



Reimbursement for Medical Radioisotopes in the United States

Mo99 Topical Meeting

Santa Fe, NM

December 4-7, 2011

Reimbursement for Medical Radioisotopes in the United States

- I. Scale of Mo-99 Medical Usage
- II. US Reimbursement Schemes
- III. Medicare and Medicaid Reimbursement Mechanisms
- IV. Impact of Alternate LEU Source
- V. Strategies for Mitigation
- VI. Conclusion

Scale of Mo-99 Medical Usage

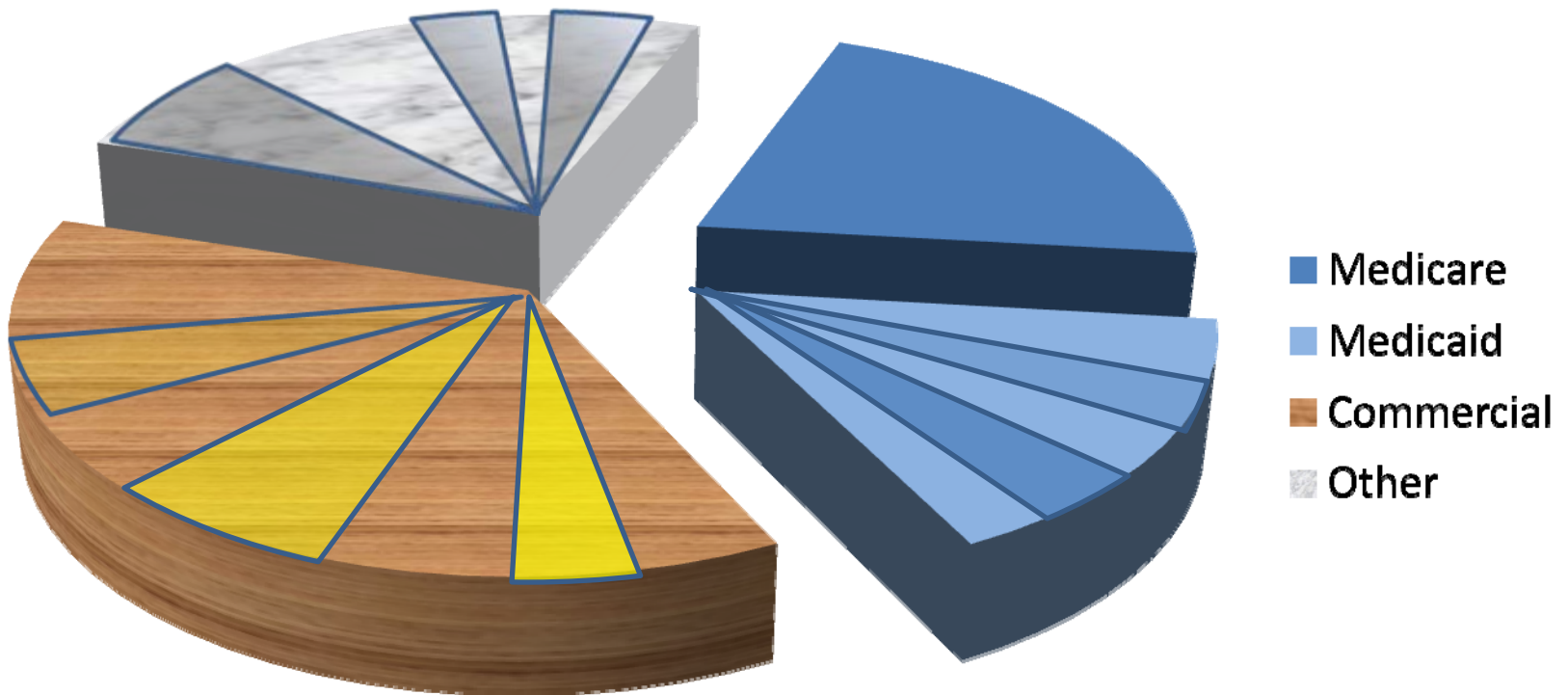
- Order of magnitude *conservative* estimations
 - US Demand: 60% of world market
 - 80% Medical Use is Tc-99m Diagnostic Imaging
 - 30M doses per year at 1.5 doses per procedure
 - 120,000 generators per year
 - Average utilization 200 doses per 10 Ci generator
 - Expected dose 30 mCi

Scope of Tc-99m Usage

- 80% is SPECT imaging
- Myocardial Perfusion imaging 60%
- Bone scans
- Sentinel node detection
- Blood pool imaging
- Brain, GB, Renal, etc.

U.S. Reimbursement Schemes

Multi Payer System: Market Share



US Reimbursement Schemes

- Medicare 21% Market Share SINGLE Payer
 - Prospective Payment Systems
- Medicaid 16% Market Share MANY Payers
 - Percent of Medicare, Percent of Charges
- Commercial 37% across MANY payers
 - Percent of Charges
- Other 26% Self pay, unpaid, VA, Tri-Care, etc.
 - Variable reimbursement

Medicare and Medicaid Reimbursement Mechanisms (IP)

- Inpatient Prospective Payment System
 - Inpatient Care
 - Large bundle
 - Diagnostic Related Groups
 - Average inpatient cost of stay for a given diagnosis
 - Not responsive to single elements
 - Updated annually (18 month average cost lag)
 - Example: DRG 313 Chest Pain \$2993 (2012)

Medicare and Medicaid Reimbursement Mechanisms (Office)

- Medicare Physician Fee Schedule
 - Office (or equivalent Testing Facility)
 - Fee schedule
 - CPT (procedure) code based
 - Set payment based on relative use of resources
 - Adjusted by Sustainable Growth Rate
 - Practice expense changes only when revalued
 - Example: 78452 Myocardial SPECT: \$478 (2011)

Medicare and Medicaid Reimbursement Mechanisms (OP)

- Outpatient Prospective Payment System
 - Outpatient Care
 - Small bundle
 - Ambulatory Payment Classifications
 - Average cost of a service in a group of related procedures (hospital cost = purchase price)
 - Not responsive to small cost elements
 - Updated annually (18 month average cost lag)
 - Example: 78452 Myocardial SPECT: \$760 (2011)

Impact of Alternate LEU Source

- Magnitude of Cost Change
 - Technology Impact
 - Subsidization Impact
 - Amortization Impact
 - Supply-Demand Impact
- Estimations of Cost Change
 - +10% (study)
 - +50% (with risk reserve)
- Healthcare System ability to absorb cost increases

Production cost

- Data
 - \$225 per 6d Ci in 2008
 - \$1900 per 10 Ci generator in 2005
 - \$11.00 per 30mCi dose of Tc-99m in 2005, variation >20%
- Assumptions (2012)
 - \$2500 per 10 Ci generator
 - \$12.50 per dose +/- 20%

Imaging APCs Payment Ranges

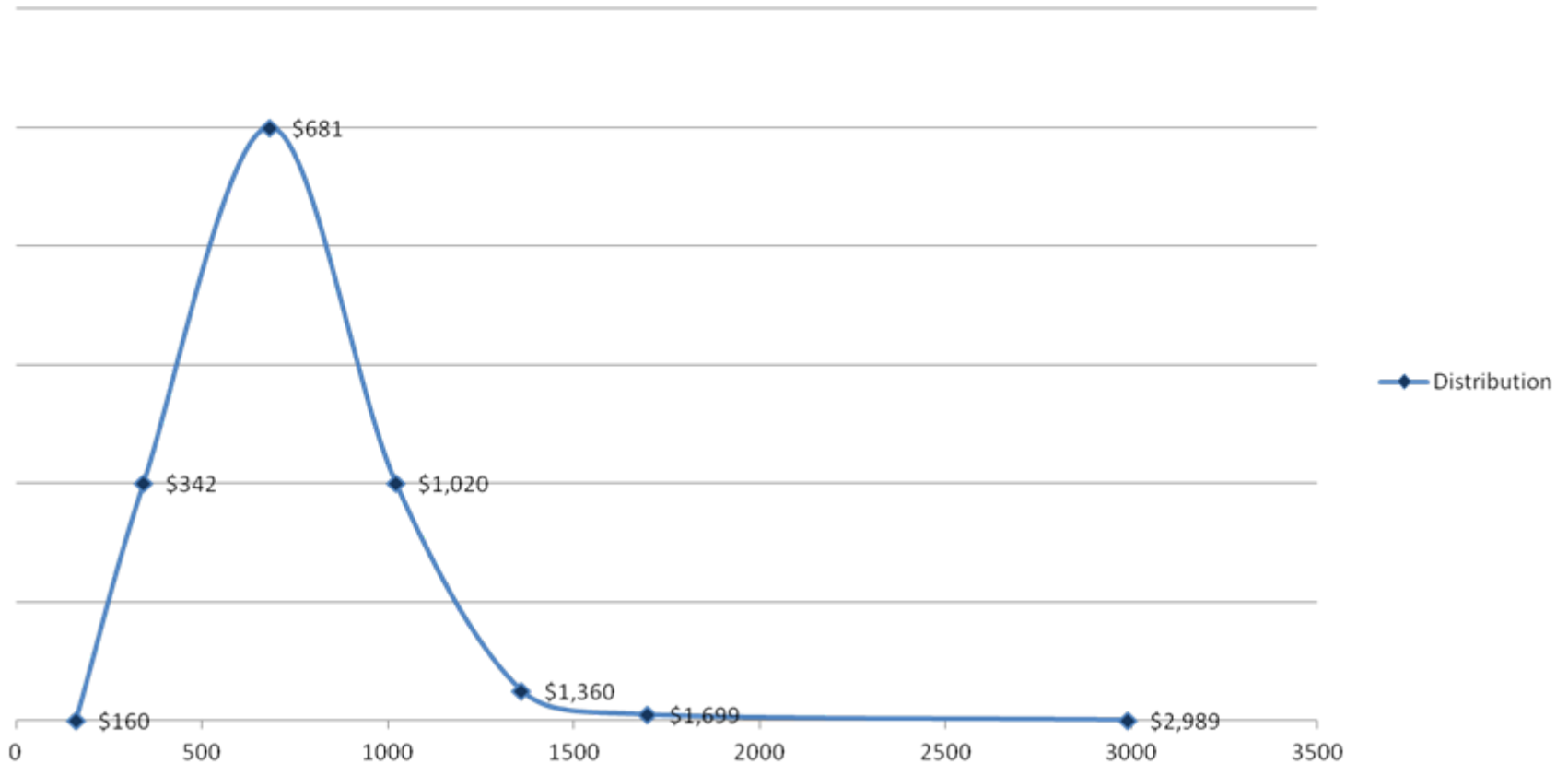
CY 2012 APC	CY 2012 APC Title	Payment
0308	Positron Emission Tomography (PET) Imaging	1042
0377	Level II Cardiac Imaging.	760
0378	Level II Pulmonary Imaging.	320
0389	Level I Non-imaging Nuclear Medicine.	101
0390	Level I Endocrine Imaging.	133
0391	Level II Endocrine Imaging.	219
0392	Level II Non-imaging Nuclear Medicine.	174
0393	Hematologic Processing & Studies.	418
0394	Hepatobiliary Imaging.	265
0395	GI Tract Imaging.	239
0396	Bone Imaging.	244
0397	Vascular Imaging.	200
0398	Level I Cardiac Imaging.	291
0400	Hematopoietic Imaging.	257
0401	Level I Pulmonary Imaging.	197
0402	Level II Nervous System Imaging.	596
0403	Level I Nervous System Imaging.	240
0404	Renal and Genitourinary Studies.	321
0406	Level I Tumor/Infection Imaging.	290
0408	Level III Tumor/Infection Imaging.	825
0414	Level II Tumor/Infection Imaging.	475

Cardiology II Payment Ranges

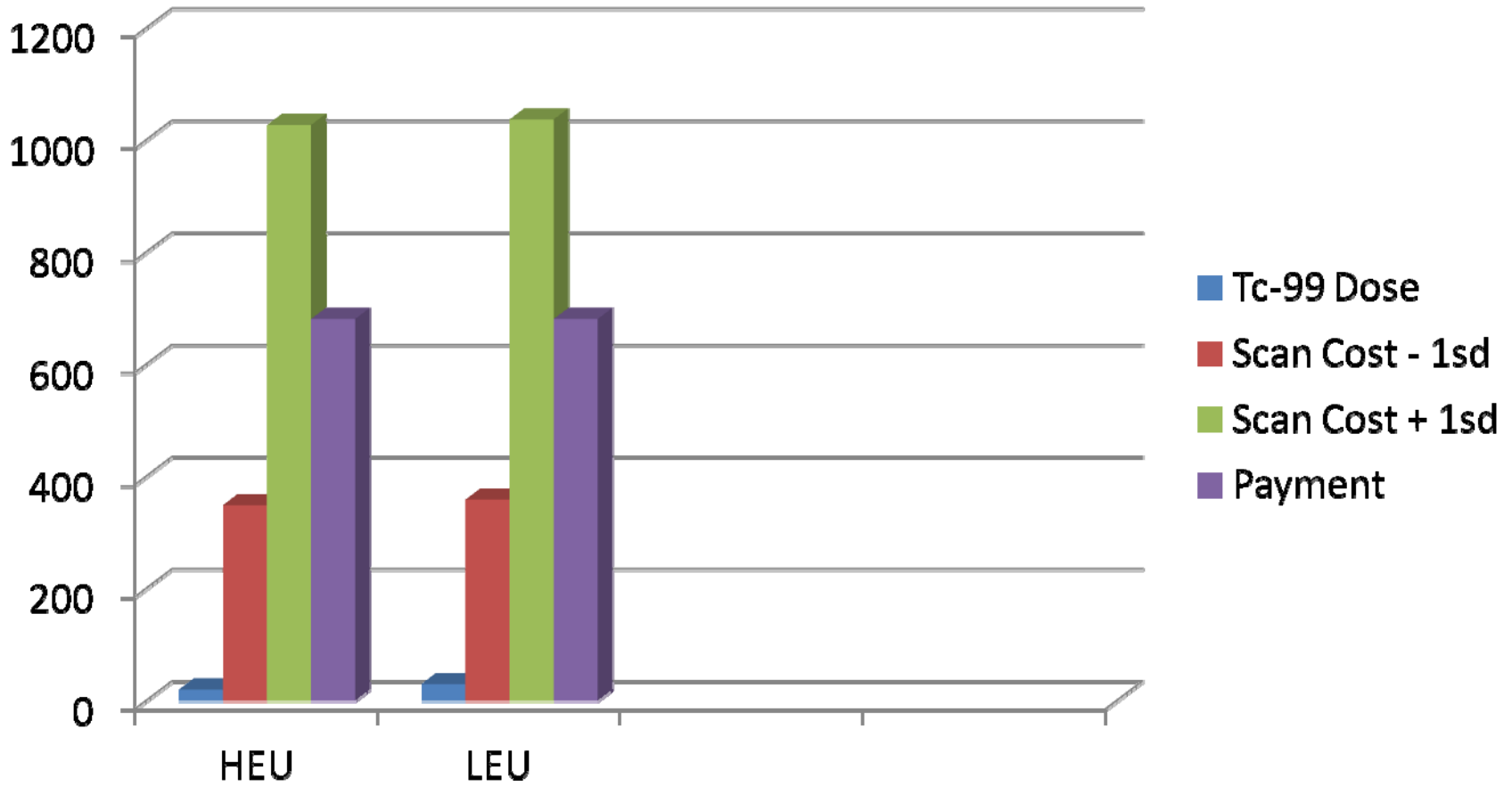
Procedure Code	Procedure	Median Cost
78451	Ht muscle image spect sing	\$484.27
78454	Ht muscle image planar mult	\$646.14
78453	Ht muscle image planar sing	\$561.77
78452	Ht muscle image spect mult	\$681.23

CPT 78452 Procedure Cost Ranges

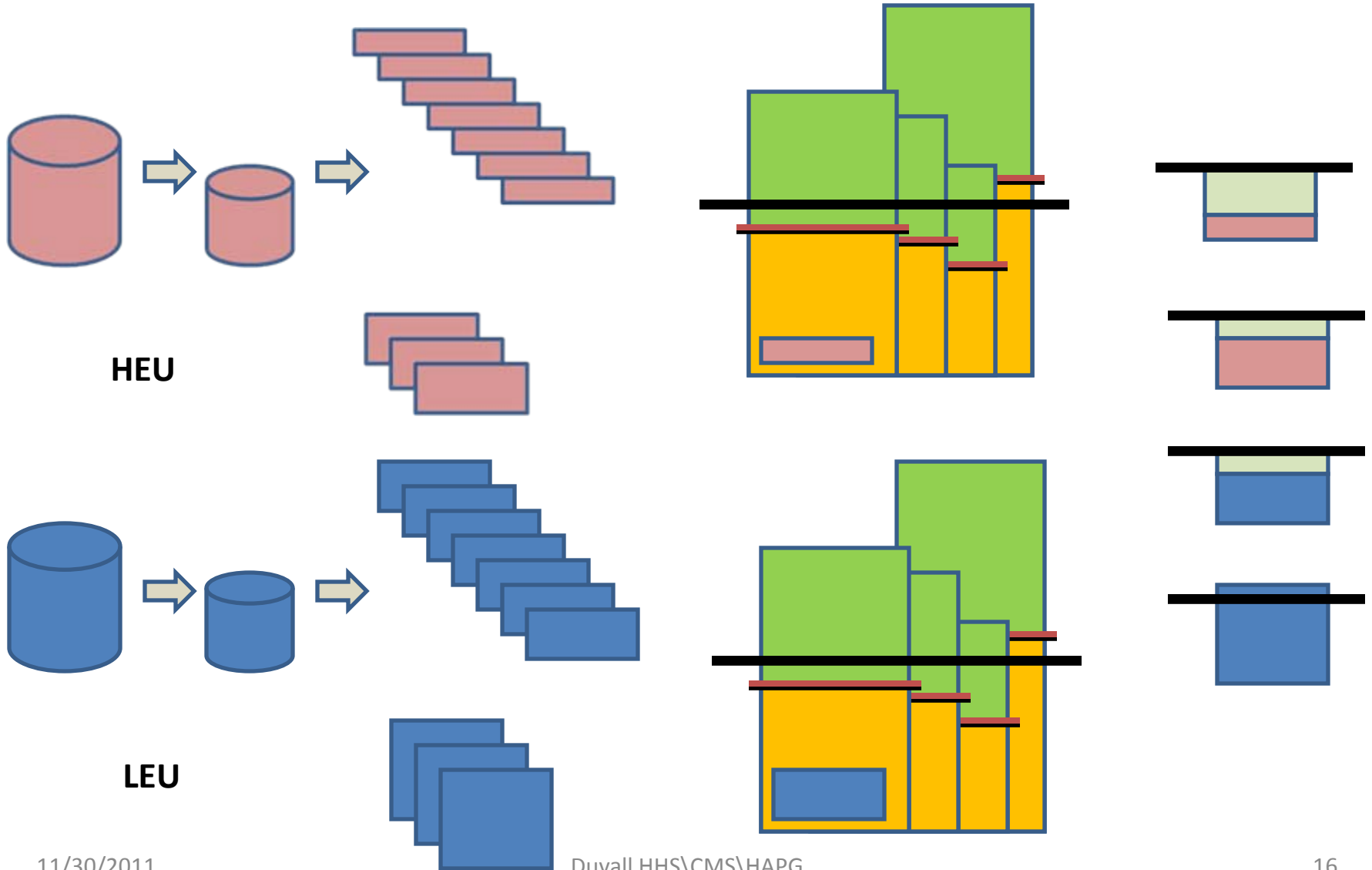
Distribution of Hospital Reported Costs



Payment Impact of 50% Price Increase



Procedure Cost Related to Dose



Payment Adequacy vs. Payment Differential

Payment Adequacy

- Supported by Prospective Payment
 - Packaged
 - Separate
- Supported by % of charges
- Capital investment can be included in price
- Time lag irrelevant for single supplier

Payment Differential

- Not supported by Prospective Payment
 - No differential if packaged
 - No differential if separate
- Not supported by % of charges
- Requires direct cost reimbursement of individual supplier level costs

Strategies for Mitigation

- Remove Barriers to Entry
 - Cost
 - Lead time
- Insure ROI
 - Payment stability
 - Stable growth (4%/year)
 - Emerging markets (China)
- Decrease competitive disadvantage
 - Exposed cost (e.g. separate payment) removes cost control pressure
 - Does not remove competitive disadvantage unless differential payments exist for HEU and LEU sourcing

Strategies for Mitigation

Residual Risk:

- Price sensitive alternatives
 - PET, helical and high resolution CT, thallium, N-13,
- Technological stability (New alternative imaging)
 - Predictable incremental resolution improvement
 - Alternatives for cellular data transmission require breakthrough (unpredictable) improvement
 - Long investment horizon makes predictions tenuous

Conclusion

- US health care is reactive not proactive
- The Medicare payment system and US healthcare in general absorbs cost very well
- Cost differential is a more important issue than payment adequacy
- End user payments are not an ideal vehicle for mitigating the cost impact of different sources of a functionally identical product
- Total healthcare expenditures can be expected to continue to increase cost pressure which emphasizes cost differential