STUDIES NEEDED COMPARING NEW ALGORITHMS ACHIEVABLE ON DIGITAL SLIDES WITH ADVANCED MOLECULAR METHODS