The current focus on Health Care cost control has been from the perspectives of the inputs to the system; namely physician charges, hospital charges and drug costs. This paper attempts to present an outcome driven analysis of Health Care costs to show that focusing in the outcomes and then on the microstructure of procedures allows for the development of significantly different policy alternatives. We first develop a model for the demand side of health care and demonstrate that demand can be controlled by pricing, namely exogenous factors, as well as by endogenous factors relating to the management of the Health Care process in the United States. We then address several issues on the supply side, starting first at the quality issue and then in terms of short and long term productivity issues. Health Care is a highly distributed process that is an ideal candidate for the distributed information infrastructures that will be available in the twenty first century. It is
## Contents

1  Introduction .............................................................................................................. 11
   1.1  The Key Issues ................................................................................................. 11
   1.2  Key Change Elements ..................................................................................... 13
   1.3  World View Changes ....................................................................................... 21
   1.4  Current Proposals ............................................................................................ 23

2  Fundamental Health Care Statistics ................................................................. 26
   2.1.1  The Problem ................................................................................................. 28
   2.1.2  The Demand ................................................................................................. 29
   2.1.3  The Supply ................................................................................................. 30
   2.1.4  Technology ................................................................................................. 30
   2.1.5  The Economic Implications ......................................................................... 31
   2.1.6  Policy Options ............................................................................................. 35
   2.2  Overview ........................................................................................................... 35
       2.2.1  Preventable ............................................................................................... 36
       2.2.2  Remediable ............................................................................................... 39
       2.2.3  The Problem ............................................................................................. 39
       2.2.4  The Problem Elements .......................................................................... 40
       2.2.5  Key Issues ............................................................................................... 44
       2.2.6  Reform Elements ..................................................................................... 45

2.3  The Demand Model .......................................................................................... 47
   2.3.1  Demographic Factors .................................................................................. 47
   2.3.2  Disease States .............................................................................................. 51
   2.3.3  Implications of the Demand Model ........................................................... 58

2.4  The Supply Model ............................................................................................ 59
   2.4.1  Cost Factors ................................................................................................. 59
   2.4.2  Incidents and Unit Costs .......................................................................... 63
   2.4.3  Payers and Providers ................................................................................. 66
   2.4.4  Implications of the Supply Model ............................................................. 79
<table>
<thead>
<tr>
<th>Section</th>
<th>Title</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.5</td>
<td>Technology</td>
<td>82</td>
</tr>
<tr>
<td>2.5.1</td>
<td>A Proposed Technology Strategy</td>
<td>83</td>
</tr>
<tr>
<td>2.5.2</td>
<td>The Example of Office Billing</td>
<td>85</td>
</tr>
<tr>
<td>2.6</td>
<td>Policy Alternatives</td>
<td>92</td>
</tr>
<tr>
<td>2.6.1</td>
<td>The Obama Plan</td>
<td>93</td>
</tr>
<tr>
<td>2.6.2</td>
<td>The Old Hillary Plan</td>
<td>95</td>
</tr>
<tr>
<td>2.6.3</td>
<td>Alternatives</td>
<td>97</td>
</tr>
<tr>
<td>2.6.4</td>
<td>The Luft Plan</td>
<td>100</td>
</tr>
<tr>
<td>2.6.5</td>
<td>Proposed Plan</td>
<td>101</td>
</tr>
<tr>
<td>3</td>
<td>Diabetes, A Preventable Cost</td>
<td>106</td>
</tr>
<tr>
<td>3.1</td>
<td>Epidemiology</td>
<td>107</td>
</tr>
<tr>
<td>3.1.1</td>
<td>Causes</td>
<td>107</td>
</tr>
<tr>
<td>3.1.2</td>
<td>Incidence and Prevalence</td>
<td>110</td>
</tr>
<tr>
<td>3.1.3</td>
<td>Complications</td>
<td>114</td>
</tr>
<tr>
<td>3.1.4</td>
<td>Treatments</td>
<td>116</td>
</tr>
<tr>
<td>3.2</td>
<td>Costs</td>
<td>118</td>
</tr>
<tr>
<td>3.2.1</td>
<td>Secondary Disorders</td>
<td>118</td>
</tr>
<tr>
<td>3.2.2</td>
<td>Procedure and Costs</td>
<td>121</td>
</tr>
<tr>
<td>3.2.3</td>
<td>Total Annual Costs</td>
<td>123</td>
</tr>
<tr>
<td>3.3</td>
<td>Economics of Control</td>
<td>123</td>
</tr>
<tr>
<td>3.3.1</td>
<td>The Economic Implications</td>
<td>124</td>
</tr>
<tr>
<td>3.3.2</td>
<td>Methods of Remediation</td>
<td>128</td>
</tr>
<tr>
<td>3.4</td>
<td>Conclusions</td>
<td>128</td>
</tr>
<tr>
<td>4</td>
<td>Controllable Diseases; Cancers</td>
<td>129</td>
</tr>
<tr>
<td>4.1.1</td>
<td>Assumptions</td>
<td>129</td>
</tr>
<tr>
<td>4.1.2</td>
<td>Basic Incidence</td>
<td>131</td>
</tr>
<tr>
<td>4.1.3</td>
<td>Mechanisms of Controllability</td>
<td>135</td>
</tr>
<tr>
<td>4.1.4</td>
<td>Proposed Time/Event Path</td>
<td>136</td>
</tr>
<tr>
<td>4.2</td>
<td>Genetic Implications</td>
<td>138</td>
</tr>
<tr>
<td>4.2.1</td>
<td>Current Understanding</td>
<td>138</td>
</tr>
<tr>
<td>4.2.2</td>
<td>Genetic Flaws</td>
<td>140</td>
</tr>
<tr>
<td>4.3</td>
<td>Target Disease Sets</td>
<td>142</td>
</tr>
<tr>
<td>4.3.1</td>
<td>Colon Cancer</td>
<td>142</td>
</tr>
<tr>
<td>4.3.2</td>
<td>Prostate Cancer</td>
<td>144</td>
</tr>
</tbody>
</table>
HEALTH CARE POLICY: POLITICS VS REALITY

<table>
<thead>
<tr>
<th>Section</th>
<th>Title</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.3.3</td>
<td>Breast Cancer</td>
<td>154</td>
</tr>
<tr>
<td>4.3.4</td>
<td>Melanoma</td>
<td>156</td>
</tr>
<tr>
<td>4.3.5</td>
<td>Ovarian Cancer</td>
<td>158</td>
</tr>
<tr>
<td>4.3.6</td>
<td>Lung Cancer</td>
<td>161</td>
</tr>
<tr>
<td>4.3.7</td>
<td>Cervix</td>
<td>162</td>
</tr>
<tr>
<td>4.3.8</td>
<td>Testis</td>
<td>164</td>
</tr>
<tr>
<td>4.4</td>
<td>Cost Impact</td>
<td>169</td>
</tr>
<tr>
<td>4.4.1</td>
<td>Methodology</td>
<td>169</td>
</tr>
<tr>
<td>4.4.2</td>
<td>Cost Elements</td>
<td>170</td>
</tr>
<tr>
<td>4.4.3</td>
<td>Specific Cost Analyses</td>
<td>170</td>
</tr>
<tr>
<td>4.4.4</td>
<td>Impact of Controllability</td>
<td>176</td>
</tr>
<tr>
<td>4.4.5</td>
<td>Remediation Plan</td>
<td>182</td>
</tr>
<tr>
<td>4.5</td>
<td>Conclusions and Recommendations</td>
<td>183</td>
</tr>
<tr>
<td>4.6</td>
<td>Appendix A World View</td>
<td>185</td>
</tr>
<tr>
<td>5</td>
<td>The Electronic Medical Record</td>
<td>188</td>
</tr>
<tr>
<td>5.1.1</td>
<td>Electronic Medical Record (EMR)</td>
<td>190</td>
</tr>
<tr>
<td>5.2</td>
<td>Past Policy Positions</td>
<td>207</td>
</tr>
<tr>
<td>5.3</td>
<td>Conclusions and Recommendations</td>
<td>209</td>
</tr>
<tr>
<td>5.3.1</td>
<td>EMRs have Value</td>
<td>209</td>
</tr>
<tr>
<td>5.3.2</td>
<td>EMRs Must be Designed to Ensure Patient Care</td>
<td>209</td>
</tr>
<tr>
<td>5.3.3</td>
<td>EMRs Must be Developed Over Time; They Must Evolve</td>
<td>209</td>
</tr>
<tr>
<td>5.3.4</td>
<td>Throwing Money at EMRs is Just Wasting Money</td>
<td>209</td>
</tr>
<tr>
<td></td>
<td>Improper Use of EMR and Too Rapid a Deployment May Increase Costs and</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Increase Mortality and Morbidity</td>
<td>210</td>
</tr>
<tr>
<td>5.3.6</td>
<td>The US Government Should Play No Role</td>
<td>210</td>
</tr>
<tr>
<td>6</td>
<td>Quality: The Health Care Principle</td>
<td>211</td>
</tr>
<tr>
<td>6.1.1</td>
<td>What is Quality</td>
<td>211</td>
</tr>
<tr>
<td>6.1.2</td>
<td>Outcomes and Quality</td>
<td>214</td>
</tr>
<tr>
<td>6.2</td>
<td>Quality as a Measurement</td>
<td>218</td>
</tr>
<tr>
<td>6.2.1</td>
<td>A Case Study: Prostatectomy</td>
<td>218</td>
</tr>
<tr>
<td>6.2.2</td>
<td>Measurement of Quality</td>
<td>220</td>
</tr>
<tr>
<td>6.2.3</td>
<td>The QALY Concept</td>
<td>223</td>
</tr>
<tr>
<td>6.2.4</td>
<td>QALY Extension</td>
<td>225</td>
</tr>
<tr>
<td>6.3</td>
<td>Quality as a Perception</td>
<td>227</td>
</tr>
<tr>
<td>6.3.1</td>
<td>What is Quality: Subjective vs Objective</td>
<td>227</td>
</tr>
<tr>
<td>Section</td>
<td>Title</td>
<td>Page</td>
</tr>
<tr>
<td>---------</td>
<td>-------</td>
<td>------</td>
</tr>
<tr>
<td>9.7</td>
<td>The Problem with Comparative Clinical Effectiveness</td>
<td>318</td>
</tr>
<tr>
<td>9.7.1</td>
<td>Colonoscopies</td>
<td>318</td>
</tr>
<tr>
<td>9.7.2</td>
<td>Ovarian Cancer Screening</td>
<td>321</td>
</tr>
<tr>
<td>9.7.3</td>
<td>Prostate Cancer</td>
<td>324</td>
</tr>
<tr>
<td>9.7.4</td>
<td>Impact on CCE</td>
<td>330</td>
</tr>
<tr>
<td>9.8</td>
<td>Conclusions</td>
<td>331</td>
</tr>
<tr>
<td>10</td>
<td>References</td>
<td>337</td>
</tr>
</tbody>
</table>
Preface

The current focus on Health Care cost control has been from the perspectives of the inputs to the system; namely physician charges, hospital charges and drug costs. This paper attempts to present an outcome driven analysis of HealthCare costs to show that focusing in the outcomes and then on the Microstructure of procedures allows for the development of significantly different policy alternatives. We first develop a model for the demand side of health care and demonstrate that demand can be controlled by pricing, namely exogenous factors, as well as by endogenous factors relating to the management of the Health Care process in the United States. We then address several issues on the supply side, starting first at the quality issue and then in terms of short and long term productivity issues. Health Care is a highly distributed process that is an ideal candidate for the distributed information infrastructures that will be available in the twenty first century.

This books was the result of evaluating health care options over the past twenty years. Health care in the United States is one of the best if not the best in the world. It has expanded to deal with the most complex of issues and it has managed to improve the lives of hundreds of millions. Yet the costs of health care have also increased. Our intent in writing this book was to provide a different perspective of the field, one which looks at various elements and current proposals. The material is current but its currency has a long term perspective. No matter what happens in the next decades, the issues discussed herein will have lasting merit.

The author would like to thank Dominick Benedetto M.D. for his questioning that resulted in the development of this book and his continued discussions and for affording the opportunity to present some of these ideas to his colleagues. I would also like to thank Ted Treves M.D. at Harvard and the Children's Hospital who got me in this area in the first place a quarter century ago and has remained a close and good friend all that time. Also to Jonathan LaPook M.D. at Columbia P&S and New York Presbyterian for the years of friendship and insight to the complexities of the practicing medical mind at work, and in his case a true first class mind, and finally to David Margulies M.D., who has been the initial instigator of this process that quarter century ago and also has remained a close friend and window to the world of genetic medicine. Notwithstanding the advice and comments of others the opinions and conclusions in this book, those errors which may be included without any intent, are mine alone, and in fact may dramatically differ from the opinions of those with whom I conferred.

Terrence P. McGarty
Florham Park, NJ, October 2009
Dedication

To my grandmother Hattie F. Kruger M.D., who taught me how to solve puzzles, a talent which has been quite useful in life. A woman who spent her early life treating TB patients at Sea View Hospital when the cure was still distant and who spent her last days there, at her own insistence, when it was changed to a hospital for the aged. Hattie, the onetime head of the Socialist Party in New York, and their candidate for U.S. Senate, trained my mind the way it is today.
1 INTRODUCTION

Health care is a complex issue. It has evolved in just a hundred years from a relationship between a physician and a patient to a relationship between a citizen and their Government. The major reason for this is in many ways the nature in which payment is made for health care. Auto and home insurance does not reflect the complexity that health insurance does. The prime reason is that there are some many intermediaries in the process including employers and Government agencies that it creates a massive amount of overhead and also a vast army of vested interests. Unions, hospitals, pharmaceutical companies just to name a few all have their hands in the stew.

We hope in this book to accomplish the setting out of facts that can be the basis for looking at health care in a more holistic manner. The Government has managed to get itself involved in a manner which exceeds any other segment of our economy, even banking. Understanding the facts is critical. Yet more important is understanding the health care is a changing process, it is continually evolving, and making decisions based upon the continuity of the past opens the door for massive mistakes. Thus we also attempt to lay out how things are changing and what that change means.

1.1 The Key Issues

There are several key issues which drive the movement in health care and its debate. We depict them below.
The issues are:

Universal Coverage: Like any insurance policy, say auto, all drivers must have insurance. For if they do not then in the event of an accident, which may be inevitable in the life of all drivers, those with insurance will underwrite those without. It is a principle of fairness.

Comparative Clinical Effectiveness: This is the issue of doing the right thing and not more and not less. Medicine is a continually evolving profession. The classic tale of the Harvard Medical School grads being told that when they get their MDs and set out to commence their really learning the profession, that half of what they learned is now wrong has a ring of truth. Read a Harrison’s from 1965 and you would be shocked to see what was accepted then. New techniques, new medicines, and the elimination of truly ineffective or not harmful medications is rant through the text. This will not change, it will evolve. The CCE debate is in my opinion the wrong debate. Medicine has been a continuing process of learning and adapting. The Government would be the last place to institutionalize that process. The JAMA and NEJM journals are always updating practice changes. In my opinion it works so do not break it. On the other hand if you want to delimit the practice of medicine put that in the hands of the Government.

Government Funded Plan: There is a strong push by many for a Government funded plan. There already is one, it is Medicare. Medicare works well but the problem with Medicare is the Government who takes the funds put in its accounts and spends it elsewhere and then complains that Medicare costs too much. It costs less than what has
been contributed as well shall demonstrate. So where is the money? Spent elsewhere by Congress. Why would anyone expect a Government plan to be any different.

Bundling: This is the process of paying for a disease and not a procedure. The problem is twofold. First every disease in every patient is different. No disease is the same. Thus there are different procedures for the same diagnosis for each patient. Second it begs the question of who is in charge, the physician of some third party. We went through the HMO debacle of the 1990s and this would make that look benign by comparison.

Electronic Medical Records: The EMR is an ideal direction to drive towards. Yet the complexity of the medical establishment will make it incremental and evolutionary. Records are often complex multimedia documents with the words, charts, images, path studies and the like. The drive to rapidly implement this is in error. It is by nature evolutionary, akin the Internet, changing all the time. Yes we should start but do not expect to ever finish.

1.2 Key Change Elements

Medicine is an evolving science and profession. What was correct fifty years ago may most likely have been improved upon. Thus to understand how to deal with health care one must appreciate and anticipate these changes.

We now look at four issue which we believe go to the heart of this changing process. They are depicted below and we discuss them here and throughout the book in some detail.

They are:

Demand Reduction: There has been little discussion of demand reduction in health care. We believe that the demand for health care can be modulated by many means, including taxing such things as carbohydrate consumption and tobacco.

Cost Reduction: Costs can be reduced in a variety of ways. Physicians still work in an rather inefficient manner, burdened by greater overhead, and hospitals are one of the most inefficient entities known to man.

Genetic Procedures: Genetic procedures are opening new ways to practice medicine. They will be used for screening, staging, and treatment.

Payment Process Improvements: Payment processes are one of the greatest cost impediments in health care. They are complex and they cost everyone.
DEMAND REDUCTION IN HEALTH CARE IS ACHIEVABLE AND IS REQUIRED TO ACHIEVE ANY GOAL. BY ADDRESSING PREVENTABLE AND REMEDIABLE DISEASES IT IS POSSIBLE TO REDUCE LONG TERM HEALTH CARE COSTS BY 25% OR MORE. DEMAND REDUCTION IS AN ESSENTIAL STRATEGY TO BE DEPLOYED IN ANY HEALTH CARE ENVIRONMENT AND IT IS ONE STEP THAT IS MOST SUCCESSFULLY PERFORMED WITH THE SUPPORT OF GOVERNMENT.
All the policy makers assume that demand is inelastic, namely the demand by people for health care is independent of price. A simple counter example is cigarette smoking. Taxes on cigarettes have driven male deaths from lung cancers down 35%-40% from their peak.

The counter to that is the epidemic in Type 2 diabetes driven almost solely by obesity. If we were to continue the trend, we will go from the current 8% of health care being spent on Type 2 Diabetes and its consequences, heart, kidney, neurological, eye, and other problems to almost 20% by 2030! Type 2 diabetes is a simple disease to cure, just lose weight, exercise and drop the carbohydrate intake.

Taxing carbs, as Governor Patterson of New York suggested, is a great first step. Banning carbs, high fructose corn syrup, and frankly many carbs, will do more for reducing health care costs than reducing everyone’s LDL! This is a superb example of how Government can cut costs by using taxation as a negative modulator. Cigarette smoking and over eating if controlled can prevent the two major threats to cost explosion in health care. They are preventable disease and preventable by demonstrated Government action.

The second area of disease management if remediable diseases, namely those which if screening is used then the impact will be significant reductions in long term costs. In this case I have analyzed the list of top screenable cancers. I have analyzed this and determining that it is possible by universal screening, the cost can be reduced by 5%.
The costs of the supply side of health care can be reduced by a multiple of means, and a total reduction approaching 15% to 20% is achievable. This will require a combine technological, medical mindset, regulatory and governmental set of changes.

Health care costs are assumed to be managed and controlled by external controls such as insurance companies and the Government. We argue that this is not the case. In fact there are facts to demonstrate that Government regulation is one of the significant drivers in the explosive overhead costs of health care.

Thus there are several things which will reduce the costs of health care delivery.

First, electronic medical records are critical but their development and introduction must be organic and evolutionary. Like the Internet, which was organically and evolutionarily developed via the Internet Engineering Task Force, the IETF, the EMR should see a similar development, facilitated but not controlled by the Government. It is well known that Government is not good at picking market winners and at managing ill defined programs. Thus the Government should facilitate and not manage.
Second, medical billing and collections should be fully integrated and automated. There is a plethora of such systems and medical practices are all too often placed in the position of financing insurance companies and Medicare via accounts receivable and bad debts. Third, a set of best practices oversight to reduce nosocomial infections, faulty diagnoses and misapplications of drugs is essential. The three of these and many more can reduce health care costs by 12-15%.

Third, there are many "housecleaning" issues that can dramatically reduce costs. These include control of nosocomial infections, misdiagnoses and treatments, and drug errors in hospitals. These issues have been around for years and account for well over 200,000 deaths per year in aggregate, not to mention well over a million cases of increased and costly morbidity.

We believe that the following specific actions are then required:

1. Billing Coordination
   a. Implement single entry billing process
   b. Implement short time payment

2. Electronic Medical Records
   a. Develop profession supported EMR system
   b. Utilize an IETF framework for implementation
   c. Evolve it in time, not all at once

3. Nosocomial Infections, Mis-Diagnoses, Drug Errors
   a. Implement best practices to reduce nosocomial infections
   b. Utilize integrated EMR/Billing systems to reduce drug errors
   c. Use the EMR as a means to track compliance with these areas requiring compliance

THERE WILL BE A MASSIVE CHANGE IN HEALTH CARE RESULTING FROM THE APPLICATION OF GENETIC TECHNIQUES IN THE AREAS OF SCREENING, STAGING, TREATMENT AND PREVENTION. THESE CHANGES WILL RESULT IN AN UPHEAVAL IN THE VERY ARCHITECTURE OF HEALTH CARE DELIVERY IN THE UNITED STATES. IF THE US
Genetic testing can be used for screening, staging, treatment and prevention. These applications of genetic methods will be explosively expanded in the next ten years. After that will be genetic applications to treatment and prevention. Thus in a twenty year span we expect to see a dramatic change in the delivery of health care whereby disease we see causing the greatest burden can be dramatically and economically managed in a totally outpatient basis. Thus we argue that any health care policy must not only consider this effect in its development but must stress these efforts in its implementation.

1. Screening: The screening for the BRCA gene in breast cancer and of many other genes in cancers can provide the physician with better insight to how best to treat the disease. Companies like Correlagen in Cambridge screen for genes for which remediation can be achieved, not just telling the patient that they may have a problem. Screening can dramatically reduce certain disease mortality and morbidity and also create an environment for more focused management and monitoring.

2. Staging: Looking for the presence of a Philadelphia chromosome in CML and other genetic tests can assist in the staging of the disease once it is detected. In prostate cancer, for example the staging can be done with the following genes: (i) TMPRSS2
Promoter and TES Transcription, (ii) Androgen receptor pathways, and (iii) PTEN and HER2.

3. Treatment: New treatment methods using targeted genes are in thousands of clinical trials. Again in prostate cancer we have: (i) Immune based gene therapy, (ii) Cytotoxic gene therapy, suicide genes, and (iii) Conditionally replicating oncolytic adenoviruses.

4. Prevention: The use of the vaccine in cervical cancer to treat the influence of papilloma virus is a prime example.

We know that looking solely at the past as prologue to the future to be patently false. Consider two past examples; infectious diseases and psychiatry.

In the early part of the 20th century health care was dominated by the management of infectious diseases. New York City had its own Tuberculosis hospital, Sea View Hospital, which was filled with TB cases which the City cared for. With the introduction of an aggressive public health care system in New York and the ultimate development of drugs such as Rifampin and isoniazid, cures or at least strong containment of TB could be achieved. Thus it is no longer the case that one needs massive numbers of beds for TB patients.

The psychiatric centers such as Willow Brook Hospital on Staten Island in New York City were filled with psychiatric patients until the early 1970s. With the advent of drugs such as haloperidol and the like they closed in just a few years. The Commonwealth of Massachusetts had in 1965 a total of 45,000 hospital beds occupied every day. 25,000 of those were for psychiatric patients. By 1975, the psychiatric beds were reduced to 6,000 and today they are less than 1,000.

Thus, if we planned health care in 1965 for twenty years into the future using the past and not recognizing the impact of the new "technologies" then we would have been grossly in error! This is a clear warning as the Government approaches this task.

Also it is critical to understand that if the U.S. continues to dominate the genetic medical field that it is also establishing a base for a truly expansive economy throughout the current century. This is an area where the Government, through its funding and clinical support, can be of significant assistance. I see this also missing from the discussion of a plan by the current Administration.

**RESTRUCTURING THE OVERALL HEALTH CARE APPARATUS IN THE U.S. CAN BE ACHIEVED IN AN INCREMENTAL MANNER. HOWEVER CERTAIN PRINCIPLES ARE REQUIRED.**

Finally, I address the issue of a plan and the principles of a plan. I strongly believe that the above prior three issues must be discussed before or at least contemporaneously with the health plan structural issues. Otherwise the "what" one plans for is not a true
reality or reflection of the future. In fact, planning for the wrong "what" can cause a great deal more harm to the optimal path discussed above.

The following I believe are essential for any evolving health care plan:

• Catastrophic Coverage: There should be coverage of catastrophic incidents such as cancers, stroke, and long term disabling diseases such as MS, ALS, Parkinson’s and Alzheimer’s. The costs of these catastrophic diseases are on average low but to those who are affected they are disastrous. They are not preventable and in the most part currently not curable. Any one or family in one of these cases should be financially protected and should be available with the best of care, medical and palliative.

• Universal: Like the Massachusetts Plan, it must require all to participate. Unless the requirement for coverage is universal it cannot work. Arbitrage will occur and the system will not work as an insurance system but almost akin to a hedge fund, with the taxpayers paying for those who lose their bet. Coverage should not be denied and pre-existing conditions should not be factored into rates. Having Type 1 diabetes is a matter of fate not a matter of choice. Yet as we have stated earlier certain choice results such as Type 2 Diabetes and lung disorders related to smoking may have excess premiums applied.

• Choice: The Plan(s) must allow choice so that a patient may choose their health care provider and hospital. The physician must also have broad flexibility, since any stringent application of evidence base medicine or comparative clinical effectiveness applied too broadly is destined to disaster. Choice should also be allowed to selection of plans. Plans should at a minimum cover catastrophic coverage and other drastic forms of coverage. However any broadly based coverage and out of pocket expenses should be discretionary.

• Motivate Removal of “Bad Habits”: Use economic rewards and taxes to remove such things as obesity and improve screening.

• Reward Good Health: There must be a system which incentivizes good health practices and dis-incentivizes bad ones.

• Establish Public Health Facilities: Utilize Public Health Clinics in place of the ER as a means of dealing with those in need of non-urgent care. Facilitate this by staffing with Medical School Graduates with tuition repayment.

• Evolve Enabling Technology: Mandating technology solutions means the Government is choosing winners and losers and this always leads to increased costs and reduced quality of care. Thus allow the health care community to evolve their own solutions within the community and not have a Federal mandate. Federal "czars" breed politically
correct solutions to non-problems and these solutions line the pockets of favorites at the expense of the taxpayers.

Finally it is essential that any health care plan look forward and not backward. Addressing the payment mechanism without addressing the other three more critical elements is a major failure. It will just keep the past frozen in the future. The current assumption is that the provisioning of health care will be a natural extension of the current practice. This is an approach of accountants and economists. They are the archeologists of our economy. We need future looking insight not recriminatory looks at the past.

My concerns reflect those of one who has successfully run business as well as having been professionally and academically involved in medicine. The problem that I see with many of the others proposing a health care policy is that their proposals all too often are just too academic. Books like those of Luft, Porter, Cutler and others, with their academically contrived plans, reflect views from the ivory tower of academe and grossly fail to do what any good business person would do. Namely they fail to look ahead as well as look at reducing costs. They all focus on the issue of how to pay for "it". That approach to me is vacuous.

These changes that we face in the provision of health care are sea changes that exceed those in health care in the past. It is essential I believe that we develop and implement a new health care policy in an orderly and business-like manner and just not rearrange the deck chairs which is a costly and non-productive exercise.

1.3 World View Changes

Health care as we have argued is in need of a comprehensive evaluation. That evaluation requires looking at the problem in a manner which is different that the common approaches. The presently accepted health care analysis takes many assumptions for granted. We believe that those assumptions should be expressly stated and their present and projected condition stated. Secondly health care policy development takes the past as the established framework for projecting the future. As we must reassess the tacit assumptions we must also reject the approach of relying on past practices for future projections.

The following is a framework based upon priority and facts which we believe is an essential foundation for developing a viable health care policy.

1. The current core assumption of those in health care policy is that demand is inelastic. Namely that people will demand a certain amount of health care services no matter what the price. We argue that health care is elastic and the simple example of taxing cigarettes and the dramatic reduction in male deaths due to lung cancer and cigarette
related diseases are evidence. We would argue that the same can be applied to Type 2 Diabetes and its cause, morbid obesity and overweight. These two disease and their disease clusters are examples of economically market preventable diseases. We also argue that there are a class of market incentivized remediable diseases, whose incidence and mortality and morbidity can be reduced, and thus costs reduced, by proper screening. These are colon, prostate, breast and ovarian cancers. We estimate that the preventable disease controls can reduce the costs of health care by 12% and the remediable disease management can reduce the cost of health care by 6%. This is a total of 18% reduction.

2. The current assumption is that the provisioning of health care will be a natural extension of the current practice. We know that to be patently false. Consider two past examples; infectious diseases and psychiatry. In the early part of the 20th century health care was dominated by the management of infectious diseases. New York City had its own Tuberculosis hospital, Sea View, which was filled with TB cases which the City cared for. This is no longer the case. The psychiatric centers such as Willow Brook in New York City were filled with psychiatric patients until the early 1970s. With the advent of drugs such as haloperidol and the like they closed in just a few years. These were sea change in health care. Today we face a similar change. Take cancers for example. Genetic testing can be used for screening and staging. These will be explosively expanded in the next ten years. After that will be genetic applications to treatment and prevention. Thus in a twenty year span we expect to see a dramatic change in the delivery of health care whereby disease we see causing the greatest burden can be dramatically and economically managed in a totally outpatient basis. Thus we argue that any health care policy must not only consider this effect in its development but must stress these efforts in its implementation.

This is a world view change as we depict below. At one time TB was viewed as unstoppable, then psychiatric hospitals, then AIDS. That world view then gets projected forward and becomes the paradigm for the next set of changes. We argue that we must look forward for the new world view and not backward. Genetics is most likely the key element of that change. Perhaps genetic treatments will drive out hospitals altogether, except for accidents and other trauma
1.4 Current Proposals

Health care costs are assumed to be managed by external controls. We argue that this is not the case. In fact there are facts to demonstrate that Government regulation is one of the significant drivers in the explosive overhead costs of health care. Thus there are several things which will reduce the costs of health care delivery.

First, electronic medical records are critical but their introduction must be organic and evolutionary. Like the Internet, which was organically and evolutionarily developed via the Internet Engineering Task Force, the IETF, the EMR should see a similar development, facilitated but not controlled by the Government. It is well known that Government is not god at picking market winners and at managing ill defined programs. Thus the Government should facilitate and not manage.

Second, medical billing and collections should be fully integrated and automated. There is a plethora of such systems and medical practices are all too often placed in the position of financing insurance companies and Medicare via accounts receivable and bad debts.

Third, a set of best practices oversight to reduce nosocomial infections, faulty diagnoses and misapplications of drugs is essential. The three of these and many more can reduce health care costs by 12-15%.

The Figure below highlights some of these issues.
We finally list several preliminary recommendations which focus on:

1. Universal Coverage, or the all in plan.

2. Catastrophic Coverage

3. Minimal Benefit Set

4. Dis-incent Bad Behaviour:

5. Expand Public Health

6. Utilize Electronic Information Technologies

We will spend the greater part of this book discussing these issues in detail.
## Recommendations

<table>
<thead>
<tr>
<th>Category</th>
<th>Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Universal Coverage</td>
<td>• Require universal coverage</td>
</tr>
<tr>
<td>Catastrophic Coverage</td>
<td>• Provide universal “insurance” for catastrophic events</td>
</tr>
<tr>
<td>Minimal Coverage Plan</td>
<td>• Plan must cover excess costs above threshold</td>
</tr>
<tr>
<td></td>
<td>• Choice in plan, physician, hospitals</td>
</tr>
<tr>
<td>Disincent “Bad Habits”</td>
<td>• Tax bad habits such as smoking, drinking, carbs.</td>
</tr>
<tr>
<td></td>
<td>• Reward Good habits</td>
</tr>
<tr>
<td>Expand Public Health</td>
<td>• Establish broad based public health service</td>
</tr>
<tr>
<td>Utilize Technology</td>
<td>• Utilize EMR but involve practitioners and remove Government</td>
</tr>
<tr>
<td></td>
<td>• Simplify Payments</td>
</tr>
</tbody>
</table>
2 FUNDAMENTAL HEALTH CARE STATISTICS

The Healthcare issue has been a growing problem which now appears to have the capability to continue unbounded. It requires a fresh look and a new assessment of what can reasonably be achieved within the confines of what exists and what can be changed. Unlike many of the approaches which assume that the demand is a given and a continually growing given and all one focus on is to determine how to pay for this, otherwise rationing will be required as was proposed by the Hillary Healthcare proposal of 1993, we believe that both demand and supply can be adjusted. We further believe that free market mechanisms function and that technology can play a significant role in this approach proposed herein.

In 1993 in response to the Hillary Healthcare Plan we prepared a Healthcare Policy paper which presaged many of the current issues. That was sixteen years ago, and in many ways nothing much has changed except then Healthcare was going on $900 billion now it will approach $2.5 Trillion!

One is always reminded of Kahn’s law, “what we expect tomorrow frequently never occurs, and what we anticipate in the distant future frequently occurs tomorrow”. Thus anyone who prognosticates the future will inevitably bear the burden of totally missing the target. The prognosticator may be focusing on all of the things which never come to be. The strength of any guesser in the future is one who has keen insight into the obvious that is also the strength of the securities trader, focus on the next step, chess games are not always the rules of life, and Brownian motion is a more likely model!

Yet what we thought was going to take a while is now at our doorstep, exploding Healthcare costs and their impact on quality of care and what we though sixteen years ago was readily achievable, namely technology to reduce the costs and expand the access has never gotten there.

Health care is in need of a comprehensive evaluation. That evaluation requires looking at the problem in a manner which is different that the common approaches. The presently accepted health care analysis takes many assumptions for granted. We believe that those assumptions should be expressly stated and their present and projected condition stated. Secondly health care policy development takes the past as the established framework for projecting the future. As we must reassess the tacit assumptions we must also reject the approach of relying on past practices for future projections.

1 The author hear Bob Kahn, the key player when at ARPA in creating what is now the Internet and also not at the Center for National Research Initiatives.
The following is a framework based upon priority and facts which we believe is an essential foundation for developing a viable health care policy.

1. The current core assumption of those in health care policy is that demand is inelastic. Namely that people will demand a certain amount of health care services no matter what the price. We argue that health care is elastic and the simple example of taxing cigarettes and the dramatic reduction in male deaths due to lung cancer and cigarette related diseases are evidence. We would argue that the same can be applied to Type 2 Diabetes and its cause, morbid obesity and overweight. These two disease and their disease clusters are examples of economically market preventable diseases. We also argue that there are a class of market incentivized remediable diseases, whose incidence and mortality and morbidity can be reduced, and thus costs reduced, by proper screening. These are colon, prostate, breast and ovarian cancers. We estimate that the preventable disease controls can reduce the costs of health care by 12% and the remediable disease management can reduce the cost of health care by 6%. This is a total of 18% reduction.

2. The current assumption is that the provisioning of health care will be a natural extension of the current practice. We know that to be patently false. Consider two past examples; infectious diseases and psychiatry. In the early part of the 20th century health care was dominated by the management of infectious diseases. New York City had its own Tuberculosis hospital, Sea View, which was filled with TB cases which the City cared for. This is no longer the case. The psychiatric centers such as Willow Brook in New York City were filled with psychiatric patients until the early 1970s. With the advent of drugs such as haloperidol and the like they closed in just a few years. These were sea change in health care. Today we face a similar change. Take cancers for example. Genetic testing can be used for screening and staging. These will be explosively expanded in the next ten years. After that will be genetic applications to treatment and prevention. Thus in a twenty year span we expect to see a dramatic change in the delivery of health care whereby disease we see causing the greatest burden can be dramatically and economically managed in a totally outpatient basis. Thus we argue that any health care policy must not only consider this effect in its development but must stress these efforts in its implementation.

3. Health care costs are assumed to be managed by external controls. We argue that this is not the case. In fact there are facts to demonstrate that Government regulation is one of the significant drivers in the explosive overhead costs of health care. Thus there are several things which will reduce the costs of health care delivery. First, electronic medical records are critical but their introduction must be organic and evolutionary. Like the Internet, which was organically and evolutionarily developed via the Internet Engineering Task Force, the IETF, the EMR should see a similar development, facilitated but not controlled by the Government. It is well known that Government is not god at picking market winners and at managing ill defined programs. Thus the Government
should facilitate and not manage. Second, medical billing and collections should be fully integrated and automated. There is a plethora of such systems and medical practices are all too often placed in the position of financing insurance companies and Medicare via accounts receivable and bad debts. Third, a set of best practices oversight to reduce nosocomial infections, faulty diagnoses and misapplications of drugs is essential. The three of these and many more can reduce health care costs by 12-15%.

2.1.1 The Problem

There are many who purport to know the problem and the solution. We start by assessing the facts and their impact on the Healthcare system. From these facts arise sets of the problem. The problem is not just simply inefficient systems and a patch quilt of plans and a mass of uninsured. The problem stems from the individual and then works outward.

The healthcare system in the United States is not broken; it is just a simple problem of supply and demand compounded by a plethora of complex government regulations which add to costs rather than achieving efficiencies and quality of care.

We strongly believe in supply and demand. To some degree this is a free market concept but since the Government has such a strong role to play here and since good health at reasonable costs, in what already is a universal delivery system, is a Government problem, it must be looked at from a fully economic basis and demand is as important as supply.

The supply-demand analysis clearly starts with the patient-citizen where demand can be modulated by lifestyle management and preventative care and management rather than dealing with exacerbated problems due to neglect resulting from fear of costs and consequences. Secondly supply costs may be modulated and reduced by more effective consolidation of overhead and management costs through proper legislation and the utilization of effective and accepted information technologies.

There has always been a debate as to the existence of demand modulation in Healthcare. The answer is quite simple, any economic entity where there are costs associated with usage and those costs are by the purchaser results in decisions being made. In our proposals the costs relate to things which improve health, thus rather than having a patient choose between medical procedures and in turn quality of care, the patient in an a priori manner makes the choice via a lifestyle costs decision.

There are simple and straightforward cost metrics which allow for the optimization of delivery which minimizing the costs of delivery of Healthcare. These must be applied to the current system and used to drive down and manage costs more effectively. In many cases this means shedding burdensome costs required by outdate legislation.
The details must be considered and only from the analysis of what drives demand and supply costs can one seek to obtain a rational policy.

2.1.2 The Demand

Demand is driven by two simple elements; the population and the diseases incident in that population. There is a third subtler element which is the actual "demand" by the patient or the physician to certain procedures, medications and the like. Two simple examples explain this phenomenon. First, a trial performed almost twenty years ago showed that if a physician was presented with costs for procedures, such a lab work, then frequently the physician became more judicious in selecting what they needed and there was a reduction in excess procedures. Second, patient demand for medications driven by pharmaceutical advertising has dramatically increased the demand for non-generic pharmaceuticals to treat common ailments.

We have reached the following conclusions regarding demand:

**DEMOGRAPHIC FACTORS ARE SUCH THAT THE TOTAL POPULATION, THE PERCENT OVER 65 AND THE NUMBER OF NEW IMMIGRANTS AND THEIR OFFSPRING ARE GROWING AT DRAMATIC RATES. THIS GROWTH WILL BE THE PRIME DRIVER FOR DEMAND.**

The population will exceed 450 million in 2050, the percent over 65 will approach 40% and the number of Hispanic will exceed 30%, In addition Hispanics generally have 33% with no insurance and are the predominant users of ER care. This will place a tremendous load on healthcare.

**THERE ARE CERTAIN DISEASE WHICH ARE POTENTIALLY CONTROLLABLE AND PREVENTABLE AND OTHERS WHICH ARE CONTROLLABLE AND REMEDIAIBLE. THE PREVENTABLE CLASS IS DRIVEN BY LIFESTYLE CHOICES SUCH AS SMOKING AND EATING. THE REMEDIAIBLE ARE THOSE WHICH IF DETECTED EARLY CAN BE MANAGED OR CURED.**

We already know what behavior causes what diseases and what diseases are amenable to remediation by early examination and care. This just requires acting on these and then obtaining the reductions in incidence.

**THE CLASSIC DEMAND MODEL FOR HEALTHCARE ASSUMES A FIXED UNCHANGEABLE DEMAND. WE OBTAIN A MODEL WHERE DEMAND CAN BE MODULATED THROUGH THE MEANS OF CONTROLLING THE PREVENTABLE BY TAXATION AND THE REMEDIAIBLE BY PREVENTIVE CARE. WE ALSO PROPOSE THE REINSTITUTION OF PUBLIC HEALTH FACILITIES TO REPLACE THE EXCESSIVE AND HIGHLY COSTLY DEMAND FOR ER SERVICES.**

Gov Patterson of New York has suggested a "carb" tax on sweetened sodas and the like. Mayor Bloomberg demanded that polyunsaturated fats be removed from restaurants.
These are current example of Government intervention in the market by taxing or preventing. They are happening now and will have a lasting effect.

2.1.3 The Supply

Hospitals are the most significant element in the supply chain. They have been reducing in number but increasing in size over the past twenty years and it is anticipated that they will continue to do so. They are controlled by archaic compensation systems with currently more than 50% paid by Medicare and Medicaid and another 25% by private insurance. This leaves a significant portion of uninsured. There is excessive pressure on Hospital therefore to "play the reimbursement game" and add additional staff to find ways to obtain reimbursement. This becomes a vicious cycle and again increases costs. The implementation of a universal coverage, not single payer, will eliminate this problem.

2.1.4 Technology

The Obama Administration is pushing many billions for Electronic Medical Records. This is conceptually an attractive approach but it also is one rant with many unanswered structural questions. As was done in the formation of the Internet and the IETF committee, a users group, a similar effort should be the catalyst not what some third party software and networking company can provide.

One of the greatest causes of cost increase in the practice of medicine has been the added burden of billing, record keeping, drug prescriptions, privacy concerns and the like. Technology can dramatically solve this problem. If the physician has the information regarding costs of procedures, of medications, as an integral part of the prescribing practice then frequently the demand is reduce but balanced with quality care. In addition the reduction in billing costs and cash flow delay can be reduce with a common system rather than the current patchwork of multiple healthcare reimbursement systems. A Government mandated standards of electronic billing is essential.

The billing problem has been around for over thirty years. It has become explosive in terms of overhead and in terms of bad debt. It is a major cost in the provision of health care. Secondly the lack of portability of health care records results frequently in multiple procedures and more importantly the data is seen as a point in time not as a process over time. Ocular pressure, blood pressure, HbA1c, LDL, and they like should be viewed over time, not as a point sample. Thus the systems to allow that are critical, not just a system which records general facts.

The EMR has substantial value. It is essential that it follow the patient and that it utilize a national if not globally accessible network. However we believe that IT'S implementation will take substantially longer than most believe at current due
**HEALTH CARE POLICY: POLITICS VS REALITY**

**PRIMARILY TO THE COMPLEXITY OF MULTIMEDIA MEDICAL RECORDS. WE BELIEVE IT IS ESSENTIAL TO START BUT ONE MUST CAREFULLY PACE THE EFFORT SO AS NOT TO ADD ADDITIONAL BURDENS TO THE ALREADY COMPLEX PRACTICE OF MEDICINE.**

The EMR is essential but it is an evolving process. It is patient focused but it is a complex set of multimedia data objects correlatable over time. This is no mean task and it is not akin to building a bridge, a process well known since Roman times but still subject to errors. There is no blueprint for this since it involves some many human factors.

**THE REINSTITUTION OF PUBLIC HEALTH FACILITIES TO SUPPLANT THE EXCESSIVE DEMANDS ON THE ER CAN BE ACHIEVED WITH THE USE OF REMOTE MEDICINE USING BROADBAND. IN THE EVENT OF A CONSULT, THIS MAY BE ACHIEVED REMOTELY VIA BROADBAND NETWORKING AND THE ACCESS TO THE SPECIALIST, WHETHER IT IS A RADIOLOGIST, CARDIOLOGIST, OR EVEN DERMATOLOGIST, VIA THIS SYSTEM.**

The old Public Health system provided local clinics for those who could not afford more expensive health care or for other reasons could not get access to it. The Public Health clinics provided to inoculations and pediatric care, general health checkups, and care for common ailments and then referrals to the appropriate secondary locations. If one cannot afford a higher level of care then these clinics will provide a core set of services. Here technology can play a dramatic role of improving quality while reducing costs. Telemedicine and teleradiology via broadband is a major player here and these have evolved so that they can apply in the current environment.

**2.1.5 The Economic Implications**

We can now examine in simple economic terms what the impact of the proposal will be. We proceed through five steps; demand, supply (three steps) and market stability.

Consider first the demand. Here we plot demand on a price, $p$, and quantity, $q$, and diagram common to all economics. Currently demand is independent of price. The current demand is a vertical line that is fixed and independent to any costs. This is more than simplistic since we generally accept anyone into the ER and in states like California illegal immigrants are provided care independent of any status. Now if we apply to the system some "tax" for bad foods or behavior and also provide costs incentives for excessive use then we get a more normal demand curve, namely price or cost sensitivity.
Now the first step in the supply curve will be to drive out costs which are overhead costs. Thus is we reduce the cost of billing and that of report management on a per patient basis this would represent a shift in the supply curve downward as shown in the following. This is the first step in cost reduction.
The alternative would be to create scale economies in the delivery, namely making it less costly the more service that are delivered. We argue herein that using a Public Health delivery system would do so by alleviating other more costly means such as the ER. There are many more examples of such an approach. The following Figure depicts what would happen in this event. Namely we see a decline of the supply curve the larger the demand becomes, clear scale effects.

We can then combine the two effects of reducing overhead and achieving scale to create a compound new supply curve as shown in the following Figure.
Finally we can combine the Demand and the Supply curves to show what the total effect would be. This is done in the following Figure.
We note that we reduce the costs significantly while have a small but measurable decrease in the supply by means or reallocation while keeping the overall quality high. This above graphic is in essence what we propose in the plan.

2.1.6 Policy Options

The Plan proposed herein is built upon the following principles:

1. **Catástrophic Coverage**: There should be coverage of catastrophic incidents such as cancers, stroke, and long term disabling diseases such as MS, ALS, Parkinson’s and Alzheimer’s.

2. **Every One In**: Like the Massachusetts Plan, it must require all to participate.

3. **Choice**: The Plan(s) must allow choice so that a patient may choose their health care provider and hospital.

4. **Reward Good Health**: There must be a system which incentivizes good health practices and dis-incentivizes bad ones.

5. **Establish Public Health Facilities**: Utilize Public Health Clinics in place of the ER as a means of dealing with those in need of non-urgent care. Facilitate this by staffing with Medical School Graduates with tuition repayment.

6. **Evolve Enabling Technology**: Mandating technology solutions means the Government is choosing winners and losers and this always leads to increased costs and reduced quality of care.

These are basic principles which are common across many plans. They allow choice, mandate universality, and include quality. The key issue however will be the management of demand and the effective improvement in supply costs,

2.2 Overview

Healthcare has become a massively growing problem for the US economy and those involved in it in any way, which includes everyone. It will cost the US in excess of $2.5 Trillion in 2009 and this will account for over 18% of the GDP. It continues to increase at a rate in excess of annual inflation.

The approach to "solving" the problem has been one on finding ways to pay for the costs and to make it inclusive. However, very little has been focused on reducing the demand by effecting policies which reduce disease states which are amenable to such control.
There are two major categories of disease which can and must be addressed; preventable and remediable. Preventable are those due to lifestyle. Remediable are those which if detected early can be intervened and where detection is now generally accepted as being achievable.

2.2.1 Preventable

Consider two simple disease states, Type 2 Diabetes and the problems of smoking. Both result in circulatory, coronary, kidney, and other problems. Both are readily controllable by reducing their known causes.

Type 2 Diabetes is a simple carbohydrate problem, lower the carbs and lower the weight, along with exercise, and the problem goes away, if done so early enough. From the CDC the following is a summary of Type 2 Diabetes impact.

<table>
<thead>
<tr>
<th>Type 2 Diabetes Statistics</th>
</tr>
</thead>
</table>
| Total prevalence of diabetes in the United States, all ages, 2002 | Total: 18.2 million people — 6.3% of the population — have diabetes. Diagnosed: 13.0 million people
Undiagnosed: 5.2 million people |
| Prevalence of diagnosed diabetes among people under 20 years of age, United States, 2002 | About 210,000 people under 20 years of age have diabetes. This represents 0.26% of all people in this age group. Approximately one in every 400 to 500 children and adolescents has type 1 diabetes. |
| Total prevalence of diabetes among people aged 20 years or older, United States, 2002 | Age 20 years or older: 18.0 million; 8.7% of all people in this age group have diabetes.
Age 60 years or older: 8.6 million; 18.3% of all people in this age group have diabetes.
Men: 8.7 million; 8.7% of all men aged 20 years or older have diabetes.
Women: 9.3 million; 8.7% of all women aged 20 years or older have diabetes. |
| Cost of diabetes in the United States | Total (direct and indirect): $132 billion
Direct medical costs: $92 billion
Indirect costs: $40 billion (disability, work loss, premature mortality) |

The issue of controlling smoking will reduce lung cancer rates by orders of magnitude and will also dramatically reduce COPD, circulatory problems, a variety of other cancers, kidney, pancreas, larynx, oropharynx, and others.

2 https://apps.nccd.cdc.gov/sammec/five_yr_sam.asp
Average Annual Smoking-Attributable Mortality (United States, 2000-2004)$^1,2$

### Average Annual Smoking Mortality US 2000-2004

<table>
<thead>
<tr>
<th>Disease Category</th>
<th>Male</th>
<th>Female</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Malignant Neoplasia</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lip, Oral Cavity, Pharynx</td>
<td>3,749</td>
<td>1,144</td>
<td>4,893</td>
</tr>
<tr>
<td>Esophagus</td>
<td>6,961</td>
<td>1,631</td>
<td>8,593</td>
</tr>
<tr>
<td>Stomach</td>
<td>1,900</td>
<td>584</td>
<td>2,484</td>
</tr>
<tr>
<td>Pancreas</td>
<td>3,147</td>
<td>3,536</td>
<td>6,683</td>
</tr>
<tr>
<td>Larynx</td>
<td>2,446</td>
<td>563</td>
<td>3,009</td>
</tr>
<tr>
<td>Trachea, Lung, Bronchus</td>
<td>78,680</td>
<td>46,842</td>
<td>125,522</td>
</tr>
<tr>
<td>Cervix Uteri</td>
<td>0</td>
<td>447</td>
<td>447</td>
</tr>
<tr>
<td>Kidney and Renal Pelvis</td>
<td>2,827</td>
<td>216</td>
<td>3,043</td>
</tr>
<tr>
<td>Urinary Bladder</td>
<td>3,907</td>
<td>1,076</td>
<td>4,982</td>
</tr>
<tr>
<td>Acute Myeloid Leukemia</td>
<td>855</td>
<td>337</td>
<td>1,193</td>
</tr>
<tr>
<td><strong>Subtotal</strong></td>
<td>104,472</td>
<td>56,376</td>
<td>160,849</td>
</tr>
<tr>
<td><strong>Cardiovascular Diseases</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ischemic Heart Disease</td>
<td>50,884</td>
<td>29,121</td>
<td>80,005</td>
</tr>
<tr>
<td>Other Heart Disease</td>
<td>12,944</td>
<td>8,060</td>
<td>21,002</td>
</tr>
<tr>
<td>Cerebrovascular Disease</td>
<td>7,896</td>
<td>8,026</td>
<td>15,922</td>
</tr>
<tr>
<td>Atherosclerosis</td>
<td>1,282</td>
<td>611</td>
<td>1,893</td>
</tr>
<tr>
<td>Aortic Aneurysm</td>
<td>6,628</td>
<td>2,791</td>
<td>8,419</td>
</tr>
<tr>
<td>Other Circulatory Diseases</td>
<td>505</td>
<td>749</td>
<td>1,254</td>
</tr>
<tr>
<td><strong>Subtotal</strong></td>
<td>79,139</td>
<td>49,358</td>
<td>128,494</td>
</tr>
<tr>
<td><strong>Respiratory Diseases</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pneumonia, Influenza</td>
<td>6,042</td>
<td>4,381</td>
<td>10,423</td>
</tr>
<tr>
<td>Bronchitis, Emphysema</td>
<td>7,536</td>
<td>6,391</td>
<td>13,927</td>
</tr>
<tr>
<td>Chronic Airway Obstruction</td>
<td>40,217</td>
<td>38,771</td>
<td>78,988</td>
</tr>
<tr>
<td><strong>Subtotal</strong></td>
<td>53,795</td>
<td>49,543</td>
<td>103,338</td>
</tr>
<tr>
<td><strong>Average Annual Total</strong></td>
<td>237,406</td>
<td>155,277</td>
<td>392,681</td>
</tr>
</tbody>
</table>

### Smoking Attributable Productivity Losses ($000, US 2004)

<table>
<thead>
<tr>
<th>Disease Category</th>
<th>Male</th>
<th>Female</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Malignant Neoplasia</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lip, Oral Cavity, Pharynx</td>
<td>$1,688,872</td>
<td>$367,657</td>
<td>$2,056,529</td>
</tr>
<tr>
<td>Esophagus</td>
<td>$2,589,475</td>
<td>$462,886</td>
<td>$3,052,361</td>
</tr>
<tr>
<td>Stomach</td>
<td>$598,695</td>
<td>$164,244</td>
<td>$762,939</td>
</tr>
<tr>
<td>Pancreas</td>
<td>$1,213,664</td>
<td>$455,544</td>
<td>$2,159,208</td>
</tr>
<tr>
<td>Larynx</td>
<td>$883,833</td>
<td>$188,214</td>
<td>$1,072,047</td>
</tr>
<tr>
<td>Trachea, Lung, Bronchus</td>
<td>$23,851,960</td>
<td>$14,350,500</td>
<td>$38,202,460</td>
</tr>
<tr>
<td>Cervix Uteri</td>
<td>$0</td>
<td>$295,837</td>
<td>$295,837</td>
</tr>
<tr>
<td>Kidney and Renal Pelvis</td>
<td>$995,889</td>
<td>$71,613</td>
<td>$1,067,502</td>
</tr>
<tr>
<td>Urinary Bladder</td>
<td>$794,495</td>
<td>$188,602</td>
<td>$983,097</td>
</tr>
<tr>
<td>Acute Myeloid Leukemia</td>
<td>$282,374</td>
<td>$106,085</td>
<td>$388,459</td>
</tr>
<tr>
<td><strong>Subtotal</strong></td>
<td>$32,899,257</td>
<td>$17,141,182</td>
<td>$50,040,439</td>
</tr>
<tr>
<td><strong>Cardiovascular Diseases</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ischemic Heart Disease</td>
<td>$18,314,652</td>
<td>$5,965,867</td>
<td>$24,280,519</td>
</tr>
<tr>
<td>Other Heart Disease</td>
<td>$3,339,574</td>
<td>$1,271,135</td>
<td>$4,610,709</td>
</tr>
<tr>
<td>Cerebrovascular Disease</td>
<td>$3,030,005</td>
<td>$2,843,401</td>
<td>$5,873,406</td>
</tr>
</tbody>
</table>

Page 37
<table>
<thead>
<tr>
<th>Disease Category</th>
<th>Male</th>
<th>Female</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Atherosclerosis</td>
<td>$136,142</td>
<td>$39,554</td>
<td>$175,696</td>
</tr>
<tr>
<td>Aortic Aneurysm</td>
<td>$1,273,025</td>
<td>$435,256</td>
<td>$1,708,281</td>
</tr>
<tr>
<td>Other Arterial Disease</td>
<td>$133,059</td>
<td>$132,905</td>
<td>$265,964</td>
</tr>
<tr>
<td>Pneumonia, Influenza</td>
<td>$1,327,885</td>
<td>$983,201</td>
<td>$2,311,086</td>
</tr>
<tr>
<td>Chronic Airway Obstruction</td>
<td>$6,554,599</td>
<td>$5,915,617</td>
<td>$12,470,216</td>
</tr>
<tr>
<td>Respiratory Diseases</td>
<td>$8,750,475</td>
<td>$7,435,296</td>
<td>$16,185,771</td>
</tr>
</tbody>
</table>

**Economic Costs and Years of Potential Life Lost Associated with Cigarette Smoking**

- For 1997–2001, cigarette smoking was estimated to be responsible for $167 billion in annual health-related economic losses in the United States ($75 billion in direct medical costs, and $92 billion in lost productivity), or about $3,561 per adult smoker.

- The total economic costs associated with cigarette smoking are estimated at $7.18 per pack of cigarettes sold in the United States.

- Cigarette smoking results in 5.5 million years of potential life lost in the United States annually.\(^3\)

The total cost of just these two is $92 plus $75 billion or $167 billion, or 8.4% of the total Health Care budget for the sample period.

One simple way to effect this is via an aggressive tax. Tax carbs and tax nicotine. The carb tax has been proposed by Governor Patterson of New York, a superb try of eliminating the problem via an economic channel.

---


The taxing approach is an elegant approach. If people do not reduce the demand then the taxes pay for its costs. If the taxes reduce demand and thus reduce the tax revenue then the reduction in the related diseases are reduced. It becomes a zero sum game.

A second class of disease is amenable to early detection and remediation thus dramatically reducing costs. The most obvious of late are prostate, breast and colon cancers, each of which can be detected in many if not most cases, well before the time they become invasive. The costs per remediated disease can be kept lower than the cost of dealing with an un-remediated disease.

2.2.2 Remediable

The second major thrust is at remediable disease, those which can be detected early using available techniques. The following is a list of such and their incidence in cases in 2008.

Remedial Diseases

<table>
<thead>
<tr>
<th>Disease</th>
<th>Incidence</th>
<th>Mortality</th>
<th>Survival 5 Year</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Total</td>
<td>Male</td>
<td>Female</td>
</tr>
<tr>
<td>Colon &amp; Rectum:</td>
<td>153,854</td>
<td>180,003</td>
<td>133,178</td>
</tr>
<tr>
<td>Breast</td>
<td>208,281</td>
<td>3,649</td>
<td>383,419</td>
</tr>
<tr>
<td>Cervix uteri</td>
<td>13,379</td>
<td>-</td>
<td>25,541</td>
</tr>
<tr>
<td>Prostate</td>
<td>218,923</td>
<td>495,617</td>
<td>-</td>
</tr>
<tr>
<td>Melanoma of the skin</td>
<td>58,988</td>
<td>74,799</td>
<td>47,433</td>
</tr>
<tr>
<td>Total</td>
<td>653,424</td>
<td>754,068</td>
<td>589,572</td>
</tr>
</tbody>
</table>

Removing the Lung from this Table because it was accounted for above we find we have a total of 653,242 cases per year at the base population of 304 million. This a bit more complex since the incidence is for every year and during the five year survival period we treat the new incidents plus the remaining survivors. Costs per incident can vary but estimates between $50,000 and $100,000 are reasonable. Thus at the upper end we can see $65 billion spent on these remediable diseases.

Added to the preventable we have a total of almost $250 billion which can be addressed immediately, well in excess of a 12% reduction.

2.2.3 The Problem

The actual problem can be laid out in a few terms:

1. Total Cost Healthcare 2007 is $2.1 Trillion
2. GDP was $11 Trillion; Healthcare was 19% of GDP!
3. Total Population is approximately 300 Million
4. Cost Per person, whether it is used or not, $7,000
5. Health Insurance per person in healthy family is $9,000 per year, $2,000 more than it costs!
6. Approximately 18% are uninsured, or a total of almost 54 Million
7. If 82% are paying for the remaining 18% then the 82% are paying the cost of the uninsured already!
8. Therefore there is NO COST to fixing the system, just fairness.
9. AND, if costs can be reduced by proper allocation, the current costs can be reduced!

The question is, however, is this a cost and allocation problem or is it a demand control problem, preventable and remediable, or is it a combination of both. We believe it is clearly both.

2.2.4 The Problem Elements

We present here the problem element in some structured detail. Specifically we see this as a problem in supply and demand and in the supply side one readily amenable to significant cost reductions. The logical structure we apply is based on the current mindsets which are as follows:

1. The current primary focus is on how to pay for the services not at all on why they cost so much.

All of the current approaches are ones which assume an exogenous demand. One which is fixed and not subject to change. In many ways it is akin to the Marshall model of economics before the advent of Keynes. We believe that demand can be modulated by market means as well as lifestyle modification.

2. The critical issue is how to improve the current poor health conditions and thus reduce demand for service.

The demand modulation is a combination of lifestyle as well as the delivery mechanism. The use of medications in place of lifestyle change and proper healthcare management just exponentially drive up the costs which increasing demand. The Type 2 Diabetes patient, by not losing the weight, uses Metformin, then insulin, then has retinopathy, then renal failure and then on and on.

3. Then the issue is how to reduce each cost element associated with those service delivery elements.
The delivery systems are archaic to say the least. There are overhead costs which can be saved and scale economies which can be achieved.

4. Then determine a way to provide them on a universal basis.

Universal care is essential. That means care before disease sets in and the proper application of healthcare facilities at the proper time. The ER is not the location for chronic care nor for care which should not have resulted in an emergency.

The analysis in this Report then looks at the following:

1. Disease Incidence and Prevalence: A detailed assessment of the current incidence and prevalence of the major cost drivers in the delivery of healthcare.

2. Cause of Incidence: Exogenous and Endogenous, Preventable and Unpreventable. This requires both an initial assessment and an ongoing process to assess what is controllable and what measures are useful in its control.

3. The Elements and Processes of provisioning of healthcare services. A bottoms up analysis and continuing cost improvement process must be effected in the provision chain of healthcare. What are the processes and why are they done in the manner currently used. We provide several key examples but a broader analysis is clearly required.

4. The cost elements of provisioning. What does it cost and why. What are the costs of all the processes, current and proposed? Are all of these costs required and are they controllable and is there scale.

Then the focus is on the following set of simple questions:

1. What can be done to reduce incidence? Ultimately everyone dies but the path between birth and death can be ameliorated in such a manner that the plethora of chronic diseases can be reduced.

2. What can be done to reduce costs? Costs are a combination of what is provided and what the unit costs are as to what constitutes those provisions.

3. What can be done to provide coverage? Universal coverage has become a mandate. This is driven by the fact that there is de facto universal coverage now. Thus we must find a way to institutionalize that in a cost effective manner.

4. Who can effect these the best delivery? The current delivery systems are a patchwork of ancient practices and systems which have evolved in a regulatory framework which does not function efficiently. The single practitioner may soon be a
thing of the past and the hospital as an organism that maximizes billable charges must also change.

Let us consider first a basic paradigm for what occurs in the provision of Healthcare. We first use the Figure below and an example.

The Patient is the source of the demand for Healthcare and there are two drivers for that source, lifestyle and endogenous causes (such as genetic processes) which result in disease states. Once the patient enters into one or more disease states then treatment of some form may apply. In the treatment process we have essential costs related to the direct providers of services and overhead costs associated with the slack inherent in such a massive system. Finally we have a payment mechanism which provides a distribution of moneys collected from patients and others to be distributed to the essential providers and overhead providers.

The following Figure depicts the cost paradigm in some detail. This may be a bit simplified but it can be a useful tool in addressing each element.
The above chart then divides the costs into five categories; (i) the first is the basic driver of a disease state, such as heart disease, or colon cancer, (ii) then there is the issue of how many separate presentations of this disease state need addressing such as an MI or a colon resection, (iii) then there are the specific actions to address the presentation such as a stent versus a graft or a resection versus some form of palliative care such as radiation, (iv) then there are all of the steps involved such as anesthesiologist, surgeon, pathologist, internist, nurses and the like, and (v) finally the unit costs for each of these. There should on the cost element also be a break out of direct and overhead costs.

In the following we show several cost breakouts for such unit costs and this is also descriptive of what some of the issues are; it is not the cost of the physician, it is all the other costs that drive up the overall costs of healthcare.
The above does reflect ways to reduce costs in addition to what has been presented. Specifically cost reduction can be effected by reducing overhead via electronic medical record keeping, billing, and coordinating tests and medications. We will discuss that latter.

2.2.5 Key Issues

The improvement in the overall Healthcare system can be effected by addressing the following set of issues:

1. Controlling Reimbursement without understanding and coming to grips with the detailed cost elements will result in rationing.

2. Mandating unfunded actions atop a controlled reimbursement scheme will exacerbate the process. Thus the mandating of an EMR system, a delayed reimbursement system, multiple reimbursement methods and the like.

3. Adding regulation, administration and overhead adds to costs. Such laudable regulatory elements such as HIPPA for privacy have costs. Billing is a massive cost element not only due to the issue of labor but more importantly due to the need for working capital, receivables frequently in excess of 180 days on Medicare alone and a year or more on Medicaid.
2.2.6 Reform Elements

Healthcare reform must include the participation of four elements; patient, providers, processes, and payments. Specifically:

1. Patient: The Patient’s predisposition to a disease state, the Patient’s management of the health-disease state and the Patient’s pattern of care.

2. Provider: What are the costs and who are the people and entities required to support the Physician in the delivery of the care.

3. Process: The set of Processes that are used to treat the disease states and their effectiveness and efficacy.


We depict the relationship amongst these elements in the following Figure.

For each of these four elements we present some key issues we will focus on:

2.2.6.1 Patient

1. Patient’s Lifestyle is a key to maintaining good health and reducing costs.
2. Patient must take responsibility for controllable disease states as well as addressing uncontrollable in a timely manner.
3. Patient must be covered for any and all catastrophic problems in a quality manner.
4. Patient must “contribute” to payment and select what the pay for.

2.2.6.2 Provider

1. Provider includes all participants who act in the delivery of the Patients care
2. Providers have been alleged to have indiscriminately been the cause of increased costs
3. Key Provider participants are the Physicians, Pharmaceuticals and Hospitals.
4. Provider cost element analysis is a key to understanding cost maintenance

2.2.6.3 Process

1. Allow flexibility to ensure innovation
2. Assess the implementation of a EBM process
3. Maintain overall Quality of Care
4. Permit Patient Choice

For example the use of the ER is a high costs process for what a Public Health System could provide.

2.2.6.4 Payment

1. Target Universal Coverage
2. Target catastrophic coverage
3. Allow choice
4. Require payment
5. Mandate portability
6. Issue “Individually”
7. Control nationally
8. Insure due process and remedies from Payers

The above a but a few of the payment issues which need focus. Nationalizing healthcare was rejected under the Hillary Healthcare proposal. Perhaps the rejection may have been as much a rejection of the way it was done as what was done. The Obama Plan, vague and uncertain in its current incarnation, is expected to change as it flows from the Senate, most likely the Kennedy office.
2.3 The Demand Model

We first examine the healthcare market from the demand side and then we will look at the supply side. The demand portion is driven by the population and the disease rates. The assumption by many is that the demand is given and unalterable. We will argue that demand may be reduced as well as the cost associated with supply. Demand is driven by the incidence and severity of disease as well as the growing prevalence. It is also driven by simple demographics, namely total population and any aging phenomenon which may exist in that population. We begin with those basics and then continue on to examine the separate disease states.

In this section we address the elements of a demand model for healthcare. The elements are shown in the following figure:

We first look at the underlying numbers of demographic factors, the people and their distribution. In addition we look at the specifics of the distribution in terms of propensity to pay, namely the uninsured. Then we examine the disease states, those controllable and those not, those catastrophic and those chronic. The output is a simple demand model.

2.3.1 Demographic Factors

There are two major demographic factors which we want to consider. The first is population growth and the second is aging.
2.3.1.1 Population

The following Figure shows the unending growth in population in just the last 8 years. We now exceed 300 million and by 2050 we anticipate 450,000,000 population. Details under these demographics also show an expansion in a population with less skills and more demands on healthcare. This means a potentially lower income base to draw upon for support of this system.

![Population of the US Graph](image)

2.3.1.2 Aging

The aging of the population is a more significant driver. The following Figure depicts this trend. It shows a growth from 12% in 2010 to 20% in 2035. That means one in five would be on Medicare if we retain the current system. In addition since Medicare currently handles almost 35% of the Hospital Admissions and this is at a 11% over 65 rate then by doubling this we would expect to see Medicare handling more than 60% of Hospital costs. This is a dramatic change. The burden of aging is then on Hospitals and much less on Physicians office visits.
2.3.1.3  **Uninsured and Ethnicity**

The issue of who is and is not uninsured and how the demographic long term factors will be impacted by this can be seen in the following Figure. Currently 12% of whites are uninsured whereas 36% of Hispanics are uninsured. This is a 3 to 1 variation. Although 45% of the total uninsured is white, 34% are Hispanic. The growth of the Hispanic population is well beyond the growth rate of the white, and it will double in the next thirty years and if this trend continues then we can expect the total uninsured to also almost double. The affect of aging and the percent uninsured then will place the burden much more heavily on the back of those few paying.
The following Figure shows the growth of the Hispanic population. It grows from just over 10% to almost 35% by 2050. This is the fastest growing segment and the least uninsured segment. If it is just less than 50 million now with 15 million uninsured and it grows to almost 150 million with possibly 55 million uninsured. That by itself exceeds all we have in 2009!
2.3.2 Disease States

We now will detail the specifics regarding a collection of important disease states and where they are handled in the current healthcare system. The next Figure shows the top disease states and the number or people and where they are handled; hospital versus outpatient. The largest states are trauma, COPD and hypertension.
The next Figure presents the number of events for each of the aforementioned disease states.
Finally the following Figure depicts the costs for each of these disease states per location of service.
The interesting observation from the above are:

1. Heart disease is the dominant state. As we have stated earlier, smoking and Type 2 Diabetes are major causes of heart disease and are also exacerbaters of the state. In addition hyperlipidemia and hypertension, independent of the prior two exacerbaters, are in themselves major causes. Thus there is a great deal of potential if we can control this behavior via market mechanisms that the drivers making these increase can be reversed.

2. Trauma is a second factor. This means accidents and crime. To some degree the crime side has been handled in a reasonable manner in many metropolitan areas. More work can still be done. Accidents are all too frequently less controllable and are not amenable to exogenous financial drivers. However it can be prudent to add accident insurance coverage to any catastrophic plan.

3. Cancer is the third and it too has many elements which we have already presented to mitigate its effects.

Another view is to rank these disorders by total contacts including: Outpatient, Hospital, ER, Prescriptions, Home, as compared to just one. The difference in ordering is significant since cancer has few but costly contacts whereas COPD has many contacts across the board. This shows that we have disease states which require costly "repair"
and others with "constant maintenance". There are varying ways to optimize the delivery of each.

The following Figures returns to the specifics of Cancer incidence and mortality. We discussed this earlier and the remediable cancers are seen as looming large on this chart. However there are scores of others which will still need both significant hospital care and ongoing patient care. Some of this ongoing care, such as the use of chemotherapeutics with CML are quite costly but are efficacious in both morbidity and mortality effects.
### Cancer Incidence CDC

http://apps.nccd.cdc.gov/uscs/Table.aspx?Group=TableAll&Year=2005&Display=n

<table>
<thead>
<tr>
<th>Cancer Type</th>
<th>Rate per 100,000 Age Adjusted</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prostate</td>
<td>160.00</td>
</tr>
<tr>
<td>Female Breast</td>
<td>120.00</td>
</tr>
<tr>
<td>Lung and Bronchus</td>
<td>100.00</td>
</tr>
<tr>
<td>Colon and Rectum</td>
<td>80.00</td>
</tr>
<tr>
<td>Corpus</td>
<td>60.00</td>
</tr>
<tr>
<td>Lymphomas</td>
<td>40.00</td>
</tr>
<tr>
<td>Urinary Bladder</td>
<td>20.00</td>
</tr>
<tr>
<td>Non-Hodgkin Lymphoma</td>
<td>10.00</td>
</tr>
<tr>
<td>Miscellaneous</td>
<td>2.00</td>
</tr>
<tr>
<td>Kidney and Renal Pelvis</td>
<td>1.00</td>
</tr>
<tr>
<td>Rectum and Rectosigmoid</td>
<td>0.00</td>
</tr>
<tr>
<td>Ovary</td>
<td>0.00</td>
</tr>
<tr>
<td>Leukemias</td>
<td>0.00</td>
</tr>
<tr>
<td>Pancreas</td>
<td>0.00</td>
</tr>
<tr>
<td>Endocrine System</td>
<td>0.00</td>
</tr>
<tr>
<td>Thyroid</td>
<td>0.00</td>
</tr>
<tr>
<td>Cervix</td>
<td>0.00</td>
</tr>
<tr>
<td>Stomach</td>
<td>0.00</td>
</tr>
<tr>
<td>Brain</td>
<td>0.00</td>
</tr>
<tr>
<td>Liver and Intrahepatic Bile</td>
<td>0.00</td>
</tr>
<tr>
<td>Testis</td>
<td>0.00</td>
</tr>
<tr>
<td>Myeloma</td>
<td>0.00</td>
</tr>
<tr>
<td>Esophagus</td>
<td>0.00</td>
</tr>
<tr>
<td>Larynx</td>
<td>0.00</td>
</tr>
<tr>
<td>Chronic Lymphocytic</td>
<td>0.00</td>
</tr>
<tr>
<td>Acute Myeloid</td>
<td>0.00</td>
</tr>
</tbody>
</table>

---

Cancer Incidence CDC

http://apps.nccd.cdc.gov/uscs/Table.aspx?Group=TableAll&Year=2005&Display=n

[Graph showing cancer incidence rates adjusted for age.]
The following Figure details the Remediable or Controllable disease factors.
The above shows the percent of the population having one of the major controllable disease drivers. Many have multiple drivers. Clearly Diabetes, obesity and cigarettes are controllable by economic means. Cholesterol is a bit more problematic but it correlates well with the first three as does hypertension. The high cholesterol and hypertension have few idiopathic causes and few pure genetic causes, most are secondary resulting from the first three. Thus we believe that addressing the first three will also have a dramatic impact on the remaining two.

2.3.3 Implications of the Demand Model

We can now look at the demand model for healthcare. Since there is no limitation of demand then demand is simply fixed and is exogenous. It is a vertical line in the following. If however we introduce some consumption tax then the higher the tax the lower the demand since we actually reduce incidence and thus demand.
2.4 The Supply Model

We now consider the supply side. This looks at who supplies the services, in what amounts and at what costs. We further look in details at specific costs related to hospitals.

2.4.1 Cost Factors

The following Figure depicts the growth in healthcare costs over the past decades. The growth rate has well exceeded inflation for a variety of reasons, one being the aging population and another being the increased in uninsured who in turn utilize the ER facilities at much higher rates. A third factor is the one we have discussed again and again which is a deterioration in lifestyle as regards to good health.
The following Figure is one which can be truly disturbing. It plots healthcare costs as a percent of GDP. From 1960 to 2015 we have gone from 5% to 20% as anticipated. This is a fourfold increase in healthcare relative to the underlying size of the economy. Healthcare will exceed any and all other sectors of the economy, well eclipsing Defense and other more classic elements.
If we then look at where the costs are spent, in 2006 the following Figure depicts that Hospital dominate the amount of money spent and physicians, with their associated overhead costs are a mere second. Prescription drugs are the third largest. Public Health is well down on the scale of expenditures.
The following Figure now shows the growth rates in each of these sectors.
Note that Home Health Care is the largest growth rate, apparently due to the intent to get patients from the hospital to home care, but that prescription drugs is a strong second or third tied with administrative overhead. The physician services are growing slightly ahead of inflation due mainly to the increased demand on overhead from mandated processes and procedures. For example, the costs of implementing HIPPA in many Family Medical practices are costly.

2.4.2 Incidents and Unit Costs

We now proceed to analyze the detail costs by disease and location of service. The following Figure depicts several of the major cost elements. As expected the costs of hospital care dominate. On a procedure basis the hospital costs are orders of magnitude higher but their incidence is generally lower.
The next Figure shows the annual per person contact with each of the provider entities. The highest is prescription provisioning and then outcare support. As we noted the hospital albeit high has a lower contact unit.
The following Figure depicts the overall costs accruing from each point of supply. We will examine these in more detail in the next section when looking at the supply function.
2.4.3 Payers and Providers

The supply side of healthcare consists of the Providers and the Payers. The Providers consist of physicians, hospitals, pharmaceuticals, laboratories, hospices, nursing homes to name a few. In this section we focus on the physician and hospital elements. The payers consist of the major ones; Medicare, Medicaid, Private Plans, Government plans and other third party players. We briefly review the Payers in the next

2.4.3.1 Payers

The following Figure depicts the current structure of the Payers of healthcare.
2.4.3.2 Providers

We focus on two of the providers; hospitals and physicians. The reason for this is that hospitals are the most complex in their operations and cost structure and physicians are generally accused as being the major cost element. We reach the conclusion that the first assertion has substantial merit and the second is lacking total merit.

2.4.3.2.1 Hospitals

As of 2005 there were 5756 hospitals in the US and declining. The Figure below shows this decline. The hospitals also dominate the healthcare costs. They are institutions which for the most part receive their compensation from Medicare and Medicaid.
Hospitals receive:

1. 31% from Medicare. Approximately 88% of the payment is for inpatient services.
2. 17% from Medicaid.
3. 33% from Private Insurers

The hospitals have a significant staff as exemplified by the following Table which is from Roger Williams Hospital in Rhode Island. This is a 150 bed hospital, small by most measures but eh salary for staff exceeds $50 million.

---

The following is a summary for Roger Williams. The expense per patient is $3,400 and the salary portion of that is $1,200. The physician's costs are added on to that as additional costs.
## Costs and Cost per Bed, Roger Williams Hospital

<table>
<thead>
<tr>
<th>Item</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Salaries</td>
<td>$51,937,372</td>
</tr>
<tr>
<td>Beds</td>
<td>154</td>
</tr>
<tr>
<td>Patients</td>
<td>40,488</td>
</tr>
<tr>
<td>Expenses</td>
<td>$137,650,592</td>
</tr>
</tbody>
</table>

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Expense per Patient</td>
<td>$3,400</td>
</tr>
<tr>
<td>Expense per Bed</td>
<td>$893,835</td>
</tr>
<tr>
<td>Salary per Patient</td>
<td>$1,283</td>
</tr>
<tr>
<td>Salary per Bed</td>
<td>$337,256</td>
</tr>
</tbody>
</table>

The next step is to look at the charges per procedure. We have data for California hospitals and one is shown below. These costs are by DRG.
### Average Charges for Top 25 DRG in California Hospital 2008

<table>
<thead>
<tr>
<th>DRG Description (By Hosp)</th>
<th># of Discharges by Hospital</th>
<th>Average Charge by Hospital</th>
<th>Average Charge Statewide*</th>
</tr>
</thead>
<tbody>
<tr>
<td>RESPIRATORY SYSTEM DIAGNOSIS W VENTILATOR SUPPORT</td>
<td>99</td>
<td>$208,865</td>
<td>$177,927</td>
</tr>
<tr>
<td>CARDIOVASCULAR DX</td>
<td>58</td>
<td>$101,375</td>
<td>$71,431</td>
</tr>
<tr>
<td>SEPTICEMIA AGE &gt;17</td>
<td>92</td>
<td>$99,613</td>
<td>$76,815</td>
</tr>
<tr>
<td>MAJOR JOINT REPLACEMENT OR REATTACHMENT OF LOWER EXTREMITY</td>
<td>690</td>
<td>$82,001</td>
<td>$68,773</td>
</tr>
<tr>
<td>RENAL FAILURE</td>
<td>154</td>
<td>$57,153</td>
<td>$45,295</td>
</tr>
<tr>
<td>INTRACRANIAL HEMORRHAGE OR CEREBRAL INFARCTION</td>
<td>142</td>
<td>$52,343</td>
<td>$45,919</td>
</tr>
<tr>
<td>SIMPLE PNEUMONIA &amp; PLEURISY AGE &gt;17 W CC</td>
<td>167</td>
<td>$44,281</td>
<td>$37,489</td>
</tr>
<tr>
<td>HEART FAILURE &amp; SHOCK</td>
<td>268</td>
<td>$42,773</td>
<td>$36,694</td>
</tr>
<tr>
<td>ESOPHAGITIS, GASTROENTERITIS &amp; MISC DIGEST DISORDERS AGE &gt;17 W CC</td>
<td>124</td>
<td>$42,031</td>
<td>$29,982</td>
</tr>
<tr>
<td>CHRONIC OBSTRUCTIVE PULMONARY DISEASE</td>
<td>266</td>
<td>$41,376</td>
<td>$32,905</td>
</tr>
<tr>
<td>GASTROINTESTINAL HEMORRHAGE W CC</td>
<td>110</td>
<td>$41,155</td>
<td>$35,507</td>
</tr>
<tr>
<td>CELLULITIS AGE &gt;17 W CC</td>
<td>49</td>
<td>$36,143</td>
<td>$30,278</td>
</tr>
<tr>
<td>KIDNEY &amp; URINARY TRACT INFECTIONS AGE &gt;17 W CC</td>
<td>100</td>
<td>$36,058</td>
<td>$30,568</td>
</tr>
<tr>
<td>CARDIAC ARRHYTHMIA &amp; CONDUCTION DISORDERS W CC</td>
<td>64</td>
<td>$31,184</td>
<td>$30,004</td>
</tr>
<tr>
<td>NUTRITIONAL &amp; MISC METABOLIC DISORDERS AGE &gt;17 W CC</td>
<td>145</td>
<td>$29,739</td>
<td>$27,917</td>
</tr>
<tr>
<td>CESAREAN SECTION W CC</td>
<td>178</td>
<td>$28,718</td>
<td>$29,196</td>
</tr>
<tr>
<td>UTERINE &amp; ADNEXA PROC FOR NON-MALIGNANCY W/O CC</td>
<td>182</td>
<td>$28,650</td>
<td>$28,660</td>
</tr>
<tr>
<td>PSYCHOSES</td>
<td>7</td>
<td>$26,086</td>
<td>$18,956</td>
</tr>
<tr>
<td>CESAREAN SECTION W/O CC</td>
<td>479</td>
<td>$22,602</td>
<td>$21,291</td>
</tr>
<tr>
<td>CHEST PAIN</td>
<td>481</td>
<td>$22,210</td>
<td>$16,943</td>
</tr>
<tr>
<td>VAGINAL DELIVERY W COMPLICATING DIAGNOSES</td>
<td>193</td>
<td>$17,166</td>
<td>$16,010</td>
</tr>
<tr>
<td>VAGINAL DELIVERY W/O COMPLICATING DIAGNOSES</td>
<td>1,536</td>
<td>$12,428</td>
<td>$11,511</td>
</tr>
<tr>
<td>NEONATE W OTHER SIGNIFICANT PROBLEMS</td>
<td>249</td>
<td>$9,203</td>
<td>$7,775</td>
</tr>
<tr>
<td>NORMAL NEWBORN</td>
<td>1,994</td>
<td>$4,144</td>
<td>$3,038</td>
</tr>
</tbody>
</table>

The above list shows that the total charge for certain DRGs can be quite considerable, the greatest being in excess of $200,000. The lowest in this example is $4,000 for a simple new born birth support. That is just for the birth support procedure and does not include any delivery costs which are $12,000 without any complications. Thus a simple

---

newborn without complications including the infant and delivery, without any stay is $16,000. This is also growing at 6% per annum.

The outpatient costs are shown in the following Table. Note that the cardiac cath is upwards of $36,000 and this is a procedure commonly used in MI cases. A simple ER visit is $625. This is in sharp contrast to a simple Family Physician visit of $95. The ER is used to treat many of the uninsured and migrants and these costs then gets passed on. If there were an open Public Health system with facilities than one could anticipate that the ER charges would drop dramatically.
Outpatient Procedure Costs California Hospital 2008

<table>
<thead>
<tr>
<th>Evaluation &amp; Management Services (CPT Codes 99201-99499)</th>
<th>2008 CPT Code</th>
<th>Average Charge</th>
</tr>
</thead>
<tbody>
<tr>
<td>Emergency Room Visit, Level 2 (low to moderate severity)</td>
<td>99282</td>
<td>$625</td>
</tr>
<tr>
<td>Emergency Room Visit, Level 3 (moderate severity)</td>
<td>99283</td>
<td>$984</td>
</tr>
<tr>
<td>Emergency Room Visit, Level 4 (high severity)</td>
<td>99284</td>
<td>$1,458</td>
</tr>
<tr>
<td>Outpatient Visit, established patient, 15 minutes</td>
<td>99213</td>
<td>$381</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Laboratory &amp; Pathology Services (CPT Codes 80048-89356)</th>
<th>2008 CPT Code</th>
<th>Average Charge</th>
</tr>
</thead>
<tbody>
<tr>
<td>Basic Metabolic Panel</td>
<td>80048</td>
<td>$270</td>
</tr>
<tr>
<td>Blood Gas Analysis, including O2 saturation</td>
<td>82805</td>
<td>$544</td>
</tr>
<tr>
<td>Complete Blood Count, automated</td>
<td>85027</td>
<td>$131</td>
</tr>
<tr>
<td>Complete Blood Count, with differential WBC, automated</td>
<td>85025</td>
<td>$141</td>
</tr>
<tr>
<td>Comprehensive Metabolic Panel</td>
<td>80053</td>
<td>$335</td>
</tr>
<tr>
<td>Creatine Kinase (CK), (CPK), Total</td>
<td>82550</td>
<td>$192</td>
</tr>
<tr>
<td>Lipid Panel</td>
<td>80061</td>
<td>$306</td>
</tr>
<tr>
<td>Partial Thromboplastin Time</td>
<td>85730</td>
<td>$120</td>
</tr>
<tr>
<td>Prothrombin Time</td>
<td>85610</td>
<td>$93</td>
</tr>
<tr>
<td>Thyroid Stimulating Hormone</td>
<td>84443</td>
<td>$264</td>
</tr>
<tr>
<td>Troponin, Quantitative</td>
<td>84484</td>
<td>$228</td>
</tr>
<tr>
<td>Urinalysis, without microscopy</td>
<td>81002 or 81003</td>
<td>$51</td>
</tr>
<tr>
<td>Urinalysis, with microscopy</td>
<td>81000 or 81001</td>
<td>$87</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Radiology Services (CPT Codes 70010-79999)</th>
<th>2008 CPT Code</th>
<th>Average Charge</th>
</tr>
</thead>
<tbody>
<tr>
<td>CT Scan, Abdomen, with contrast</td>
<td>74160</td>
<td>$3,564</td>
</tr>
<tr>
<td>CT Scan, Head or Brain, without contrast</td>
<td>70450</td>
<td>$2,934</td>
</tr>
<tr>
<td>CT Scan, Pelvis, with contrast</td>
<td>72193</td>
<td>$3,564</td>
</tr>
<tr>
<td>Mammography, Screening, Bilateral</td>
<td>77057</td>
<td>n/a</td>
</tr>
<tr>
<td>MRI, Head or Brain, without contrast, followed by contrast</td>
<td>70553</td>
<td>n/a</td>
</tr>
<tr>
<td>Ultrasound, Abdomen, Complete</td>
<td>76700</td>
<td>$941</td>
</tr>
<tr>
<td>Ultrasound, OB, 14 weeks or more, transabdominal</td>
<td>76805</td>
<td>$939</td>
</tr>
<tr>
<td>X-Ray, Lower Back, four views</td>
<td>72110</td>
<td>$1,042</td>
</tr>
<tr>
<td>X-Ray, Chest, two views</td>
<td>71020</td>
<td>$537</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Medicine Services (CPT Codes 90281-99607)</th>
<th>2008 CPT Code</th>
<th>Average Charge</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiac Catheterization, Left Heart, percutaneous</td>
<td>93510</td>
<td>$35,546</td>
</tr>
<tr>
<td>Echocardiography, complete</td>
<td>93307</td>
<td>$1,076</td>
</tr>
<tr>
<td>Electrocardiogram, routine, tracing only, w/o interpretation and report</td>
<td>93005</td>
<td>$125</td>
</tr>
<tr>
<td>Inhalation Treatment, pressurized or nonpressurized</td>
<td>94640</td>
<td>$597</td>
</tr>
<tr>
<td>Physical Therapy, Evaluation</td>
<td>97001</td>
<td>$207</td>
</tr>
<tr>
<td>Physical Therapy, Gait Training</td>
<td>97116</td>
<td>$85</td>
</tr>
<tr>
<td>Physical Therapy, Therapeutic Exercise</td>
<td>97110</td>
<td>$82</td>
</tr>
</tbody>
</table>

The conclusions we can reach on hospitals are as follows:

1. They are massively overstaffed and have in many if not all cases bloated overhead.

2. The ER is used as a replacement for insurance by a significant portion of the population and the ER costs 8 to 9 times a regular Family Practice visit and in excess of what a well staffed Public Health facility could provide.

3. Costs per DRG and costs per procedure are continuing to increase at rates which exceed inflation. The costs are dominated by salaries and overhead that extend well beyond the physician.

2.4.3.2.2 Physicians

The physicians are a second element in the supply side, and an essential element. They are more manageable in terms of costs because they charge separately and there is substantial transparency in their charges. The Table below depicts the allocation by specialty and includes their compensation.

<table>
<thead>
<tr>
<th>Distribution of Physician and Salary by Practice Area</th>
</tr>
</thead>
<tbody>
<tr>
<td>Percent</td>
</tr>
<tr>
<td>Total</td>
</tr>
<tr>
<td>Primary care</td>
</tr>
<tr>
<td>Family medicine and general practice</td>
</tr>
<tr>
<td>Internal medicine</td>
</tr>
<tr>
<td>Obstetrics &amp; gynecology</td>
</tr>
<tr>
<td>Pediatrics</td>
</tr>
<tr>
<td>Specialties</td>
</tr>
<tr>
<td>Anesthesiology</td>
</tr>
<tr>
<td>Psychiatry</td>
</tr>
<tr>
<td>Surgical specialties, selected</td>
</tr>
<tr>
<td>All other specialties</td>
</tr>
<tr>
<td>Total</td>
</tr>
</tbody>
</table>

The following depicts the Physician salaries as an element of the supply side.
We now show the salaries as a percent of healthcare costs in each of the major areas of service delivery in the following Figure.
It is interesting to note from the above Figure the following:

1. Specialties have the highest contribution coming from physician salaries. The ObGyn is one of the smallest accounted for by the high costs associated with the hospital. Most people do not recognize that the dominant costs in the current delivery of children are the hospital cost and the cost of malpractice. In view of the dramatic growth in population especially from the growing Hispanic population which for the most part uninsured this implies dramatic costs for this cost element.

2. Primary care also is dominated by administrative overhead and medications. The typical Family Physician charges $75 for a 10 minute visit but the physician has a dramatic overhead in records, billing, nurse care and the like. The fully loaded $750 per hour has allocated costs of in excess of $450 per hour just for direct overhead. One should remember that a new Harvard Law Graduate on Wall Street was getting a $200,000 plus salary in 2008!

The last point is a key point for change in Healthcare. As we have pointed out previously:
One can start be looking at some recent data. In a paper in The New England Journal of Medicine, the authors present data on college and professional education, focusing on medical training, but that is just the specific example. However, the cost of medical training is an excellent example of the problem. It is a field which has now more than 50% of the entrants being women and with 25% of the recent graduates being over $200,000 in debt, the day the complete their degree. It could just get worse from there. This economic fact will have dramatic impacts on the field or medicine in the next fifty years, and the effects are starting now.

The following graph is from the Steinbrook article (this is copyrighted by NEJM 2008). Several key observations are noted:

(1) The average compensation for a primary care physician has risen with the CPI, about 30% in ten years (1998-2008).

(2) Private school tuition for college has risen at 70% for the same period (Now $25,000 per annum, growing at 6-8% per annum going forward).

(3) Private and public Medical School tuition is now in excess of $40,000 per annum and growing between 40% and 110% over the ten year period.

---

The implications of these bubbles like change are most likely to be:

1) Potential default on tuition payments. This continued explosion of tuition and reasonable growth of salaries will soon collide. It will result in defaults.

The following Table depicts the Medical School Enrollment.

---

8 From NEJM The Case for More U.S. Medical Students, Volume 343:213-217 July 20, 2000 Number 3, Copyright NEJM.
Thus the costs to finance all medical school students at $40,000 per year are about $2.5 billion. This is a de minimis amount compared to all other costs and would clearly be a low cost alternative to the results that would come from the exploding costs and shift away from medicine of some of the better students no looking at alternative careers. We will see what is happening to engineering despite that area actually being financed.

(2) Funneling of physicians into "institutional" like practices and the ultimate demise of the single or small group practice. No physician with such existing debt could take on additional debt of buying out or starting a new practice.

(3) The view of the profession as a job.

(4) The loss of the best in class to professions paying better compensation with low cost of entry such as corporate positions, start-up companies, investment banking and venture capital.

(5) The "dumbing down" of the family practice since the better students will be driven to alternative career options.

2.4.4 Implications of the Supply Model
Based upon the preceding we can stipulate a Supply model. Namely we have one as follows:

Now the first step in the supply curve will be to drive out costs which are overhead costs. Thus is we reduce the cost of billing and that of report management on a per patient basis this would represent a shift in the supply curve downward as shown in the following. This is the first step in cost reduction.

The alternative would be to create scale economies in the delivery, namely making it less costly the more service that are delivered. We argue herein that using a Public Health delivery system would do so by alleviating other more costly means such as the ER. There are many more examples of such an approach. The following Figure depicts what would happen in this event. Namely we see a decline of the supply curve the larger the demand becomes, clear scale effects.
We can then combine the two effects of reducing overhead and achieving scale to create a compound new supply curve as shown in the following Figure.

Finally we can combine the Demand and the Supply curves to show what the total effect would be. This is done in the following Figure.
We note that we reduce the costs significantly while have a small but measurable decrease in the supply by means or reallocation while keeping the overall quality high. This above graphic is in essence what we propose in the plan.

Note that we now have a lower price and slightly lower demand. This approach deals with the healthcare problem on two levels. It dramatically creates a sensitive endogenous demand and allows for both a shift and scale in supply. The reduction in cost is significant and the supply provided is shifted by channels of supply not quality.

2.5 Technology

Technology is not a panacea for all the problems of cost containment. Technology in many cases adds to the costs but in many ways improves the quality of life for the patient. The introduction of the MRI and CAT systems dramatically changed the way we see internal problems. These are but two of many examples of technological improvements, costly but of great advantage to the delivery of healthcare.

Technology can address three major areas in the delivery of healthcare. Specifically:

1. Cost Reduction: The impact of technology on cost reduction can be massive. The practice of medicine has exploded with overhead in the past thirty years. Record keeping is a time consuming and expensive process, and one that in many important cases fails to properly present patient data. On the other hand it is historically a
holographic record used in any litigation. Electronic Medical Records, an idea whose time may be coming, can dramatically effect improvement if and only if implemented wisely. Another area is billing and payment. This is an almost unworkable area. Medicare has established a system which somewhat functions but each insurer creates a new and separate system. Delays and denials in payments create great cash flow and overhead costs for the physician and hospitals. Technology has been applied to this area for twenty five years with glacial progress. The institutional and structural issues still dominate.

2. Quality of Care: Technology improves quality of care but is costly if used in areas where the utilization is low. A CAT or MRI can be costly if used infrequently.

3. Risk Reduction: The area of risk reduction is a significant one. The simplest example is the washing of hands to reduce MRSA infections in hospitals. Nosocomial infections are a major cause of hospital morbidity and mortality. This simple issue can be addressed by technology which forces healthcare professionals to comply. The proper administration of medications is another area. All too often patients in hospitals are administered the wrong drug, dosage, or not obtaining the medications required. This can be handled technically as well. Measuring, monitoring and repairing processes which cause increased morbidity and mortality are essential, and thus these can be best effected by technology. Certain institutions, and even providers, have poor records of delivery.

2.5.1 A Proposed Technology Strategy

The three operative terms in the delivery of Healthcare are universality, quality and cost. They are all based upon a six point strategy, as described below.

(i) Productivity Improvements: Develop a system of healthcare delivery that fits paradigms of comparable service businesses that measure and manage the delivery of service efficiencies and organize to maximize this effectiveness. In essence, measure, organize, and remeasure to gain productivity.

(ii) Cost Awareness: All health care professionals and the customers, the patients, should be aware of the costs or prices. Namely, the patient and the physician should be made aware to the cost of the sets of possible procedures and the risks. The patient and the physician as a team must make a cost effective decision. Angiography as a means for diagnosing coronary disease is an expensive and risky procedure. Alternative therapies that address both the symptoms and the underlying disorder may be equally efficacious if the patient and the physician are made aware of the costs. The physician must have that awareness across procedures as well as providers. Thus lab tests must also be priced by test as well as by vendor.

(iii) Alternative Awareness: The alternative procedures must be made aware to the patient. These procedures are not only costs based but risk and efficacy based. MRIs are
a very effective tool in diagnosing disorders and have a low risk profile. Angiographies are invasive and have higher risks. The patient must become part of the choice process along with the physician. The patient must become an economic choice selector in the process.

(iv) **Centers of Excellence:** Not every hospital can perform heart transplants, kidney transplants, and neurosurgery. The Center of Excellence strategy recognizes that large geographical areas need to join together to select what institution has which facilities. This is for both interventional as well as diagnostic facilities. The New Hampshire plan is one that takes a total state view of such care, having a single tertiary teaching hospital act as the primary center and refocus from that for other select centers. This clearly puts the burden on the Hospital system and not just on the individual hospital.

(v) **Electronic Transaction Intensive:** Paperwork is the bane of healthcare. No other industry, other than the regulated monopolistic telephone companies, can sustain the burden of the paperwork that exists in healthcare. From the physician’s office through the clinical and administrative realms of the hospital; there is an excessive amount of paperwork. It is essential that electronic transaction systems be put in place that are - integrated and meet standards of interfaces. This will result in increased productivity, enable the efficient use of centers of excellence, reduce the cost of creating and handling the paper, and allow an enabling capability to measure, monitor and manage the expenditures, the productivity, and the quality of patient care. Transaction systems, using both text and multimedia formats, are at the heart of the structural reform.

(vi) **Quality Care Management:** Having the transaction capabilities allows for the monitoring of all patient care on a real time basis. It is the ability to monitor the rate of diseases development, the relative and absolute performance of physicians and hospitals, and the interactive informing of physicians of better alternatives and options. It is interventional as well as monitoring. Measurements assure the consistent delivery of quality care. Variance in physician or geographical mortality and morbidity can be determined at the micro level. These can then be addressed and resolved. Standards for quality can be communicated, updated and improved. Quality care can then follow more closely the most effective and efficacious approaches available.

The six point strategy articulated above can be met through the use of five key technology areas:

(i) **Multimedia Communications:** Multimedia communications is more than just the technology for combining video, voice and data. It is a paradigm shift in interpersonal communications. It is an enabling technology for the use of multimedia data elements, such as real time voice, text that is stored, images and real time video, in a fully conversational mode by a group of participants. Multimedia communications is a confluence of technologies that is end user driven, focuses on the seasoning of users together. This in many ways transcends what we have today in the Internet since in the
provision of medical services the media used are extensive, complex, interrelated and are critical to the overall care of the patient.

(ii) **Multimedia Databases**: Disparate date elements in multimedia databases must be associated with one another in a temporal, spatial and logical context. Multimedia database technology allows this to happen. It permits the binding together of voice segments, annotating with a mouse a full motion video element. The multimedia database is also much more complex than what we see today in any Internet use. One must be able to search images and videos as well as we can search text and data elements.

(iii) **Networking**: The current watchword here is broadband. Access to broadband has increased and has become cost effective in many ways. However it still suffers from several shortcomings such as universal availability and security.

(v) **Transaction Networking**: Transactions must be at the heart of the technology. Each interaction must be monitored, measured, logged, billed, and evaluated. This means that behind the technology of interaction is a technology of transaction. The transaction network enables the price tag mechanism that is so critical for the natural forces of economics to play themselves out.

### 2.5.2 The Example of Office Billing

Medical Practice is both the provision of the healing arts and the management of a business. The business aspect of a practice is one which has take a significantly lesser role in the minds of many practitioners and thus may have resulted in the incorporation of many inefficiencies. In this paper we discuss the practice as business concept and demonstrate how significant improvements in practice management can be achieved. As a result of these structural efficiency improvements, it is argued that overall patient - quality of care can also be improved. The results in this paper are based upon data accumulated over the past two years of addressing specific practice management issues.

The physician's office management is based upon a careful balance of quality patient care and intermittent business management. The primary function of the physician is the care and management of their patients. However, the management of the practice requires both an understanding of the practice as business as well as the tools necessary to effect that management process. In this paper we describe several case studies of office management practice and discuss the key areas of practice management optimization. It has been shown that improvements of 10% to 25% in combine revenue control and cost containment can be achieved.

At the heart of the effective management of a practice as business is the implementation, use and optimization of a computer based system that allows for the
management, processing and tracking of all key office financial factors. Practice management requires that three major factors be focused upon:

(1) Effective collection of receivables: Specifically, the billing process must be viewed as the revenue generation porches and leakage from that process must be kept to a minimum. All bills must be entered, processed, tracked and collected. Lost revenue must not be left on the floor either out of lack of knowledge or through frustration with the process.

(2) Maximum productivity for reduced expenses: Inefficiency in the various elements of the practice management can increase costs and significantly reduce the flow to the bottom line. Redundant manual processes are not only prone to errors but all too frequently increase costs due to these inefficiencies.

(3) Timely management of cash: Cash flow is the heart of any business and in turn that of any practice. The focus should not only be on revenue collection but on the flow of cash in the practice. This means that the systems in place address the issues of receivables, payables, and changes in working capital. Thus, any system put into operation must deal with the whole flow of cash through the practice and optimization should occur in that area.

In this paper we address the issues of managing a practice, recognizing that it is a combination of both process and tools. The process aspect is one that starts with a recognition of the practice as business and allows for a deconstruction of the various business elements of the practice and places measure of performance on each of them. The tools part of the effort will show that to effectively implement the process portions, tools other than just good thinking are necessary. With the advent of the personal computer, networked systems and the interfacing with large scale computer systems, the tools are now becoming available at a cost effective level. This paper will focus on the confluence of process and tools.

Current Office management can be viewed as a process that begins with the patient entering the office and ends with the collection of the fee for the services rendered. The management of the office is divided into two major economic dimensions; revenue and expenses. Revenue is generally based upon an accrual system that recognizes the revenue at the time of service. Expense, similarly is based on an accrual system. We first will deal with the revenue issues and then with the expense factors.

The revenue process is shown in Figure 1. The flow is first shown as patient processing and then the submission of the of the bill for processing. The options for billing are as follows:
(1) Cash/ Fee for Service: This fraction of the practice provides for instant cash into the receivable flow and thus does not represent a major factor in cash flow management. However, many practices have a decreasing number of their patients in this pool.

(2) Managed Care: The introduction of managed care systems has had a significant impact in the West and is moving East as they are improved and demonstrate their effectiveness in containing costs for major corporations. The contract stipulates the fee accepted, the payment time and the mechanism for submitting claims. Typically significant delays occur in a Managed Care system as well as an increase in the non-collectibles. Thus the physician participating in a managed care program is faced with lower revenues per service, longer time to collect, increased non-collectibles due to a variety of causes, and finally an increase in the total billing costs. However, many of the managed care programs now have electronic interfaces and thus will allow for better control of several of these variables leading to lower losses.

(3) HMO/PPO: The HMO/PPO contract with a third party physician typically is also a contractual agreement that specifies the fee for service and thus is similar in many ways to the Managed Care program. The difference is that a HMO/PPO system may cover many companies and thus is not company specific. The same problems occur with this system.

(4) Medicare: Medicare may be a dominant factor in many practices. Specifically for the Internist, the Ophthalmologist, the Cardiologist etc. a growing number of the patients are Medicare covered. Medicare currently support electronic billing and currently requires the physician to prepare the patients billing information. Medicare must also be billed first and the fee structure is highly regulated. Assignment of Medicare is becoming more frequent and the Physician may face a growing demand from both patients

(5) Third Party FFS Assignment: The classic method of payment for many years has been Fee for Service (FFS) with a third party insurer. This is the now almost fifty year old paradigm in HealthCare insurance. In most practices, however, this form of payment is infrequently put in the assignment pool. In contrast, the patient pays either at the time of service or after billed and then is personally responsible for the processing with the insurer. Thus, this form of reimbursement is of limited impact on practice financials.

(6) Medicaid: State reimbursement plans are notoriously low and excessively delayed in reimbursement. Little if any work has been done in automating this area and the differences from state to state are staggering. The concentration on this area leaves one with the impression that there is still a great deal to be accomplished before Medicaid can be integrated effectively into the practice payment system.
Current office management practices fall into one of three extremes; manual in-office systems, service bureaus, and computerized in-office systems. They can be characterized as follows:

(1) **Manual In-Office Systems (MIOS):** In this case the patient and billing information are collected manually and stored in the patient record and billing files. In extremis, the patient billing file may be nothing more than a 3" by 5" index card system with a rolling summary of bills and receipts. The two sets of filing systems are separate and independent. The advantages of such a system are that it requires no technology, is manually under the control of the physician, and costs nothing in terms of capital or training. The disadvantages are that such a system results in very labor intensive bill preparation, tracking, auditing and is subject to the vagaries of the office manager. The most serious drawback is not the labor intensiveness of the approach it really is its lack of frequent auditability. Such systems become prone to revenue "shrinkage".

(2) **Service Bureaus:** The service bureau approach starts at the same point of the MIOS approach of manual collection of information. It then results in placing all of the manual information in the hands of a third party to perform all of the processing and collections efforts. The advantages of such an approach are that they are predictable in cost and eliminate the concerns of managing the process internally. The disadvantages are significant. Quality of service bureaus may vary greatly, most are themselves manual and do not provide adequate audit information, and some even have ethical or legal problems.

(3) **Computerized In-Office Systems (CIOS):** The CIOS approach uses a computerized system on premise that enters all patient information, all billing information, prepares the bills and electronically transmits the bills, if appropriate, the proper agencies. The advantages of such a system are obvious. First they provide auditable and control back to the practice. All the information is available and trackable at any time. Second, the systems are focused on delivering a cash flow management process to the practice which is what desired. Third is, the records are kept in an orderly and retrievable fashion. The disadvantages are those of computer systems. First is the issue of computer phobias. These however are lessening with the advent of user friendly interfaces, window environments, artificial intelligence front ends and all of the other tools that help the end user. The second disadvantage is the issue of user acceptance. namely, a computer changes the routine, it disturbs the current work flow, and it can cause emotional dissonance in the office staff. Quite frankly, so did the X-ray machine, and even the stethoscope. This must be dealt with as a human issue of office management through training and education and through leadership and direction

We will now focus on the use of computers in this environment and delineate the efficiencies and bottom line impacts to a practice.
The revenue collections flow has been shown in Figure 2. Here we have shown the bill preparation and the submission to one of several channels. The channel prepares, transmits and processes the bill. The net result is acceptance and payment, rejection, or loss due to some endogenous or exogenous factor. In this Figure we show that typically bills in these channel may pass without error 70% of the time, are rejected and re submitted 20% of the time and are lost or are non-collectable 10% of the time. We shall discuss the reasons for loss.

As we have discussed above, there are several mechanism that result in loss of cash from the practice. They naturally fall into two categories, the revenue loss and the expense burden. The details on each are:

(1) **Revenue Loss:** Revenue loss may occur from several courses.

i. Improper Billing: The submission of a bill that has been improperly prepared.

ii. Unfilled Bills: Bills that should have been filed but that have been neglected.

iii. Rejected Bills: Bills that have been filed, properly prepared, but rejected for other than procedural reasons.

iv. Lost Bills: Infrequent as it may be, some of the bills are lost after processed. Unless properly tracked, these bills are not followed up on.

(2) **Expense Flow:** This area of collections flow relates to the specific elements that are in the practice for managing the flow of revenue. Namely, the elements necessary to manage this flow, in terms of direct and indirect costs must be available. This will be discussed in detail in the next section.

The issue of infrastructure management is the one that combines the revenue management with the expense management, resulting in the management of working capital. Figure 3 shows the flow of funds from the point of practice collection to the net operating income number. The infrastructure of the practice is composed of four elements as regards to the billing process. These are shown in the Figure, specifically:

(1) **Billing Costs:** In a practice there are costs per bill in the preparation and mailing of the bills that need to be processed. For example, with patients who would pay in cash may in 30% of the cases require the bill to be sent rather than pay at time of service. Thus 30% of the cash patients say 25% of the practice, or 7.5% of the patients per month get bill sent who should have paid in cash. Medicare patients on assignment also fall in this category, as do assignments on all other bills. Finally, all HMO/PPO or Managed Care programs require bill submission. It is not unreasonable for 50% of the practice to be billed in some form. The cost per bill may frequently be a percent of the bill, for example 8% of the bill amount. Thus for this simple case, 8% of 50% is 4% of the
gross revenue being the billing costs. In a $500,000 gross revenue practice, this amounts to $20,000 per year.

(2) **Administrative Staff Costs:** There are costs of administering the preparation of forms, filing and retrieving billing data, preparing and managing the billing operators. The typical practice will have a half time person at a loaded cost of $20,000 per year.

(3) **Accounting Costs:** The preparation of the practices annual tax returns typically is based on an hourly charge. The charge is clearly dependent to the amount of prepared information on revenues and expenses that are available. Typically an electronic based system will reduce the accounting fees by a factor of two or more.

(4) **Imputed Interests:** Working Capital is the difference between Accounts Receivable and Accounts Payable. In essence it is what is owed the practice but not collected less what the practice owes but has not been paid. If the practice has a large working capital number it means that the physician is financing their patients, and that the money used to finance patients could to get a return even in a simple interest bearing account. Simply stated, for a $500,000 per year gross practice, having 90 days, or 25% of the years revenue in receivables, and having this in 40% of the cases says that $50,000 is the working capital value. At 8% interest, this is a loss of $4,000 from the practice.

This simple study states that for a $500,000 practice, $50,000 may be lost in these four channels. Practice management focuses on reducing these internal inefficiencies. Combine this with a 10% non collectible rate; this total is a $100,000 loss from the practice or 20%!

Office Practice Management systems are based upon standard practices that have been manually introduced into office practices. Recently computer based systems have been introduced into practices to address many of the issues that have been discussed in this paper. These systems have been introduced in several forms. Some have evolved from the older minicomputer systems that were originally developed for Hospital systems. Recent versions use PCs as the base platform and work as standalone systems.

In this section we present several examples of systems and describe their functions and Architectures. We also discuss how these systems may be used to address the reduction and possible elimination of the losses discussed is the past section.

An office management system that is computer based performs the following set of functions (See Hudson):

(1) **Registration:** This must take all pertinent patient information that is necessary both for the practice as well as for the billing process. This system must be intelligent enough to correct all mistakes that could latter cause billing errors. For example, simple issue
such as zip codes, dates of birth etc. must be properly filled in and Medicare information fields must be complete. Any system must assure the integrity of the registration fields.

(2) Accounting: This module of the system must track all receivables, must do aging and must be integratable into a full accounting package to enter payables as well and have a full chart of accounts. Since the patient system is revenue focused it looks primarily at receivables or cash into the practice. It does not have to be a full accounting system.

(3) Electronic Billing: The system module must interface into all Medicare systems as required, and into such third party systems as NEIC, GTE and others. It must also be flexible enough to deal with HMO/PPO and Managed Care electronic systems.

(4) Reports: All types of reports must be available. In addition the system should allow for flexible report preparation.

(5) Correspondence: Patient and other physician communications and correspondence should be available. This may include standard follow up letters and custom responses.

(6) Reminders: Patient reminders are critical. Mammogram, colonoscopy, indirect ophthalmoscopy etc. procedures must be tracked over fixed periods. Office staff may change but the system must remember these. Thus any computer system must have a fail safe reminders capability.

(7) Scheduling: Patient scheduling may be computerized or may best be left in "the Book". The choice here is up to the practice but the need is still there to register the patient.

(8) Forms: The system must prepare forms of all types. These are the HCFA, Workmen's Comp, Camp/School Physicals and many other forms. These may be practice specific, but with the use of laser printers, flexible form creation is readily available.

(9) Rules Updates: Any effective system must have a rules engine and a rules update process. This is especially true in the time of changing Medicare rules and other reimbursement rules. The vendors must demonstrate how effectively they can keep the system up to date with these changing rules. If they are not kept current, all of the efficiencies discussed will disappear.

These functions are then providing a computer database with all of the information that may them be cross referenced, retrieved, processed, transmitted, or displayed to perform all of the tasks in the office management process.

The features that are necessary in any such CIOS are those that make it both functionally easy to use but also upgradeable in the context of a growing practice or changing reimbursement environment. These features are;
(1) **Ease of Access:** The end user interface of any system must be easy to understand, access, and recover from. There should be a flexible window type design, avoiding the menu approach of dated systems. Menus reflect minicomputer/mainframe computer styles of the 1970's, whereas the windowing environment is the paradigm of the 2000's.

(2) **Flexibility of Data Base:** The data base must be flexible and handle all types of fields that can be entered. In addition the database must allow for the use by many users in a transaction mode with minimum delay in processing.

(3) **Modularity of Design:** The design must be modular, allowing the practice to get what is needed, to build by adding new modules, and to allow the modules to be updated, each as needed. Some systems are all one lump of computer code. This makes for an inflexible design and system.

(4) **Extensibility of the System:** An extensible system is one that easily allows growth; both in terms of new users and new uses. Atypical system may start out as a single workstation and then may expand into a network. The network may be on premises or between premises. The system must be able to grow in any direction.

(5) **Communications Enhanced:** The system must be able to communicate in many modes. Simply, it must have a modem to deal with electronic claims. But it must also allow for other communications in such areas as on-line in-office hospital admissions, the entering and receiving of pathology, x-ray and lab tests, and the access of medical information. This means that higher data speeds must be supportable and the system may also have to deal with images.

All of these features should be considered in choosing a system for a practice. The lack of any one feature could result in a situation that would require a replacement and the change over costs could be quite significant.

In order to fully understand the impact of electronic office practice systems we have taken two examples of practices that have used the system and the impact on the practice with the introduction of an electronic billing system.

The practices analyzed have fallen into two categories; a high volume low fee per visit practice and a low volume high fee per visit practice. The former may be that of an Internist or Pediatrician and the latter that of a Gastroenterologist.

2.6 **Policy Alternatives**

As we presented in the Executive Summary, the key elements of any Healthcare Policy should include the following:
1. Catastrophic Coverage: There should be coverage of catastrophic incidents such as cancers, stroke, and long term disabling diseases such as MS, ALS, Parkinson’s and Alzheimer’s

2. Every One In: Like the Massachusetts Plan, it must require all to participate.

3. Choice: The Plan(s) must allow choice so that a patient may choose their health care provider and hospital.

4. Reward Good Health: There must be a system which incentivizes good health practices and dis-incentivizes bad ones.

5. Establish Public Health Facilities: Utilize Public Health Clinics in place of the ER as a means of dealing with those in need of non-urgent care. Facilitate this by staffing with Medical School Graduates with tuition repayment.

6. Evolve Enabling Technology: Mandating technology solutions means the Government is choosing winners and losers and this always leads to increased costs and reduced quality of care.

We now review several of the Plans and make our recommendations.

2.6.1 The Obama Plan

The Obama Plan has been out there for the past election and it seems to have remained intact. It is detailed below. The problem is that it contain broad generalities and there is not analysis as to how it will reduce costs while ensuring quality. We will avoid those details herein since any discussion would be pure speculation.

<table>
<thead>
<tr>
<th>Area</th>
<th>Impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>(1) INVEST IN ELECTRONIC HEALTH INFORMATION TECHNOLOGY SYSTEMS</td>
<td>Invest $10 billion a year over the next five years to move the U.S. health care system to broad adoption of standards-based electronic health information systems, including electronic health records. $77 billion of savings would be realized each year.</td>
</tr>
<tr>
<td>(2) IMPROVE ACCESS TO PREVENTION AND PROVEN DISEASE MANAGEMENT PROGRAMS. Support disease management programs.</td>
<td>Over seventy-five percent of total health care dollars are spent on patients with one or more chronic conditions, such as diabetes, heart disease, and high blood pressure. Many patients with chronic diseases benefit greatly from disease management programs.</td>
</tr>
<tr>
<td>Area</td>
<td>Impact</td>
</tr>
<tr>
<td>-----------------------------------------------------------</td>
<td>--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Coordinate and integrate care.</td>
<td>Rates of chronic diseases have skyrocketed in the last 2 decades. Over 133 million Americans have at least one chronic disease and these chronic conditions cost a staggering $1.7 trillion yearly. Support providers to put in place care management programs and encourage team care through implementation of medical home type models.</td>
</tr>
<tr>
<td>Require full transparency regarding quality and costs.</td>
<td>Require hospitals and providers to collect and publicly report measures of health care costs and quality, will require providers to report preventable medical errors, and support hospital and physician practice improvement to prevent future errors.</td>
</tr>
<tr>
<td>Promote patient safety.</td>
<td>Providers will be rewarded for achieving performance thresholds on physician-validated outcome measures.</td>
</tr>
<tr>
<td>Align incentives for excellence.</td>
<td></td>
</tr>
<tr>
<td>Comparative effectivens reviews and research.</td>
<td>Comparative effectiveness reviews and research. This information is developed by reviewing existing literature, analyzing electronic health care data, and conducting simple, real world studies of new technologies and will establish an independent institute.</td>
</tr>
<tr>
<td>Tackle disparities in health care.</td>
<td>Implementing and funding evidence-based interventions.</td>
</tr>
<tr>
<td>Reform medical malpractice while preserving patient rights.</td>
<td>Strengthen antitrust laws to prevent insurers from overcharging physicians for their malpractice insurance.</td>
</tr>
<tr>
<td>(3) LOWER COSTS BY TAKING ON ANTICOMPETITIVE ACTIONS IN THE DRUG AND INSURANCE COMPANIES. Increasing competition in the insurance industry.</td>
<td>Eliminate the excessive subsidies to Medicare Advantage plans and pay them the same amount it would cost to treat the same patients under regular Medicare. drug companies from keeping generics out of markets.</td>
</tr>
<tr>
<td>Prevent private insurance waste and abuse in Medicare.</td>
<td>Allow Americans to buy their medicines from other developed countries if the drugs are safe and prices are lower outside the U.S. and increase use of generic.</td>
</tr>
<tr>
<td>Allow consumers to import safe drugs from other countries.</td>
<td>The plan will work to ensure that market power does not lead to higher prices for consumers.</td>
</tr>
<tr>
<td>Prevent drug companies from blocking generic drugs from consumers.</td>
<td>Repeal the ban on direct negotiation with drug companies.</td>
</tr>
<tr>
<td>Allow Medicare to negotiate for cheaper drug prices</td>
<td></td>
</tr>
<tr>
<td>(4) REDUCE COSTS OF CATASTROPHIC ILLNESSES FOR EMPLOYERS AND THEIR EMPLOYEES.</td>
<td>Catastrophic health expenditures account for 49 percent of the overall health care dollar. Offsetting some of the catastrophic costs would make health care more affordable for employers, workers and their families.</td>
</tr>
<tr>
<td>(1) GUARANTEED ELIGIBILITY.</td>
<td>Require insurance companies to cover pre-existing conditions so all Americans, regardless of their health status or history, can get comprehensive benefits at fair and stable premiums.</td>
</tr>
<tr>
<td>Area</td>
<td>Impact</td>
</tr>
<tr>
<td>----------------------------------------------------------------------</td>
<td>--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>(2) NEW AFFORDABLE, ACCESSIBLE HEALTH INSURANCE OPTIONS.</td>
<td>Create a National Health Insurance Exchange to help individuals purchase new affordable health care options if they are uninsured or want new health insurance. The Exchange will require that all the plans offered are at least as generous as the new public plan and meet the same standards for quality and efficiency. Comprehensive benefits. The benefit package will be similar to that offered through the Federal Employees Health Benefits Program (FEHBP) Affordable premiums, co-pays and deductibles. Participants will be charged fair premiums and minimal co-pays for deductibles for preventive services. Simplified paperwork. The plan will simplify paperwork for providers and will increase savings to the system overall. Easy enrollment. All Exchange health insurance plans will be simple to enroll in and provide ready access to coverage. Portability and choice. Participants will be able to move from job to job without changing or jeopardizing their health care coverage. Quality and efficiency. Participating hospitals and providers that participate in the new public plan will be required to collect and report data to ensure that standards for health care quality, health information technology and administration are being met.</td>
</tr>
<tr>
<td>(3) TAX CREDITS FOR FAMILIES AND SMALL BUSINESSES.</td>
<td>The health care plan will provide tax credits to all individuals who need it for their premiums. They will also create a new Small Business Health Tax Credit to provide small businesses with a refundable tax credit of up to 50 percent on premiums paid by small businesses on behalf of their employees.</td>
</tr>
<tr>
<td>(4) EMPLOYER CONTRIBUTION.</td>
<td>Large employers that do not offer meaningful coverage or make a meaningful contribution to the cost of quality health coverage for their employees will be required to contribute a percentage of payroll toward the costs of the national plan.</td>
</tr>
<tr>
<td>(5) REQUIRE COVERAGE OF CHILDREN.</td>
<td>Require that all children have health care coverage. will expand the number of options for young adults to get coverage by allowing young people up to age 25 to continue coverage through their parents’ plans.</td>
</tr>
<tr>
<td>(6) EXPANSION OF MEDICAID AND SCHIP</td>
<td>will expand eligibility for the Medicaid and SCHIP programs and ensure that these programs continue to serve their critical safety net function.</td>
</tr>
<tr>
<td>(7) FLEXIBILITY FOR STATE PLANS.</td>
<td>Due to federal inaction, some states have taken the lead in health care reform. Under the plan, states can continue to experiment, provided they meet the minimum standards of the national plan.</td>
</tr>
</tbody>
</table>

**2.6.2 The Old Hillary Plan**

It is worth looking at the 1993 Hillary Healthcare Plan to see the dramatic difference. The Hillary Plan was clearly a socialization of Healthcare. Whereas the AMA is today a supporter of the Obama Plan, frankly who could not since it is full of the right platitudes,
the Hillary Plan evoked massive outcries. Its review is educational, for she presented details.

**Hillary Healthcare Plan 1993**

<table>
<thead>
<tr>
<th>Element</th>
<th>Clinton Plan</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coverage</td>
<td>Universal coverage of all persons in the United States. Mandated participation no matter what religious beliefs a person may have.</td>
</tr>
<tr>
<td>Responsibility</td>
<td>The employer of the individual is responsible for payment. The individual has no personal responsibility for any participation, payment, selection, or offerings.</td>
</tr>
<tr>
<td>Children</td>
<td>Plans cover individuals or families as appropriate.</td>
</tr>
<tr>
<td>Over 65</td>
<td>Become members of state alliances.</td>
</tr>
<tr>
<td>Payment</td>
<td>Each participant is responsible for 20% of the plans payment.</td>
</tr>
<tr>
<td>Pricing</td>
<td>All prices shall be set by agents of the National Health Board.</td>
</tr>
<tr>
<td>Choice</td>
<td>There is choice of alliance approved managed care plans. Within a managed care plan no U.S. citizen, other than the President and Congress, shall have any choice in any health care delivery. Any U.S. citizen, other than the President and Congress, shall be held in violation of Federal law in seeking out any services not mandated by the managed care plan. Any physician participating or delivering such unauthorized and mandated services shall also be in violation of Federal law.</td>
</tr>
<tr>
<td>Catastrophic Coverage</td>
<td>No specific control for catastrophic coverage. It is combined with the total plan.</td>
</tr>
<tr>
<td>Quality Control</td>
<td>Quality control shall be mandated by the National Health Board. The Federal government shall mandate quality measures and physician service delivery standards for every possible health process. Violation of such a standard by a physician may be viewed as a violation of the law. The state and the state alliances also will have a role in the policing of these federally mandated standards.</td>
</tr>
<tr>
<td>Management Control</td>
<td>There will be a national database system that will use the HCFA 1500 form or equivalent. All information will be analyzed and preceded by the Health Board or its agents and the state alliances.</td>
</tr>
<tr>
<td>Price Control</td>
<td>All provider prices shall be fixed and controlled at a maximum level. Violation of these will be viewed as a Federal crime.</td>
</tr>
<tr>
<td>Demand Control</td>
<td>Demand control is managed by the primary care physician disallowing patient requests via a managed care plan. There will be no patient recourse. Each alliance shall have a budget which shall not be exceeded. Each alliance shall increase its budget in a fashion consistent with inflation. The alliance budget shall in no way reflect changes in health patterns or population demographics.</td>
</tr>
<tr>
<td>Supply Control</td>
<td>Price controls and caps will be placed upon the provision of services. Criminal penalties will be placed on the provision of services in deviation from the federal plan.</td>
</tr>
<tr>
<td><strong>Element</strong></td>
<td><strong>Clinton Plan</strong></td>
</tr>
<tr>
<td>-----------------------------------</td>
<td>------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Workforce Management</td>
<td>The current union based workforce will be maintained and expended where possible. Healthcare is viewed as a segment for employment growth and growth in a segment with increased union involvement.</td>
</tr>
<tr>
<td>Oversight</td>
<td>Oversight is by a complex structure of federal, state, insurer, provider groups. The structure allows for multiple levels of appeals.</td>
</tr>
<tr>
<td>Payment</td>
<td>All employers will be responsible for paying for the plan and for collecting the employee’s contribution.</td>
</tr>
<tr>
<td>Coverage Management</td>
<td>All citizens of the United States are covered. Each individual is mandated to join a local state health alliance is forbidden by law from using services outside of that alliance. Criminal penalties shall apply to any patient seeking to obtain services from providers not in their assigned alliance.</td>
</tr>
<tr>
<td>Medical Education</td>
<td>Federally mandated selection on specializations. Federally mandated selection of quotas for appropriate representation of racial, ethnic, sex, and lifestyle participants in order for the physician mix to reflect the mix in the population as a whole. Federally mandated control of curricula to focus on primary health care delivery and dramatic reduction on any form of specialization.</td>
</tr>
<tr>
<td>Medical Research</td>
<td>Federally mandated selection of specialization will result in a diminution of capable researchers. Research will focus on Prevention and Health Service respectively. There is a diminution of basic research. Prevention will focus on the establishment of new federal programs to education disenfranchised groups and those needing special education in health matters. Health services will focus on new and innovative ways to monitor physician health care delivery.</td>
</tr>
<tr>
<td>Physician Peer Review</td>
<td>Physician and other provider review shall be the responsibility of the Federal Government. The National Health Board shall set either directly or otherwise standards of performance. The proposed federal information gathering system shall monitor the practice patterns of physicians and shall take the appropriate measures to mandate compliance with federally set mandates and performance levels.</td>
</tr>
<tr>
<td>Patient Responsibility and Patient Training</td>
<td>The patient or individual has no personal responsibility or choice. The plan dictates from the federal level any and all procedures, access to specialized care required, or other accesses to health care. There is no intent to inform the individual of risk factors other than through the process of taxation of at risk consumable. At risk behavior is still considered the individual choice and the individual will not be held responsible.</td>
</tr>
</tbody>
</table>

### 2.6.3 Alternatives

This section presents an overview of some of two of the more current plans.
2.6.3.1 AMA Plan

The AMA proposal would expand health insurance coverage and improve fairness by shifting government spending toward those most likely to be uninsured—people with lower incomes. It would also reduce the hidden bias favoring employment-based coverage, which provides special employee income tax breaks for insurance obtained through an employer. Reducing this bias has important advantages, as well as potential drawbacks, that must be addressed. Those without the option of insurance through a job don’t get this tax break, and would finally get assistance under the AMA proposal. Employees who are dissatisfied with their employers’ health plan offerings could choose to buy insurance elsewhere and still be eligible for assistance.

Reducing the bias, however, could accelerate the decline in employment-based insurance, causing further disruption. Especially in this context, strong safeguards are needed to ensure that people with predictably high medical costs can afford coverage. Health insurance market regulations should be reformed to establish fair rules that protect vulnerable populations without unduly driving up premiums for the rest of the population. Regulations should also allow market experimentation to find the most attractive combinations of plan benefits, patient cost-sharing and premiums. In short, the AMA advocates a clear role for government in financing and regulating health insurance coverage, with health plans and health care services being provided through private markets, as they are currently. The AMA proposal gives patients more control over our nation’s health care.

The AMA proposal to expand health insurance coverage is based on three pillars:

Helping people buy health insurance through tax credits or vouchers. These tax credits or vouchers should be more generous at lower income levels, and should be earmarked for health insurance coverage. It is important to note that the government already gives people financial assistance to buy private health insurance—well over $125 billion each year. The form of this support—an employee income tax break on job-based insurance—is hidden from public view. This tax break gives more assistance to those in higher tax brackets, and gives no assistance to those without employee health benefits. Shifting some of this assistance to tax credits or vouchers for lower-income people would reduce the number of uninsured and improve fairness in the health care system. One way this can be achieved, for example, is by putting limits on the existing tax break so that employees do not get a bigger income tax break for simply enrolling in more expensive health plans. Under this scenario, premiums for employee health insurance below a specified limit could still be tax-free, with additional spending becoming subject to income tax. Limiting the $125 billion tax break for job-based insurance would yield additional revenue for the government, which could be used to fund tax credits and vouchers for those who currently get little or no assistance. The limit would also
encourage insurers, employers and employees to avoid excessively generous health plans, curbing the rising cost of health care and insurance premiums.

Choice for individuals and families in what health plan to join. Today, people are effectively locked into the health plans their employers offer, often just one or two, which are subject to change from year to year. A change in employment typically means a change in insurance coverage. In contrast, under the AMA plan, people could use tax credits or vouchers to help pay for premiums of any available insurance, whether offered through a job, another arrangement or the open market. As with job-based insurance today, health plans would still have to meet federal guidelines in covered benefits, but people would have greater say in what types of benefits and plan features they value. Coupled with individual choice, tax credits benefit recipients directly, and everyone indirectly, by stimulating the market for health insurance. If enough people have enough purchasing power—and enough say over how that purchasing power is used—insurers will be compelled to step up to the plate with better, more affordable coverage options that are within reach of more people.

Fair rules of the game: Regulating markets and protecting high-risk patients. For markets to function properly, it is important to establish fair ground rules. A proliferation of state and federal health insurance market regulations has made it more difficult and expensive for insurers to do business in many markets. The AMA proposes streamlined, more uniform health insurance market regulations. Regulations should permit market experimentation to find the most attractive combinations of plan benefits, patient cost-sharing and premiums. It is also important that market regulations reward, not penalize, insurers for taking all types of patients. Market regulations intended to protect people with high health risks have typically backfired, sometimes disastrously, by driving up premiums for younger, healthier people and leading them to drop coverage.

2.6.3.2 Massachusetts Plan

1. Massachusetts’ health spending increased by 34.7 percent between 2000 and 2004, or 7.7 percent per year.
2. On a per capita basis, health spending is more than 26 percent higher in Massachusetts than in the United States as a whole and grew somewhat faster between 1991 and 2004. Spending in Massachusetts increased from $3,249 per capita in 1991 to $6,683 per capita in 2004. The comparable numbers for the United States as a whole were $2,654 in 1991 and $5,283 in 2004.
3. While health care spending increased by 33 percent between 2000 and 2004 in Massachusetts, health insurance premiums increased by 53 percent for individual policies and 44 percent for family policies.
4. Health insurance premiums increased by 8.9 percent per year in Massachusetts between 2001 and 2007, faster than the U.S. average growth in premiums of 7.7 percent.
2.6.4 The Luft Plan

Harold Luft is a Health Care policy professor from Berkeley. One is drawn to his plan by a review in the New England Journal of Medicine (360: 5 pp547-549) which somewhat praised the book. However upon reading it one sees a rambling style of pedantic text that leads nowhere. Let me clarify:

1. The author structures the book about what he calls his SecurePlan. The Plan basically takes healthcare and breaks it into two types: (i) major acute and major chronic and (ii) everything else.

2. The author states that universal care is essential as a given and that his proposed plan is the way to achieve it.

3. The author proposes amongst others that a Federal Reserve type structure be established to provide for the distribution of the universal essential services.

4. The author suggests the restructuring of the payments into a fee for intervention for the major acute and major chronic issues and a fee for service for most others.

5. The fee for intervention assumes that there are medical teams which group together and do, say cardiac catheterization under the rubric of a hospital. He in effect places the hospital as the arbiter. He also in effect removes from the patient the choice of the team elements. You get what the hospital has contracted with.

6. His proposal would require a massive restructuring of all health care as we know it today.

Now let me look at some details that are missing:

1. The plan is based upon a de minimis number of facts. It reads like an op-ed piece but it drones on forever. It is often quite difficult to see where the author is going.

2. The author is purportedly an economist and he seems to neglect the economics of the problem. As most economists strangely do, the modulation of demand is never considered in the analysis of health care. They all assume that the demand for healthcare is inelastic. That is, the health care services are truly price independent to the consumer, the patient or future patient. We know that to be blatantly false. For example, as we increased taxes on cigarettes we have seen almost a 50% reduction in lung cancer among men.

Thus there can be a market effect which can be useful in reducing demand. This can be extended to Type 2 Diabetes if one does as Gov Patterson of New York suggests and tax carbs. Obesity is the major cause of all Type 2 Diabetes and reducing the Body Mass
Index below 22.5 eliminates the disease in over 90% of the cases. No drugs, no secondary diseases, no treatment, the reduction of BMI takes away the overload on blood sugar. This alone would save 10% of the current expenditures in health care in the US. Then there are remediable diseases which by screening can also see their costs dropped by 50%.

Screening for colon, breast, prostate, and similar cancers, means that we can, including screening costs, reduce the total cost burden for treatment of that specific disease from the current 12% of health care costs to 6%. Then we can address the cost equation or the supply curve; namely improving billing, using EMR, managing nosocomial infections, reducing diagnosis errors and the like. Treat the health care delivery as a process as one would do in any production or manufacturing industry, drive out costs and improve quality. Imagine if semiconductors were managed like health care; costly, unreliable, and the list would go on. The author totally disregards these issues as he invents his plan.

3. The Hillary Health Care Plan of the early 1990s was also a centralized control plan and we saw where that went.

Finally one may ask why all of the proposers of these plans like Luft make several what I would consider fatal flaws in assumptions. They are:

1. The past is prologue to the future and in fact the future is a direct continuation of the past. This may very well not be the case here. With the explosion of genetic screening, diagnosis, staging, treatment, and prevention one would see the role of the physician as the genetic controller of disease as becoming paramount and one would hope the position of the hospital is for those which we have not yet understood. The problem with most of the health care proposals is that they delimit the future and plan as if nothing will change.

2. The development of a change architecture depends upon one's world view and this per Kuhn is contingent upon the paradigms which create our understandings. The Luft paradigms are in middle 20th Century medicine and are thus directed at how one pays for "it" and never questions what "it" may be evolving to, and even more so, how can we get "it" to evolve better.

Thus Luft sits between Porter's recent regurgitation of Strategy, Redefining Health Care, and Cutler's Your Money or Your Life, a paean on Hillary Health.

2.6.5 Proposed Plan

The following is the detail we see in a modern Healthcare Policy Plan. We have called this the "Preferred" Plan. It has changed little from our proposal in 1993. It now
includes, however, details that are consistent with the overall principles we have presented at the beginning if this report.

### Suggested Healthcare Plan Elements

<table>
<thead>
<tr>
<th>Element</th>
<th>&quot;Preferred&quot; Plan</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coverage</td>
<td>Universal coverage, if not objected to on religious or other grounds, of all citizens of the United States. Maintains ability of those practicing their rights under the First Amendment of the Constitution to refrain from mandated health coverage.</td>
</tr>
<tr>
<td>Responsibility</td>
<td>The Individual is responsible directly. There will be no Group Plans and there will be no groups or collusive buying groups. Each individual will be responsible for procurement of an individual policy.</td>
</tr>
<tr>
<td>Children</td>
<td>All dependent children will be covered individually by a plan paid for by their parent, legal guardian, or by the state, if there is no such guardian.</td>
</tr>
<tr>
<td>Over 65</td>
<td>All current Medicare eligible individuals will purchase a plan from a registered provider, and the Government will pay for the base price of the base plan, directly.</td>
</tr>
<tr>
<td>Payment</td>
<td>Each individual will be responsible for selecting and paying for an insurance plan. Each family will be responsible for their children and payment for a children's plan. If there individual or family is not able to purchase the plan because of financial reasons, lack of employment or other accepted reason, the Government shall provide that individual with a subsidy per person equal to that of the fee for the minimal service provided by the lowest cost provider. The subsidy shall be paid directly to that provider on behalf of the subscriber. In the event that the patient does not purchase a plan and seeks services, and is not covered by a self selected waiver, then the patient will be personally responsible for payment of all fees, will have subsequent fees paid out of their taxes, and shall be fined for the failure. It will be the IRS responsibility to collect said fees.</td>
</tr>
<tr>
<td>Pricing</td>
<td>There shall be a set of standard offerings, with the minimal offering of a basic medical plan. No provider shall offer other plans unless they offer the standard minimal common plans. There shall be no difference in such plans. All providers shall list publicly the price per person per plan. There shall be no difference between any person based upon age, sex, health history, or for any other reason. Each person shall pay the same insurer the same price for the same plan. Insurers may offer the basis plan in combination with other plans, but the subscriber must be able to buy the basis plan alone.</td>
</tr>
<tr>
<td>Choice</td>
<td>There is total and complete freedom of choice. The patient may choose any physician at any time for any purpose. The physician may charge any fee for any service as long as the physician's fees are posted with common knowledge of what those fees are to any interested party.</td>
</tr>
<tr>
<td>Catastrophic Coverage</td>
<td>There will be a list of catastrophic diseases. Any and all expenses of services directly related to meeting the needs of such a disease shall be paid for from a Federal fund. No individual shall be charged a deductible for any disease that is deemed catastrophic.</td>
</tr>
<tr>
<td>Element</td>
<td>&quot;Preferred&quot; Plan</td>
</tr>
<tr>
<td>----------------------</td>
<td>--------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Quality Control</td>
<td>There shall be a state, federal, and/or other regulatory oversight control on physician, hospital, or other providers of services monitoring the quality of health care provided. The patients shall have immediate and direct access to this. There shall be a minimal level or standard established and there shall be monitoring of such providers to assure that they meet the standard. In the event that said standard if not met, the provider will be immediately denied the right to continue to provide service.</td>
</tr>
<tr>
<td>Management Control</td>
<td>All patient records will be computerized. There will be a standard patient billing record and said record will be generated at the provider’s premises at the time the services are rendered. There will be a copy of that record available to the insurer and the patient and a summary available to the appropriate governing bodies and state and federal agencies.</td>
</tr>
<tr>
<td>Price Control</td>
<td>Each provider of services shall have available to them at the time of referral, the list of prices on all drugs, diagnostic services, referral services, or other services not directly provided by them. They must provide those prices to the patient at the time of referral. These prices must be provided in writing and must be honored at the time at which they are provided to the patient.</td>
</tr>
<tr>
<td>Demand Control</td>
<td>Each individual will have a deductible of 5% of their gross income or equivalent, and families will have to pay a deductible of 2% of their gross family income for each child. All deductibles are on an annual basis and the deductible will be renewed each calendar year.</td>
</tr>
<tr>
<td>Supply Control</td>
<td>The desire is to have a health care system that “clears the market” from an economic perspective. To achieve this, there will be no subsidies of any type to providers of any type for the provision of service other than the fees provided by purchasers of said services. There shall be no government subsidies and there shall be no control on prices.</td>
</tr>
<tr>
<td>Workforce Management</td>
<td>Productivity is to be the measure of performance with quality being maintained by mandate. By means of the supply demand relationship and by means of the market clearing activities of no supports, inefficient providers shall be driven from the market. Providers shall be responsible for the manner in which they provide the most efficient service at the desired level of quality.</td>
</tr>
<tr>
<td>Oversight</td>
<td>Oversight is by a mutually acceptable professional, state, and/or federal oversight Board. There shall be no compensation for participation on this Board.</td>
</tr>
<tr>
<td>Element</td>
<td>&quot;Preferred&quot; Plan</td>
</tr>
<tr>
<td>-------------------------------</td>
<td>-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Payment</td>
<td>Each Provider of Health Care must offer a set of minimal benefit packages, such packages being identical from one provider to another. Each Provider must offer the package at the same price per person and such a price must be a matter of public record. Each provider of service will have real time access to the amount paid by the individual at the time of service. If the amount is still within the deductible level, the provider is responsible for collecting the amount at the time of service. If the amount is now above the deductible, in total, the provider shall be reimbursed by the insurer of record within forty eight hours of the provision of service. There shall be no denial of payment. Post service audits may be performed, and in the event that fraud has been perpetrated, it shall be a federal crime.</td>
</tr>
<tr>
<td>Coverage Management</td>
<td>All citizens of the United States must be covered. The responsibility is that of the individual to seek out an obtain insurance. Those individuals not desiring insurance because of their own ability to pay, because of religious reasons or because of other personal beliefs, may not be compelled to purchase insurance. However, in the event that such individuals seek medical care, they will be charged a full and complete fee and will be held personally liable for all charges render. These individuals will be informed as such at the time of service provision.</td>
</tr>
<tr>
<td>Medical Education</td>
<td>There shall be no controls of any type on the nature of, the operations of, the choice of, the content of, of any other element of medical training. The market forces of the supply and demand elements of the health care business shall be the only controls. The selection of individuals shall be based on academic performance and clinical performance only. The goal in physician selection is on capabilities and performance, and no other factors shall be considered.</td>
</tr>
<tr>
<td>Medical Research</td>
<td>There shall be no control or influence over the nature of research. Current research policies shall be continued and improved upon. The goal is to continue to foster and improve medical delivery through innovation and productivity, while maintaining the highest quality.</td>
</tr>
<tr>
<td>Physician Peer Review</td>
<td>Quality of delivery is the ultimate goal, in a free market competitive environment. Patient complaints, provider's malpractice, and other deviations from quality shall be dealt with immediately and severely to resolve them in a timely fashion. There shall be a Peer review process set in place with patient representatives having at least on third the deciding positions.</td>
</tr>
<tr>
<td>Patient Responsibility and Patient Training</td>
<td>The individual is held ultimately responsible for their own individual health and well being. The individual will not in any way be disenfranchised or otherwise discriminated against for any and all genetically related disorders. However the individual will be responsible for their behavior that places them at risk. As such, there will be health information made readily available describing risky behavior and indicating that such behavior has penalties. Where possible, the government shall take the elements of such behavior such as with tobacco or alcohol.</td>
</tr>
</tbody>
</table>
3 DIABETES, A PREVENTABLE COST

Type 2 Diabetes has become a pandemic in all societies. It leads to kidney failure, blindness, nerve damage, vascular damage, heart attacks, and a vast panoply of other tertiary diseases. It has started to creep down in age in incidence. It consumes almost 10-12% of the total health care costs in the United States alone. It also is an almost totally preventable disease. It is in almost all cases a disease of life style. It presents a case study for handling the delivery of health care in the United States. For we argue herein that this disease, which in many ways is akin to the disorders related to smoking, is a totally preventable disorder. It is a disease which can be modulated and reduced by economic means.

Type 2 Diabetes is a disease of insulin production. The pancreas no longer produces adequate insulin to transport the glucose produced by sugar and carbohydrate consumption and the net result is an excessive rise of glucose in the blood stream. In simple terms this excess glucose catalyzes many reactions which in turn cause the circulatory, renal, optic, and neurological damage. The excess of glucose in simple terms wears down these systems in rapid order.

The primary drive of this process leading to Type 2 Diabetes is excess consumption of carbohydrates and generally this excess is directly exhibited in overweight individuals. Weight impact on health is measure by the Body Mass Index calculation. If the BMI is less than 25 and greater than 20 then this is a healthy range. Overweight is defined as BMI greater than 25 and less than 30. Obese is defined as anything greater than 30. Thus a 6’3” male of 250 lbs is obese, where as if he is greater than 210 he is overweight. The most predisposing factor, and many believe causative factor of Type 2 Diabetes if being overweight, not just being obese. This now applies for any age, children included.

In 1997 about 4.7% of people were Type 2 Diabetics. In 2008 that has increased to 5.9%. By 2020 the number is anticipated to increase to 15%. The total expenditures for Type 2 Diabetes in 2008 are in excess of $250 billion, about 12% of all health care expenditures. This combination results in an expenditure of $12,500 per Type 2 Diabetic per annum.

However the problem is explosive. With health care growing at 6% per annum in excess of inflation and Type 2 Diabetes prevalence growing at 3% per annum, and the overall population growing at 1% per annum, the net result is costs growing at in excess of 10% per annum! That exceeds rate of the health care costs alone. It is conceivable that Type 2 Diabetes will reach 20% of all health care costs by 2030.

9 See Porte et al and LeRoith et al.

10 See Taube Science 2009.
We present this growth picture in the following Figure.

![Projections of Type 2 Diabetes 2010-2030](image)

3.1 Epidemiology

This section presents a brief overview of the epidemiological factors associated with Type 2 Diabetes, and reviews the causes and the incidence and prevalence.

3.1.1 Causes

The primary cause of Type 2 Diabetes is excess weight.\(^\text{11}\) It commences as a breakdown of the pancreas' \(\beta\) cells to produce adequate amounts of insulin which in turn results in excess glucose in the blood stream.\(^\text{12}\) It appears that when the body has excess weight that pancreas cannot generate the insulin fast enough and has a "run down" result. It just stops generating insulin totally. There is however a social stigma to telling a Type 2

\(^{11}\) See the paper by Lazar. This is an exceptionally good summary of the obesity argument placed within a genetic and evolutionary context.

\(^{12}\) See the paper by Marx for a recent summary of the status of the causes of Diabetes.
Diabetes patient that they are the cause of their disease due solely to their weight and their inability to control it. This is the distinct opposite to what had happened in cigarette smoking. Any attempt to modulate behavior related to caloric consumption is viewed as politically incorrect in today's environment which we believe is the main reason that we shall see an epidemic of Type 2 Diabetes especially in the young.

There is a strong relationship between Type 2 Diabetes and chronic inflammation, stresses that wear out the body's cells. As Lazar states:

"The close relationship between inflammation and diabetes is supported by the observation that stimulation of the innate immune response [by bacterial endotoxin during sepsis, for example] results in insulin resistance that contributes to the high mortality of critical illness. The interaction between inflammation and insulin signaling is also suggested by the ability of aspirin to improve insulin resistance, in part by preventing the antagonistic effects of fatty acids and cytokines."

Lazar continues:

"Why is obesity an inflammatory state and why does inflammation cause diabetes? The search for answers to these questions takes us again to evolutionary considerations. Perhaps the response to infection is more effective when glucose is shunted from muscle to the inflammatory cells involved in the immune response and tissue repair. A potentially unifying view is that the body's ability to survive major stress, including infection and starvation, is enhanced by peripheral insulin resistance that preserves the brain's glucose supply. This hypothesis might explain why cortisol, the major stress hormone, causes insulin resistance and stimulates the innate immune response, even though chronic cortisol exposure is anti-inflammatory because of down-modulation of the acquired immune response. The stress connection may extend to individual cells, as it has recently been shown that intracellular stress induces insulin resistance in a manner that is exacerbated by obesity, potentially through adipocyte-secreted factors. Moreover, chronic metabolic stress impairs the ability of pancreatic beta cells to secrete sufficient insulin to overcome insulin resistance, which is a hallmark of type 2 diabetes."

Marx states:

"Although insulin resistance and the resulting impairment in glucose tolerance are early signs of diabetes, malfunction or even death of the insulin-producing β cells also contributes to the disease. Ultimately about a third of diabetes 2 patients end up having to take insulin. Several factors seem to be involved in β-cell dysfunction, including some of the same culprits implicated in insulin resistance. For example, in experiments performed on the Zucker rat, a rodent model of obesity and diabetes, Unger’s group at UT Southwestern has found that fatty acids can trigger a form of cell death called apoptosis in β cells. The fatty acids work indirectly, the UT Southwestern team found: They are first converted in β cells to toxic compounds known as ceramides."
That suggests to Unger that the β-cell loss can be prevented. “If we block that [ceramide-producing] pathway, we can block apoptosis,” he says. Unger also suggests that this fatty acid toxicity may result from the body’s insensitivity to leptin. In his view, that hormone’s job is to keep fatty acids from accumulating in cells that aren’t designed to handle them, such as β cells and muscle. But β cells don’t have to die to contribute to diabetes 2 pathology: They can simply fail to secrete the insulin needed to handle all the glucose the body takes in.

At least in mouse models, researchers can duplicate that type of malfunction. For example, a team led by Ronald Kahn of the Joslin Diabetes Center in Boston and Mark Magnuson of Vanderbilt University School of Medicine in Nashville, Tennessee, found that they could prevent the increase in insulin secretion that normally occurs in response to glucose ingestion by specifically inactivating the insulin receptor in the β cells of mice. As a result of the consequent block in insulin activity, glucose can’t get inside the cells to trigger release of the hormone."

There are several studies which link certain genetic markers to Type 2 Diabetes. Several of these are shown below are from Marx.
### SOME CANDIDATE DIABETES 2 GENES

<table>
<thead>
<tr>
<th>Mutated Gene</th>
<th>Function</th>
<th>Effect</th>
<th>Linked to</th>
</tr>
</thead>
<tbody>
<tr>
<td>HNF-4-α, HNF-1-β</td>
<td>Transcription</td>
<td>Insulin→</td>
<td>MODY (human) secretion</td>
</tr>
<tr>
<td>IFP-1, NeuroD1</td>
<td>factors</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HNF-1-α factor</td>
<td>Transcription</td>
<td>Insulin→</td>
<td>MODY</td>
</tr>
<tr>
<td>Glucokinase</td>
<td>secretion</td>
<td>Insulin→</td>
<td>MODY</td>
</tr>
<tr>
<td>metabolism</td>
<td>Glucose secretion</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Calpain-10</td>
<td>Protease</td>
<td>Unknown Mexican and African Americans</td>
<td>Diabetes 2 in</td>
</tr>
<tr>
<td>PPAR-γ factor</td>
<td>Transcription</td>
<td>Insulin→</td>
<td>Diabetes 2</td>
</tr>
<tr>
<td>Insulin receptor</td>
<td>sensitivity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>insulin signals</td>
<td>Transmits</td>
<td>Insulin→</td>
<td>Human diabetes</td>
</tr>
<tr>
<td>into cell</td>
<td>sensitivity and</td>
<td></td>
<td></td>
</tr>
<tr>
<td>IRS1 and -2</td>
<td>Insulin</td>
<td>Insulin→</td>
<td>Mouse models</td>
</tr>
<tr>
<td>signaling</td>
<td>sensitivity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Akt2 signaling</td>
<td>Insulin</td>
<td>Insulin→</td>
<td>Mouse models</td>
</tr>
<tr>
<td>signaling</td>
<td>sensitivity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>11-β-HSD synthesis</td>
<td>Glucocorticoid</td>
<td>Blood →</td>
<td>Mouse models</td>
</tr>
<tr>
<td></td>
<td>lipids,</td>
<td>insulin sensitivity</td>
<td></td>
</tr>
<tr>
<td>UCP2</td>
<td>ATP → synthesis</td>
<td>Insulin→</td>
<td>Mouse models</td>
</tr>
<tr>
<td>Resistin</td>
<td>Fat cell</td>
<td>Insulin→</td>
<td>Mouse studies</td>
</tr>
<tr>
<td></td>
<td>“hormone”</td>
<td>sensitivity</td>
<td></td>
</tr>
<tr>
<td>Adiponectin</td>
<td>Fat cell</td>
<td>Insulin</td>
<td>Mouse, human studies</td>
</tr>
<tr>
<td></td>
<td>“hormone”</td>
<td>sensitivity</td>
<td></td>
</tr>
</tbody>
</table>

The current approach to treating Type 2 Diabetes is all too often the use of medications.\(^\text{13}\)

#### 3.1.2 Incidence and Prevalence

The incidence and prevalence of Type 2 Diabetes is dramatically increasing. We briefly review the data on these two factors.

#### 3.1.2.1 Incidence

\(^\text{13}\) See the paper by DeFronzo and the one by Padwal. The DeFronzo paper is exceptionally good as a review of the various types of medications and their effective means of reducing insulin overload and maintaining proper insulin production.
The following is a summary of the NIH review of Type 2 Diabetes. The incidence of Diagnosed Diabetes in People Younger than 20 Years of Age, United States, 2002 to 2003 is as follows:

Based on 2002 to 2003 data, 15,000 youth in the United States were newly diagnosed with type 1 diabetes annually, and about 3,700 youth were newly diagnosed with type 2 diabetes annually.

The rate of new cases among youth was 19.0 per 100,000 each year for type 1 diabetes and 5.3 per 100,000 for type 2 diabetes. Non-Hispanic white youth had the highest rate of new cases of type 1 diabetes.

Type 2 diabetes was extremely rare among youth aged <10 years. While still infrequent, rates were greater among youth aged 10 to 19 years compared with younger children, with higher rates among U.S. minority populations compared with non-Hispanic whites.

Among non-Hispanic white youth aged 10 to 19 years, the rate of new cases of type 1 diabetes was higher than for type 2 diabetes.

For Asian/Pacific Islander and American Indian youth aged 10 to 19 years, the opposite was true—the rate of new cases of type 2 was greater than the rate for type 1 diabetes.

Among African American and Hispanic youth aged 10 to 19 years, the rates of new cases of type 1 and type 2 diabetes were similar.

3.1.2.2 Prevalence

Prevalence of Diagnosed Diabetes in People Younger than 20 Years of Age, United States, 2007. About 186,300 people younger than 20 years have diabetes—type 1 or type 2. This represents 0.2 percent of all people in this age group. Estimates of undiagnosed diabetes are unavailable for this age group.

Prevalence of Diagnosed and Undiagnosed Diabetes in the United States, All Ages, 2007

Total: 23.6 million people—7.8 percent of the population—have diabetes.
Diagnosed: 17.9 million people
Undiagnosed: 5.7 million people

Prevalence of Diagnosed and Undiagnosed Diabetes among People Aged 20 Years or Older, United States, 2007

Age 20 years or older: 23.5 million, or 10.7 percent, of all people in this age group have diabetes.
Age 60 years or older: 12.2 million, or 23.1 percent, of all people in this age group have diabetes.

Men: 12.0 million, or 11.2 percent, of all men aged 20 years or older have diabetes.

Women: 11.5 million, or 10.2 percent, of all women aged 20 years or older have diabetes.

Non-Hispanic whites: 14.9 million, or 9.8 percent, of all non-Hispanic whites aged 20 years or older have diabetes.

Non-Hispanic blacks: 3.7 million, or 14.7 percent, of all non-Hispanic blacks aged 20 years or older have diabetes.

The following Figures depict prevalence over the past 25 years broken out by age group. There is an explosive growth amongst the 45-64 age group. This will of course spread as they age and create significant chronic health care costs.

The following shows the same data but now as percent of the population. Note that as before the 45-64 age group grows from 1% to over 2.5% of the total population. This is truly a worrisome factor. These are the baby boomers. They are
The overall combined prevalence is shown in the following Figure. This is a summary of the previous Figure but it rolls up all of the age categories.
3.1.3 Complications

The following is from the NIH data source.\textsuperscript{14}

Heart Disease and Stroke

- In 2004, heart disease was noted on 68 percent of diabetes-related death certificates among people aged 65 years or older.
- In 2004, stroke was noted on 16 percent of diabetes-related death certificates among people aged 65 years or older.
- Adults with diabetes have heart disease death rates about two to four times higher than adults without diabetes.
- The risk for stroke is two to four times higher among people with diabetes.

High Blood Pressure

- In 2003 to 2004, 75 percent of adults with self-reported diabetes had blood pressure greater than or equal to 130/80 millimeters of mercury (mm Hg) or used prescription medications for hypertension.

Blindness

\textsuperscript{14} See http://diabetes.niddk.nih.gov/dm/pubs/statistics/index.htm#allages
• Diabetes is the leading cause of new cases of blindness among adults aged 20 to 74 years.
• Diabetic retinopathy causes 12,000 to 24,000 new cases of blindness each year.

Kidney Disease
• Diabetes is the leading cause of kidney failure, accounting for 44 percent of new cases in 2005.
• In 2005, 46,739 people with diabetes began treatment for end-stage kidney disease in the United States and Puerto Rico.
• In 2005, a total of 178,689 people with end-stage kidney disease due to diabetes were living on chronic dialysis or with a kidney transplant in the United States and Puerto Rico.

Nervous System Disease
• About 60 to 70 percent of people with diabetes have mild to severe forms of nervous system damage. The results of such damage include impaired sensation or pain in the feet or hands, slowed digestion of food in the stomach, carpal tunnel syndrome, erectile dysfunction, or other nerve problems.
• Almost 30 percent of people with diabetes aged 40 years or older have impaired sensation in the feet—for example, at least one area that lacks feeling.
• Severe forms of diabetic nerve disease are a major contributing cause of lower-extremity amputations.

Amputations
• More than 60 percent of nontraumatic lower-limb amputations occur in people with diabetes.
• In 2004, about 71,000 nontraumatic lower-limb amputations were performed in people with diabetes.

Dental Disease
• Periodontal, or gum, disease is more common in people with diabetes. Among young adults, those with diabetes have about twice the risk of those without diabetes.
• Persons with poorly controlled diabetes (A1C > 9 percent) were nearly three times more likely to have severe periodontitis than those without diabetes.
• Almost one-third of people with diabetes have severe periodontal disease with loss of attachment of the gums to the teeth measuring 5 millimeters or more.

Complications of Pregnancy
• Poorly controlled diabetes before conception and during the first trimester of pregnancy among women with type 1 diabetes can cause major birth defects in 5 to 10 percent of pregnancies and spontaneous abortions in 15 to 20 percent of pregnancies.
• Poorly controlled diabetes during the second and third trimesters of pregnancy can result in excessively large babies, posing a risk to both mother and child.

Other Complications
• Uncontrolled diabetes often leads to biochemical imbalances that can cause acute life-threatening events, such as diabetic ketoacidosis and hyperosmolar, or nonketotic, coma.
• People with diabetes are more susceptible to many other illnesses and, once they acquire these illnesses, often have worse prognoses. For example, they are more likely to die with pneumonia or influenza than people who do not have diabetes.
• Persons with diabetes aged 60 years or older are two to three times more likely to report an inability to walk a quarter of a mile, climb stairs, do housework, or use a mobility aid compared with persons without diabetes in the same age group.

Hospitalizations resulting from Type 2 Diabetes are shown in the Figure below:

Note that in the above we find that the cardiovascular complications are the dominant factor causing a hospitalization. Most other treatments as we shall see later are chronic in nature. Type 2 Diabetes is from the perspective of treatment thus predominantly a chronic disorder which requires a great deal of complex medical treatment.

3.1.4 Treatments

The main treatment for Type 2 Diabetes is either weight reduction combined with exercise or medication.
<table>
<thead>
<tr>
<th>Drug (Trade Name, Manufacturer)</th>
<th>Usual Daily Dosage</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>First-generation sulfonylureas</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acetohexamide</td>
<td>500–750 mg</td>
<td>$14.18</td>
</tr>
<tr>
<td>Chlorpropamide (Diabenase, Pfizer)</td>
<td>250–375 mg</td>
<td>$1.19</td>
</tr>
<tr>
<td>Tolazamide</td>
<td>250–500 mg</td>
<td>$2.81</td>
</tr>
<tr>
<td>Tolbutamide</td>
<td>1000–2000 mg</td>
<td>$2.75</td>
</tr>
<tr>
<td><strong>Second-generation sulfonylureas</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Glimepiride (Amaryl, Hoechst Marion Roussel)</td>
<td>1–4 mg</td>
<td>$7.06</td>
</tr>
<tr>
<td>Glipizide</td>
<td>10–20 mg</td>
<td>$3.38</td>
</tr>
<tr>
<td>(Glucotrol, Pfizer)</td>
<td></td>
<td>$21.38</td>
</tr>
<tr>
<td>(Glucotrol XL, Pfizer)</td>
<td></td>
<td>$10.07</td>
</tr>
<tr>
<td>Glyburide</td>
<td>5–20 mg</td>
<td>$14.95</td>
</tr>
<tr>
<td>(DiaBeta, Hoechst Marion Roussel)</td>
<td></td>
<td>$20.43</td>
</tr>
<tr>
<td>(Micronase, Pharmacia &amp; Upjohn)</td>
<td></td>
<td>$22.93</td>
</tr>
<tr>
<td>(Glynase, Pharmacia &amp; Upjohn)</td>
<td></td>
<td>$20.10</td>
</tr>
<tr>
<td><strong>Nonsulfonylureas</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acarbose (Precose, Bayer)</td>
<td>150–300 mg</td>
<td>$41.05</td>
</tr>
<tr>
<td>Metformin (Glucophage, Bristol-Myers Squibb)</td>
<td>1500–2550 mg†</td>
<td>$48.38</td>
</tr>
<tr>
<td>Repaglinide (Prandin, Novo Nordisk)</td>
<td>1–4 mg</td>
<td>$57.12</td>
</tr>
<tr>
<td>Troglitazone (Rezulin, Parke-Davis)</td>
<td>400–600 mg</td>
<td>$147.20</td>
</tr>
</tbody>
</table>

The growth of these medications is shown in the Graph below.
3.2 Costs

We can now assess the costs associated with Type 2 Diabetes. We rely upon a study performed by Michael Brandle, MD et al entitled The Direct Medical Cost of Type 2 Diabetes, from the Division of Endocrinology & Metabolism, Department of Internal Medicine, University of Michigan, Ann Arbor, Michigan. This is an interesting study of benchmarking prevalence and costs by treatment type. We rely upon this data and we have updated it from 2000 cost numbers to 2008 cost numbers as well as incorporating a total US prevalence. It should be noted that certain procedures have not been costed in the model so that the actual costs are estimated to be 10-15% higher than calculated herein.

3.2.1 Secondary Disorders

Type 2 Diabetes leads to many secondary disorders. The key one we have briefly discussed before but they are as follows:

1. Retinopathy status
   a. Nonproliferative retinopathy
   b. Proliferative retinopathy
c. Macular edema

2. Nephropathy status
   a. Microalbuminuria
   b. Proteinuria
   c. ESRD with dialysis

3. Neuropathy status
   a. Neuropathy
   b. Amputation

4. Cerebrovascular disease

5. Cardiovascular status
   a. Angina
   b. MI

6. Peripheral vascular disease

7. High blood pressure BP 140/90 mmHg

In a study by Brandle the team determined the prevalence of each of these and then went and determined the costs of treatment. We shall rely on and modify the Brandle work herein as a basis for estimating the current and projected costs. The following Table presents the statistics of the study group and the prevalence of the above common secondary effects.
<table>
<thead>
<tr>
<th>Factor</th>
<th>Range</th>
<th>Mean</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample Size N</td>
<td>1,364</td>
<td>1,364</td>
<td>100.0%</td>
</tr>
<tr>
<td>Age (years)</td>
<td>66 (54–72)</td>
<td>66</td>
<td>4.8%</td>
</tr>
<tr>
<td>Diabetes duration (years)</td>
<td>8 (4–16)</td>
<td>8</td>
<td>0.6%</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>681 (50)</td>
<td>681</td>
<td>49.9%</td>
</tr>
<tr>
<td>Race</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>1,005 (74)</td>
<td>1005</td>
<td>73.7%</td>
</tr>
<tr>
<td>African American</td>
<td>176 (13)</td>
<td>176</td>
<td>12.9%</td>
</tr>
<tr>
<td>BMI (kg/m2)</td>
<td>30.7 (27.1–36.1)</td>
<td>31</td>
<td>2.3%</td>
</tr>
<tr>
<td>HbA1c (%)</td>
<td>7.1 (6.3–8.2)</td>
<td>7.00</td>
<td>0.5%</td>
</tr>
<tr>
<td>Education</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not a high school graduate</td>
<td>244 (18)</td>
<td>244</td>
<td>17.9%</td>
</tr>
<tr>
<td>High school graduate</td>
<td>397 (29)</td>
<td>397</td>
<td>29.1%</td>
</tr>
<tr>
<td>Some college</td>
<td>383 (28)</td>
<td>383</td>
<td>28.1%</td>
</tr>
<tr>
<td>College graduate</td>
<td>133 (10)</td>
<td>133</td>
<td>9.8%</td>
</tr>
<tr>
<td>Any postgraduate work</td>
<td>153 (11)</td>
<td>153</td>
<td>11.2%</td>
</tr>
<tr>
<td>Missing*</td>
<td>54 (4)</td>
<td>54</td>
<td>4.0%</td>
</tr>
<tr>
<td>Household income</td>
<td></td>
<td></td>
<td>0.0%</td>
</tr>
<tr>
<td>$40,000</td>
<td>903 (66)</td>
<td>903</td>
<td>66.2%</td>
</tr>
<tr>
<td>$40,000–69,999</td>
<td>289 (21)</td>
<td>289</td>
<td>21.2%</td>
</tr>
<tr>
<td>$70,000</td>
<td>172 (13)</td>
<td>172</td>
<td>12.6%</td>
</tr>
<tr>
<td>Diabetes treatment</td>
<td></td>
<td></td>
<td>0.0%</td>
</tr>
<tr>
<td>Diet or exercise only</td>
<td>69 (5)</td>
<td>69</td>
<td>5.1%</td>
</tr>
<tr>
<td>Oral antidiabetic medication</td>
<td>870 (64)</td>
<td>870</td>
<td>63.8%</td>
</tr>
<tr>
<td>Insulin</td>
<td>425 (31)</td>
<td>425</td>
<td>31.2%</td>
</tr>
<tr>
<td>Retinopathy status</td>
<td></td>
<td></td>
<td>0.0%</td>
</tr>
<tr>
<td>Nonproliferative retinopathy</td>
<td>170 (12)</td>
<td>170</td>
<td>12.5%</td>
</tr>
<tr>
<td>Proliferative retinopathy</td>
<td>41 (3)</td>
<td>41</td>
<td>3.0%</td>
</tr>
<tr>
<td>Macular edema</td>
<td>29 (2)</td>
<td>29</td>
<td>2.1%</td>
</tr>
<tr>
<td>Missing</td>
<td>248 (18)</td>
<td>248</td>
<td>18.2%</td>
</tr>
<tr>
<td>Nephropathy status</td>
<td></td>
<td></td>
<td>0.0%</td>
</tr>
<tr>
<td>Microalbuminuria</td>
<td>99 (2)</td>
<td>99</td>
<td>7.3%</td>
</tr>
<tr>
<td>Proteinuria</td>
<td>207 (15)</td>
<td>207</td>
<td>15.2%</td>
</tr>
<tr>
<td>ESRD with dialysis</td>
<td>6 (0.4)</td>
<td>6</td>
<td>0.4%</td>
</tr>
<tr>
<td>Missing</td>
<td>248 (18)</td>
<td>248</td>
<td>18.2%</td>
</tr>
<tr>
<td>Neuropathy status</td>
<td></td>
<td></td>
<td>0.0%</td>
</tr>
<tr>
<td>Neuropathy</td>
<td>544 (40)</td>
<td>544</td>
<td>39.9%</td>
</tr>
<tr>
<td>History of amputation</td>
<td>25 (2)</td>
<td>25</td>
<td>1.8%</td>
</tr>
<tr>
<td>Cerebrovascular disease</td>
<td></td>
<td></td>
<td>0.0%</td>
</tr>
<tr>
<td>Cerebrovascular disease</td>
<td>199 (15)</td>
<td>199</td>
<td>14.6%</td>
</tr>
<tr>
<td>Missing</td>
<td>217 (16)</td>
<td>217</td>
<td>15.9%</td>
</tr>
<tr>
<td>Cardiovascular status</td>
<td></td>
<td></td>
<td>0.0%</td>
</tr>
<tr>
<td>Angina</td>
<td>58 (4)</td>
<td>58</td>
<td>4.3%</td>
</tr>
<tr>
<td>History of MI</td>
<td>363 (27)</td>
<td>363</td>
<td>26.6%</td>
</tr>
<tr>
<td>Missing</td>
<td>205 (15)</td>
<td>205</td>
<td>15.0%</td>
</tr>
<tr>
<td>Peripheral vascular disease</td>
<td></td>
<td></td>
<td>0.0%</td>
</tr>
<tr>
<td>Peripheral vascular disease</td>
<td>538 (39)</td>
<td>538</td>
<td>39.4%</td>
</tr>
<tr>
<td>Missing</td>
<td>248 (18)</td>
<td>248</td>
<td>18.2%</td>
</tr>
<tr>
<td>High blood pressure status</td>
<td></td>
<td></td>
<td>0.0%</td>
</tr>
<tr>
<td>BP 140/90 mmHg without treatment</td>
<td>481 (35)</td>
<td>481</td>
<td>35.3%</td>
</tr>
<tr>
<td>Factor</td>
<td>Range</td>
<td>Mean</td>
<td>Percent</td>
</tr>
<tr>
<td>------------------------------</td>
<td>------------</td>
<td>------</td>
<td>---------</td>
</tr>
<tr>
<td>Treated with medication</td>
<td>416 (31)</td>
<td>416</td>
<td>30.5%</td>
</tr>
<tr>
<td>Missing</td>
<td>253 (19)</td>
<td>253</td>
<td>18.5%</td>
</tr>
<tr>
<td>Cholesterol status</td>
<td></td>
<td></td>
<td>0.0%</td>
</tr>
<tr>
<td>LDL 100 mg/dl without treatment</td>
<td>386 (28)</td>
<td>386</td>
<td>28.3%</td>
</tr>
<tr>
<td>Treated with medication</td>
<td>404 (30)</td>
<td>404</td>
<td>29.6%</td>
</tr>
<tr>
<td>Missing</td>
<td>248 (18)</td>
<td>248</td>
<td>18.2%</td>
</tr>
<tr>
<td>Cigarette smoking</td>
<td></td>
<td></td>
<td>0.0%</td>
</tr>
<tr>
<td>Current smoker</td>
<td>233 (17)</td>
<td>233</td>
<td>17.1%</td>
</tr>
<tr>
<td>Missing</td>
<td>17 (1)</td>
<td>17</td>
<td>1.2%</td>
</tr>
<tr>
<td>Total cost</td>
<td>3,715 (1,894–7,719)</td>
<td>$3,715</td>
<td>656847.1%</td>
</tr>
</tbody>
</table>

This above Table will be used again in the costing process.

3.2.2 Procedure and Costs

Using the Brandle data we again take the secondary factors and the incorporate the Brandle data using the 2000 year costs and the prevalence and then update to 2008 populations and escalated health care costs.

The following Table details the analysis of providing the 2008 costs. These costs can then be projected forward in time using the same process of scaling.
The Telmarc Group

HEALTH CARE POLICY: POLITICS VS REALITY

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>0.095 0.025</td>
<td>1.25</td>
<td>$3,722</td>
</tr>
<tr>
<td>Age</td>
<td>‡</td>
<td></td>
<td>$0</td>
</tr>
<tr>
<td>Race</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>African American</td>
<td>0.088 0.036</td>
<td>0.82</td>
<td>$2,442</td>
</tr>
<tr>
<td>Duration</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Every 1 year after onset</td>
<td>‡</td>
<td></td>
<td>$0</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Every unit 30 kg/m²</td>
<td>0.004 0.002</td>
<td>1.01</td>
<td>$3,007</td>
</tr>
<tr>
<td>Diabetes intervention</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oral antidiabetic medication</td>
<td>0.040 0.056</td>
<td>1.10</td>
<td>$3,275</td>
</tr>
<tr>
<td>Insulin</td>
<td>0.200 0.058</td>
<td>1.59</td>
<td>$4,734</td>
</tr>
<tr>
<td>High blood pressure</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Treated blood pressure</td>
<td>0.092 0.028</td>
<td>1.24</td>
<td>$3,692</td>
</tr>
<tr>
<td>Retinopathy</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nonproliferative retinopathy</td>
<td>‡</td>
<td></td>
<td>$0</td>
</tr>
<tr>
<td>Proliferative retinopathy</td>
<td>‡</td>
<td></td>
<td>$0</td>
</tr>
<tr>
<td>Macular edema</td>
<td>‡</td>
<td></td>
<td>$0</td>
</tr>
<tr>
<td>Nephropathy</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Microalbuminuria</td>
<td>0.067 0.048</td>
<td>1.17</td>
<td>$3,484</td>
</tr>
<tr>
<td>Proteinuria</td>
<td>0.113 0.036</td>
<td>1.30</td>
<td>$3,871</td>
</tr>
<tr>
<td>ESRD with dialysis</td>
<td>1.023 0.183</td>
<td>10.53</td>
<td>$31,353</td>
</tr>
<tr>
<td>Neuropathy</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clinical neuropathy</td>
<td>‡</td>
<td></td>
<td>$0</td>
</tr>
<tr>
<td>History of amputation</td>
<td>‡</td>
<td></td>
<td>$0</td>
</tr>
<tr>
<td>Cerebrovascular disease</td>
<td>0.113 0.035</td>
<td>1.30</td>
<td>$3,871</td>
</tr>
<tr>
<td>Cardiovascular disease</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Angina</td>
<td>0.239 0.061</td>
<td>1.73</td>
<td>$5,151</td>
</tr>
<tr>
<td>History of MI</td>
<td>0.278 0.029</td>
<td>1.90</td>
<td>$5,657</td>
</tr>
<tr>
<td>Peripheral vascular disease</td>
<td>0.116 0.028</td>
<td>1.31</td>
<td>$3,900</td>
</tr>
</tbody>
</table>

Finally there are three major events that Brandle notes and they are shown below, each requiring hospitalization. We have also updated their costs and their prevalence.

<table>
<thead>
<tr>
<th>Subjects who survived first year (n)</th>
<th>Total costs for 1 year after onset of acute event for subject who survived first year (2000 Dollars)</th>
<th>Costs in 2008 Dollars</th>
<th>Incidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute event</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stroke</td>
<td>88</td>
<td>$26,600 (15,400–44,900)</td>
<td>$47,031</td>
</tr>
<tr>
<td>Acute MI</td>
<td>84</td>
<td>$24,500 (15,000–50,000)</td>
<td>$43,318</td>
</tr>
<tr>
<td>Amputation</td>
<td>47</td>
<td>$37,600 (23,300–62,200)</td>
<td>$66,480</td>
</tr>
</tbody>
</table>
3.2.3 Total Annual Costs

Now taking the above data we can then combine the result to estimate total costs of Type 2 Diabetes in 2008. This is accomplished in the following Table. Here we have provided the data for only the secondary factors.

<table>
<thead>
<tr>
<th>Disease status</th>
<th>Prevalence %</th>
<th>Total Prevalence</th>
<th>Unit Cost</th>
<th>Total Cost ($000,000)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diabetes intervention</td>
<td></td>
<td></td>
<td>$0</td>
<td></td>
</tr>
<tr>
<td>Oral antidiabetic medication</td>
<td>3.32%</td>
<td>584,622</td>
<td>$3,275</td>
<td>$1,915</td>
</tr>
<tr>
<td>Insulin</td>
<td>1.45%</td>
<td>254,687</td>
<td>$4,734</td>
<td>$1,206</td>
</tr>
<tr>
<td>High blood pressure</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Treated blood pressure</td>
<td>35.26%</td>
<td>6,206,452</td>
<td>$3,692</td>
<td>$22,915</td>
</tr>
<tr>
<td>Retinopathy</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nonproliferative retinopathy</td>
<td>12.46%</td>
<td>2,193,548</td>
<td>$0</td>
<td>$0</td>
</tr>
<tr>
<td>Proliferative retinopathy</td>
<td>3.01%</td>
<td>529,032</td>
<td>$0</td>
<td>$0</td>
</tr>
<tr>
<td>Macular edema</td>
<td>2.13%</td>
<td>374,194</td>
<td>$0</td>
<td>$0</td>
</tr>
<tr>
<td>Nephropathy</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Microalbuminuria</td>
<td>7.26%</td>
<td>1,277,419</td>
<td>$3,484</td>
<td>$4,450</td>
</tr>
<tr>
<td>Proteinuria</td>
<td>15.18%</td>
<td>2,670,968</td>
<td>$3,871</td>
<td>$10,339</td>
</tr>
<tr>
<td>ESRD with dialysis</td>
<td>0.44%</td>
<td>77,419</td>
<td>$31,353</td>
<td>$2,427</td>
</tr>
<tr>
<td>Neuropathy</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clinical neuropathy</td>
<td>39.88%</td>
<td>7,019,355</td>
<td>$0</td>
<td>$0</td>
</tr>
<tr>
<td>History of amputation</td>
<td>1.83%</td>
<td>322,581</td>
<td>$0</td>
<td>$0</td>
</tr>
<tr>
<td>Cerebrovascular disease</td>
<td>14.59%</td>
<td>2,567,742</td>
<td>$3,871</td>
<td>$9,938</td>
</tr>
<tr>
<td>Cardiovascular disease</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Angina</td>
<td>4.25%</td>
<td>748,387</td>
<td>$5,151</td>
<td>$3,855</td>
</tr>
<tr>
<td>History of MI</td>
<td>26.61%</td>
<td>4,683,871</td>
<td>$5,657</td>
<td>$26,498</td>
</tr>
<tr>
<td>Peripheral vascular disease</td>
<td>39.44%</td>
<td>6,941,935</td>
<td>$3,900</td>
<td>$27,077</td>
</tr>
<tr>
<td>Acute Illnesses</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stroke</td>
<td>6.45%</td>
<td>1,135,484</td>
<td>$47,031</td>
<td>$53,403</td>
</tr>
<tr>
<td>Acute MI</td>
<td>6.16%</td>
<td>1,083,871</td>
<td>$43,318</td>
<td>$46,951</td>
</tr>
<tr>
<td>Amputation</td>
<td>3.45%</td>
<td>606,452</td>
<td>$66,480</td>
<td>$40,317</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>39,278,018</td>
<td></td>
<td>$251,291</td>
</tr>
</tbody>
</table>

The result is that we estimate that Type 2 Diabetes costs $251 billion in 2008. This does not include the retinopathy costs which were lacking. We estimate that they add an additional 10%, raising the total to $275 billion, exceeding 12% of all 2008 health care expenditures.

3.3 Economics of Control

Having developed a model for costs we now consider the economics of management and control of Type 2 Diabetes. Since we have argued that by managing weight we can control if not cure Type 2 Diabetes we can argue that this is no longer a Medical problem but an economics and social problem. We have managed to deal with cigarette
smoking and have reduced male mortality by 50% over the past 25 years and thus we argue that the same can be done for Type 2 Diabetes in even less a time period. Clearly obesity is the problem, the cause of obesity is clear. Each pound of body weight result from the consumption of 3,500 calories (Kcal) more than the sustaining level. For most people the sustaining level is 2,000 calories per day. Thus two cans of Coke, at 180 cal each, 360 cal for the two, will add a pound every 10 days, and will add 36 pounds in a year! There is no way of getting around this. The basic law of physics is:

Input-Output = Net Accumulation

3.3.1 The Economic Implications

From the NIH data source we have the Estimated Diabetes Costs in the United States in 2007:

1. Total—direct and indirect: $174 billion. Note that we have calculated a greater number for 2008 using the model developed herein.

2. Direct medical costs: $116 billion: After adjusting for population age and sex differences, average medical expenditures among people with diagnosed diabetes were 2.3 times higher than what expenditures would be in the absence of diabetes.

3. Indirect costs: $58 billion—disability, work loss, premature mortality

We can now examine in simple economic terms what the impact of the proposal will be. We proceed through five steps; demand, supply (three steps) and market stability.

Consider first the demand. Here we plot demand on a price, p, and quantity, q, and diagram common to all economics. Currently demand is independent of price. The current demand is a vertical line that is fixed and independent to any costs. This is more than simplistic since we generally accept anyone into the ER and in states like California illegal immigrants are provided care independent of any status. Now if we apply to the system some "tax" for bad foods or behavior and also provide costs incentives for excessive use then we get a more normal demand curve, namely price or cost sensitivity.
Now the first step in the supply curve will be to drive out costs which are overhead costs. Thus is we reduce the cost of billing and that of report management on a per patient basis this would represent a shift in the supply curve downward as shown in the following. This is the first step in cost reduction.
The alternative would be to create scale economies in the delivery, namely making it less costly the more service that are delivered. We argue herein that using a Public Health delivery system would do so by alleviating other more costly means such as the ER. There are many more examples of such an approach. The following Figure depicts what would happen in this event. Namely we see a decline of the supply curve the larger the demand becomes, clear scale effects.

We can then combine the two effects of reducing overhead and achieving scale to create a compound new supply curve as shown in the following Figure.
Finally we can combine the Demand and the Supply curves to show what the total effect would be. This is done in the following Figure.
We note that we reduce the costs significantly while have a small but measurable decrease in the supply by means or reallocation while keeping the overall quality high. This above graphic is in essence what we propose in the plan.

3.3.2 Methods of Remediation

Remediation of Type 2 Diabetes is readily accomplished by pricing the offending entity, in this case carbohydrates, at a point where the cost become prohibitive. This is the tax at the source approach. A second approach is tax at the result approach where we tax a person based upon BMI. Thus at BMI less than 25 we have no tax and from there upwards we tax at an aggressively increasing rate. This of course would be quite difficult to achieve. However the tax at source approach would be readily achieved.

3.4 Conclusions

This Chapter demonstrates several key conclusions:

1. Type 2 Diabetes is a disease caused by the person having it. It is a self induced disease for almost all. A very few have a massive as yet identified genetic flaw, but that is de minimis. It is obesity as the main and almost sole cause.

2. The prevalence of Type 2 Diabetes is growing exponentially and the term of epidemic is not unjustly employed. It is an epidemic resulting from childhood lack of food control, lack of exercise, and lack of recognition that the problem is moving downward in age and becoming explosive as that population itself ages.

3. The current means of managing Type 2 Diabetes with drugs such as metformin, insulin, sulfonylureas, and others mask the true problems and in many ways exacerbate the secondary disease states.

4. Type 2 Diabetes is now at 12% of the total health care costs and with its current growth rate combined with costs and population may reach 25% of the total health care budget. This disease has the sole potential for collapsing the health care system.

5. Type 2 Diabetes is a disease which can be controlled and possibly eliminated by purely open market means. By pricing carbohydrates at a point that exceed the propensity to buy, then there will be a reduction in carbohydrate driven obesity. This is akin to taxing the use of tobacco in cigarettes.

6. The use of combine drugs such as statins and the existing insulin modulating drugs oftentimes create additional tertiary health problems that add to the overall burden while also costing a great deal in the use of the drugs themselves.
4 CONTrollable DISEASES; Cancers

In our prior Chapters we have looked at the Health Care System as a totality and then we looked at preventable diseases in some detail, namely Type 2 Diabetes. In this paper we look at remediable disease, specifically a set of cancers.

There are certain pre-conceived assumptions that we have seen over and over again permeating the plans and proposals. These are mind sets, world views that seem to restrict what can be achieved as well as what can be done. We use this analysis as a means to highlight them and then to address how they can be reset to reveal alternative and improved paths of progress.

Many of the assumptions made by the analysts and policy makers in Health Care are akin to what would be done a century ago where we would be concerned about TB and infectious diseases. At that time they were growing in incidence and were causing major problems in the area of public health. If one made health care decisions based on extrapolating that world sans antibiotics and expanding public health then the results would also have shown catastrophic results. We argue herein that there is a major change occurring in the field of controllable diseases like major cancers.

This means that it may be possible to intervene early, as we are seeing with prostate, breast, melanoma, and other cancers and take remedial action. The next step is to do so earlier using genetic markers. Thus it is anticipated that in the next ten years we may readily find the genetic markers for major cancers, not cures, but predispositions and also markers relating to specific treatments. We argue that if we look forward into a world with these changes then we can readily look at developing heath care policy with a forward look hopefully more consistent with the reality we are to face.

4.1.1 Assumptions

The major fact about so many policy types is that they predicate their forward looking plans and dicta on past processes, procedures and knowledge. This can be a fatal and costly error. Medicine is at the precipice of a massive change in the delivery of healthcare as a result of the introduction of genetic methods for assessing the potential, diagnosing the presence, staging the disease, and eventually curing the disease. This means that the past is not a prolog to the future by mere extrapolation. The policy makers work under assumptions based upon past paradigms.

Let us set out some of these assumptions.

1. Healthcare Demand is independent of cost. This means that people are impervious to the costs that result in bad health. We know that this is not the case all one must do
is look at the statistics of smoking. In the states with the largest taxes the numbers of smokers has declined the greatest. The same we have argued can be accomplished with the obesity issue. We also argue that the same may be achievable with the issues relating to controllable diseases. Demand we believe can be modulated with economic incentives and penalties.

2. The Diseases today are the diseases of tomorrow. Thirty five years ago no one heard of HIV. Then it became a pandemic and now it is a controllable disease. Cervical cancer caused by papilloma virus can now be prevented. Many of the kinase activated hematological cancers can be controlled by kinase inhibitors. This disease may go from terminal to chronic. Undoubtedly the mortality and morbidity tables will change as we deal with one disorder after another.

3. The treatments today are linearly projectable into the future. This means that we will continue to use surgical and pharmaceutical means to deal with disease states and that for certain acute and significant disease states we shall continue to rely upon massive hospitalizations as we have seen grow during the latter half of the 20th century. The reality may very well be different. The treatment of disease, especially cancers, may be addressed by genetic medications, by effecting blockage of the growth of tumors and by the actual elimination of them.

4. The diagnostic tools we use today are linearly projectable into the future. What do we mean here? This means that we continue to use say X-rays MRI and CAT in mammography for the detection of breast cancer. That BRCA genes are limited to a few people and that there will be no major breakthrough in this area in early detection. It means in prostate cancer that PSA and ultrasound approaches will continue with high false alarm rates and excess procedure and that also genetic markers will be used in a limited manner. There development of genetic markers is slowly evolving into a diagnostic tool which can replace many of those we use from normal metabolic testing. However it will take time to identify and standardize them.

5. Staging of Cancers will continue to progress Using Criteria of metastasis and lymph node involvement: Again, staging of cancers is performed to assess treatment and to determine possible issue of survival. The staging criteria are based upon large sets of past data. However as is becoming quite clear the individual genetic makeup of the cancer cell, a clone in almost all cases, dictates the progression of the disease much better than gross statistics. In fact the ability to assess the genetic profile of the malignancy should in time be the sine qua non as regards to assessing both treatment and survivability.

6. Treatments will be based upon generally accepted staging criteria. This is a major concern for many cancers have almost individual characteristics albeit the same staging criteria may be met. Take prostate cancer for example. In a 70 year old male, with a PSA of 6.0, a rate of increase of say 35% per annum in PSA and no palpable node, upon an
ultrasound it is found that there are potential cancerous lesions. The Gleason grade is 6 in all sections. Thus what should be the treatment? A recent New England Journal of Medicine question gave an answer to a similar question almost equally divided between watchful waiting, surgery and implants. Specifically, "Among the 3720 votes cast, 29% were for expectant management, 33% for radiotherapy, and 39% for radical prostatectomy." It is amazing to consider that given several gross tests that the answers are so widely spread. It is not unlikely however that physicians and patients, having a choice, will select one which meets their own preconceived world views. The facts are twofold here. First the presence of certain genes, SNPs, gives a predisposition to prostate cancer and having a family member of first degree increases the risk tenfold. That is the predisposition element. It is not predictive. Then after a cancer is diagnosed the genes which the cancer cell itself expresses is a determinant for how aggressive it will be. Clearly not enough is known now as to what the best markers are and further even less is known why those markers are significant in the aggressiveness of the lesion. However, going from the above NEJM example to having markers, one could then make a much more rational decision about watchful waiting versus prostatectomy.

These assumptions must be extensively re-examined, they will not hold and the projections made from them and the policies developed based upon them are subject to failure. That failure will be quite costly.

4.1.2 Basic Incidence

The past is not prolog to the future in health care. It may provide an understanding of where we may not have acted most effectively bit it is not a deterministic path that we must try to optimize our expenditures. It is a dynamic stochastic process with some form of reasonable albeit random perturbations imposed upon it.

We briefly review the CDC data on cancer incidence\textsuperscript{15}. The following Figure depicts a broad base of cancers and their incidence. It is quite clear that lung, breast, prostate and colon dominate. Lung is almost totally controllable via cessation of cigarette smoking. The evidence of that is now overpowering. The other three are controllable by tools existing today. PSA and DRE are now accepted tools for prostate cancer, colonoscopy for colon cancer and mammography for breast cancer. They do not prevent the cancers but they allow for early detection and remediation or control of the cancer is a much less costly manner. The incidence of this cancer will not change.

\textsuperscript{15} See http://apps.nccd.cdc.gov/uscs/Table.aspx?Group=TableAll&Year=2005&Display=n
The following two Figures focus on eight cancers, the top four cancers and four other cancers. The other four are ovary, testis, melanoma, and cervix. In a sense all of these are also controllable, albeit at a cost ranging from low to high. Melanoma is an example of a controllable cancer. There is a genetic and environmental pre-disposition and if screened semi-annually, removal of superficial spreading malignant melanoma can result in reduced costs and dramatically reduced mortality and morbidity.
In the above it should be noted that lung cancers are for both male and female whereas prostate is male and breast is female. The incidence is per 100,000 of the group. Thus prostate and breast is for male and female only and it is not an incidence for all. Thus the total incidence of prostate is about 70 per 100,000 total population and the same for breast as 68 per 100,000 of the total. There is a small incidence of male breast cancer.
The following are the mortality rates for the cancers discussed above. Note that the same top three of lung, breast and prostate dominate.
4.1.3 Mechanisms of Controllability

The next issue is how these diseases can be controllable. The following table depicts the selected cancers and the detection methods which are of current use. They are all controllable but at a cost. For example colon cancer requires a colonoscopy, after baseline, of once every five years at a cost in 2008 dollars of $1500. This is $300 per annum and at this rate an extremely high percentages of colon adenomas can be detected before becoming metastatic and spreading and being removable at the time of colonoscopy. The costs are really in having adequate trained endoscopist.

The other extreme is ovarian cancer. This is a quite uncommon cancer with the incidence peaking at 70 years of age. It can be detected with transvaginal ultrasounds and CA125 testing every three months at the cost of $400 per visit or $1600 per year. The incidence is significantly lower than colon cancer and the resulting cost per detected even is more than two orders of magnitude higher. In addition the effectiveness of the screening still has some lack of specificity.
The above Table represents what is available in the current practice of medicine. The procedures provide varying degrees of sensitivity and specificity. Studies on ovarian cancers have shown variations in specificity which may result in unnecessary removal of ovaries. Colon cancer has shown that there is some lowered sensitivity on the ascending colon from a Canadian study but we have argued elsewhere that the Canadian study has flaws. The Pap smear has been a stand by and gold standard for years.

**4.1.4 Proposed Time/Event Path**

As we have discussed earlier, we see that there is a set of in going assumptions that policy makers and the like make regarding health care. In this section we attempt to break those assumptions. If one is to look at health care from 2010 through 2050 there will most likely be fundamental changes in not only the delivery of what is done now, but fundamental change in what health care is, driven by the changes in genetic diagnosis and treatment. Cancer, especially the one we consider here as well as the hematological ones will have been greatly impacted upon by these changes.

Consider the twenty year time line we have drawn below. There are four steps we anticipate and consequences from both.
The following are the steps:

1. **Gene Markers for Presence**: There has been a tremendous amount of work performed in all of the eight target cancers for gene markers for a predisposition for the cancers. Clearly having a gene is not totally predictive but it permits a measure for increasing vigilance and testing. Thus have a set of gene markers for cancers which can be remediated are quite useful. It does not stop the gold standard test of pathological resection. There as of yet does not appear to be a large set gene markers for presence. We know that the BRCA gene establish a high probability for breast and other cancers. However they in and of themselves do not establish presence. However we know that when a clonal cancer starts there will be the results of both primary and secondary pathways on the clonal cells themselves as well as other cells reacting to the clonal aberration which can be measured and used to detect presence.

2. **Gene Markers for Staging**: Gene markers for staging are the next step. This means that we can now, having detected the presence of the cancer, determine its aggressivity and then to take the appropriate actions. Prostate cancer is typical in this class. Some colon cancers also fall here as do some limited superficial spreading malignant melanomas. In fact it is know that certain melanomas regress, albeit may latter appear as a secondary met.

3. **Genetic Therapy**: There is a beginning effort in gene therapy now. It is slow and is progressing along the usual lines. However in the next twenty years this is expected to grow at a startling rate. This will be a case of many small victories until the tools are
developed and then a massive growth phase. This will dramatically reduce the morbidity and mortality. The issue is will it reduce the costs. Again with Federal funding and rights accruing to the sponsors such costs may be minimized.

4. Genetic Immunization: This is the final step in the time horizon we are looking at. Clearly there will be a way to establish what we see as an immunization. This is not akin to the cervical cancer immunization against the papilloma virus but an actual genetic insertion or modification to either repair or block the effects of the precipitating genes.

These four are also benchmark elements for policy formulation and Government funding. The basic research is completed to permit much of this to commence, albeit there are still some loopholes to be filled in, but a focused research program will be essential to remediate the cancers we have discussed herein. If this is done, then a forward looking plan, one looking at remediation of controllable diseases via genetic means will evolve and become an integral part of any long range health care plan. It is not just a question of who pays what for what is currently performed. This is an event changing program.

4.2 Genetic Implications

Cancer is a disease of lack of genetic control. The human body has cells which are reproducing continuously. Red blood cells replenish themselves every 90 days or sooner. The skin, and other epithelial tissues are being lost and being replenished. The cycle of creation and cell death, apoptosis, is ongoing and as part of that is the conversion od DNA from one cell to the new cells. Some times that does not work for a variety of reasons. This results in but a single cell going awry. Most of the time it is managed by the immune system which recognizes self from non self. Every once in the while it does not work and a clonal cancer cell explodes into full blown cancer.

4.2.1 Current Understanding

Thus to understand Cancer we must understand the genetics of this disease. Foulkes has recently reviewed the genetic factors in cancers. His summary of the major forms are detailed as follows:

Lung cancer: "Lung cancer is mainly attributable to tobacco use, and few large families with multiple cases of lung cancer are suitable for linkage analysis. Even if such families were available, it is not obvious that a single gene with a large effect would account for the cases observed. Nevertheless, one locus on chromosome 6q has been suggested by a traditional linkage study, though no gene has yet been identified. Some tumor-suppressor genes are associated with substantial increases in the risk of lung cancer, and in persons carrying mutations in these genes; tobacco smoking may be particularly dangerous. For example, in families with the Li–Fraumeni syndrome, smokers who carry
a TP53 mutation are at much higher risk for lung cancer than nonsmokers who carry the same mutation, 29 and carriers of RB1 mutations, which are associated with retinoblastoma, also have a high lifetime risk of lung cancer ..."

Breast Cancer: "Only a small proportion (≤10%) of breast cancers are due to hereditary mutations in single, dominantly acting genes, although models suggest that a larger fraction of so-called sporadic cases of breast cancer might be attributable to the action of multiple genes.48 The two most important breast-cancer genes, BRCA1 and BRCA2, confer a risk of breast cancer among carriers that is 10 to 30 times as high as the risk among women in the general population. 49 Other genes with a population frequency and risk profile similar to BRCA1 or BRCA2 are unlikely to exist. Less frequent mutations associated with a relative risk of breast cancer of 2.0 or greater have been identified ...

Colorectal: "There are three classes of colorectal-cancer susceptibility genes.... Several of the most important genes — APC, MUTYH (familial forms of polyposis), and the Lynch syndrome genes (MLH1, MSH2, MSH6, and PMS2) — account for less than 5% of all cases of colorectal cancer, but they affect young people disproportionately (see the table in the Supplementary Appendix). Testing for mutations in these genes is recommended in patients with clinicopathological features that are suggestive of these syndromes.... The underlying defect in the Lynch syndrome is defective mismatch repair. Mismatches between DNA strands that occur naturally, but erroneously, during DNA replication are not repaired because the key genes have become inactivated, usually by two “hits” — one inherited, the other acquired later in life.... This lack of repair results in numerous DNA sequence errors, particularly in runs of tandemly repeated nucleotides such as (T)n or (CA)n, where n is usually 5 or more. Errors occurring in critical genes such as BAX or TGFBRII can initiate tumors. Since this mutator phenotype accelerates the rate of carcinogenesis and results in the rapid development of colorectal cancer once polyps have formed, frequent colonoscopic screening in carriers is warranted."

Prostate: "Unraveling the genetics of prostate cancer has been difficult, and no high-risk, prostate-specific genes seem to exist. The closest candidate is BRCA2, which confers a risk of prostate cancer that is as much as 20 times the risk in the general population.84 BRCA2-associated prostate cancers are aggressive, suggesting the need for better screening in carriers. BRCA2 mutations are rare; however, in men with prostate cancer, and despite considerable collaborative efforts, no prostate-cancer genes have yet been conclusively identified by linkage analysis. Genomewide association studies have identified several new candidate genes and loci. None of these genes are associated with large risks, although some are of considerable interest. The variant near the gene MSMB is the most promising because it encodes an immunoglobulin-binding factor that is present in seminal fluid.19 There are several different risk loci on chromosome 8q24, and some of them are very frequent, especially in blacks, a population with a high prevalence of prostate cancer..."
4.2.2  Genetic Flaws

There are many types of genetic flaws. Faulkes also presents an interesting picture of these as shown below.

Faulkes also summarizes the major genetic defects in the following Table.
<table>
<thead>
<tr>
<th>Gene</th>
<th>Phenotypic Effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>MLH1</td>
<td>Monoallelic Mutations Biallelic Mutations Lynch syndrome; cancers of colorectum, endo-CMMR-D syndrome (mainly in children and adolescents); metrium, small bowel, ureter, renal pelvis parents may have Lynch syndrome Lynch syndrome; extracolonic cancers are CMMR-D syndrome (mainly in children and adolescents); frequent parents may have Lynch syndrome Lynch syndrome; endometrial cancer is common, CMMR-D syndrome (mainly in children and adolescents); other cancers are less common parents may have Lynch syndrome Lynch syndrome; lower risk of colorectal and ex-CMMR-D syndrome (mainly in children and adolescents); tracolonic cancers cancer in previous generations uncommon Hereditary breast cancer; ovarian, fallopian-tube, Fanconi’s anemia, type D1; early-childhood acute myel-peritoneal, and pancreatic cancer and melanoma oid leukemia; medulloblastoma; Wilms’ tumor Breast cancer, can be familial Fanconi’s anemia, type N; early-childhood acute myeloid leukemia; medulloblastoma; Wilms’ tumor Breast cancer, can be familial Fanconi’s anemia, type J; solid tumors Breast cancer, can be familial; T-cell leukemia Ataxia–telangiectasia, childhood and adolescent lymphomas and T-cell leukemia; a wide variety of carcinomas may develop late</td>
</tr>
<tr>
<td>MSH2</td>
<td></td>
</tr>
<tr>
<td>MSH6</td>
<td></td>
</tr>
<tr>
<td>PMS2</td>
<td></td>
</tr>
<tr>
<td>BRCA2</td>
<td></td>
</tr>
<tr>
<td>PALB2</td>
<td></td>
</tr>
<tr>
<td>BRIP1</td>
<td></td>
</tr>
<tr>
<td>ATM</td>
<td></td>
</tr>
</tbody>
</table>
4.3 Target Disease Sets

The following is a summary of the eight targeted cancers. The information is taken with modification from the National Cancer Institute web site for professionals.

4.3.1 Colon Cancer

Cancer of the colon is a highly treatable and often curable disease when localized to the bowel. Surgery is the primary form of treatment and results in cure in approximately 50% of the patients. Recurrence following surgery is a major problem and is often the ultimate cause of death.

Colonoscopy is the gold standard for determining whether there are polyps or other precancerous growths in the colon. The procedure, if performed by an experienced endoscopist, can achieve high levels of specificity and significance. Also, use of colonoscopy allows for the real-time removal of most if not all lesions for subsequent biopsy.

4.3.1.1 Prognostic Factors

The prognosis of patients with colon cancer is clearly related to the degree of penetration of the tumor through the bowel wall, the presence or absence of nodal involvement, and the presence or absence of distant metastases. These three characteristics form the basis for all staging systems developed for this disease. Bowel obstruction and bowel perforation are indicators of poor prognosis. Elevated pretreatment serum levels of carcinoembryonic antigen (CEA) have a negative prognostic significance. The American Joint Committee on Cancer and a National Cancer Institute-sponsored panel recommended that at least 12 lymph nodes be examined in patients with colon and rectal cancer to confirm the absence of nodal involvement by tumor.

This recommendation takes into consideration that the number of lymph nodes examined is a reflection of the aggressiveness of lymphovascular mesenteric dissection at the time of surgical resection and the pathologic identification of nodes in the specimen. Retrospective studies demonstrated that the number of lymph nodes examined in colon and rectal surgery may be associated with patient outcome.

Many other prognostic markers have been evaluated retrospectively for patients with colon cancer, though most, including allelic loss of chromosome 18q or thymidylate
synthase expression, have not been prospectively validated. Microsatellite instability, also associated with hereditary nonpolyposis colon cancer (HNPCC), has been associated with improved survival independent of tumor stage in a population-based series of 607 patients younger than 50 years with colorectal cancer. Treatment decisions depend on factors such as physician and patient preferences and the stage of the disease rather than the age of the patient. Racial differences in overall survival after adjuvant therapy have been observed, without differences in disease-free survival, suggesting that comorbid conditions play a role in survival outcome in different patient populations.

4.3.1.2 Risk Factors

Because of the frequency of the disease, ability to identify high-risk groups, demonstrated slow growth of primary lesions, better survival of patients with early-stage lesions, and relative simplicity and accuracy of screening tests, screening for colon cancer should be a part of routine care for all adults aged 50 years or older, especially for those with first-degree relatives with colorectal cancer. Groups that have a high incidence of colorectal cancer include those with hereditary conditions, such as familial polyposis, HNPCC or Lynch syndrome variants I and II, and those with a personal history of ulcerative colitis or Crohn colitis. Together, they account for 10% to 15% of colorectal cancers. Patients with HNPCC reportedly have better prognoses in stage-stratified survival analysis than patients with sporadic colorectal cancer, but the retrospective nature of the studies and possibility of selection factors make this observation difficult to interpret.

More common conditions with an increased risk include a personal history of colorectal cancer or adenomas; first-degree family history of colorectal cancer or adenomas; and a personal history of ovarian, endometrial, or breast cancer. These high-risk groups account for only 23% of all colorectal cancers. Limiting screening or early cancer detection to only these high-risk groups would miss the majority of colorectal cancers.

4.3.1.3 Follow-up

Following treatment of colon cancer, periodic evaluations may lead to the earlier identification and management of recurrent disease. The impact of such monitoring on overall mortality of patients with recurrent colon cancer, however, is limited by the relatively small proportion of patients in who localized, potentially curable metastases are found. To date, no large-scale randomized trials have documented the efficacy of a standard, postoperative monitoring program. CEA is a serum glycoprotein frequently used in the management of patients with colon cancer. A review of the use of this tumor marker suggests the following:

A CEA level is not a valuable screening test for colorectal cancer because of the large numbers of false-positive and false-negative reports.
Postoperative CEA testing should be restricted to patients who would be candidates for resection of liver or lung metastases. Routine use of CEA levels alone for monitoring response to treatment should not be recommended.

The optimal regimen and frequency of follow-up examinations are not well defined because the impact on patient survival is not clear, and the quality of data is poor. New surveillance methods, including CEA immunoscintigraphy and positron emission tomography, are under clinical evaluation.

4.3.1.4 Statistics

Estimated new cases and deaths from colon cancer in the United States in 2008: 1
New cases: 108,070.
Deaths (colon and rectal cancers combined): 49,960.

4.3.2 Prostate Cancer

Carcinoma of the prostate is predominantly a tumor of older men, which frequently responds to treatment when widespread and may be cured when localized. The rate of tumor growth varies from very slow to moderately rapid, and some patients may have prolonged survival even after the cancer has metastasized to distant sites such as bone. Because the median age at diagnosis is 72 years, many patients—especially those with localized tumors—may die of other illnesses without ever having suffered significant disability from the cancer. The approach to treatment is influenced by age and coexisting medical problems. Side effects of various forms of treatment should be considered in selecting appropriate management. Controversy exists in regard to the value of screening, the most appropriate staging evaluation, and the optimal treatment of each stage of the disease.

A complicating feature of any analysis of survival after treatment of prostate cancer and comparison of the various treatment strategies is the evidence of increasing diagnosis of
nonlethal tumors as diagnostic methods have changed over time. Nonrandomized comparisons of treatments may therefore be confounded not only by patient-selection factors but also by time trends. For example, a population-based study in Sweden showed that from 1960 to the late 1980s, before the use of prostate-specific antigen (PSA) for screening purposes, long-term relative survival rates after the diagnosis of prostate cancer improved substantially as more sensitive methods of diagnosis were introduced. This occurred despite the use of watchful waiting or palliative hormonal treatment as the most common treatment strategies for localized prostate cancer during the entire era (<150 radical prostatectomies per year were performed in Sweden during the late 1980s). The investigators estimated that if all cancers diagnosed between 1960 and 1964 were of the lethal variety, then at least 33% of cancers diagnosed between 1980 and 1984 were of the nonlethal variety. With the advent of PSA screening, the ability to diagnose nonlethal prostate cancers may increase further.

Another issue complicating comparisons of outcomes among nonconcurrent series of patients is the possibility of changes in criteria for histologic diagnosis of prostate cancer. This phenomenon creates a statistical artifact that can produce a false sense of therapeutic accomplishment and may also lead to more aggressive therapy. For example, prostate biopsies from a population-based cohort of 1,858 men diagnosed with prostate cancer from 1990 through 1992 were re-read in 2002 to 2004. The contemporary Gleason score readings were an average of 0.85 points higher (95% confidence interval, 0.79–0.91; \( P < .001 \)) than the same slides read in 1990 to 1992. As a result, Gleason score-standardized prostate cancer mortality for these men was artifactually improved from 2.08 to 1.50 deaths per 100 person years—a 28% decrease even though overall outcomes were unchanged.

### 4.3.2.1 Screening

The issue of screening asymptomatic men for prostate cancer with digital rectal examination (DRE), PSA, and/or ultrasound is controversial. Serum PSA and transrectal ultrasound are more sensitive and will increase the diagnostic yield of prostate cancer when used in combination with rectal examination; however, these screening methods are also associated with high false-positive rates and may identify some tumors that will not threaten the patient’s health. The issue is further complicated by the morbidity associated with work-up and treatment of such tumors and the considerable cost beyond a routine DRE. Furthermore, because a high percentage of tumors identified by PSA screening alone have spread outside the prostate, PSA screening may not improve life expectancy. In any case, the clinician who uses PSA for the detection of prostate cancer should be aware that no uniform standard exists; if a laboratory changes to a different assay kit, serial assays may yield nonequivalent PSA values. In addition, the upper limit of the normal range of PSA, and therefore the threshold at which to biopsy, is not well-defined. A multicenter trial (PLCO-1) sponsored by the National Cancer Institute is under way to test the value of early detection in reducing mortality.
Survival of the patient with prostatic carcinoma is related to the extent of the tumor. When the cancer is confined to the prostate gland, median survival in excess of 5 years can be anticipated. Patients with locally advanced cancer are not usually curable, and a substantial fraction will eventually die of the tumor, though median survival may be as long as 5 years. If prostate cancer has spread to distant organs, current therapy will not cure it. Median survival is usually 1 to 3 years, and most such patients will die of prostate cancer. Even in this group of patients, however, indolent clinical courses lasting for many years may be observed.

4.3.2.2 PSA Prognosis

Other factors affecting the prognosis of patients with prostate cancer that may be useful in making therapeutic decisions include histologic grade of the tumor, patient’s age, other medical illnesses, and level of PSA. Poorly differentiated tumors are more likely to have already metastasized by the time of diagnosis and are associated with a poorer prognosis. For patients treated with radiation therapy, the combination of clinical tumor stage, Gleason score, and pretreatment PSA level can be used to more accurately estimate the risk of relapse. In most studies, flow cytometry has shown that nuclear DNA ploidy is an independent prognostic indicator for progression and for cause-specific survival in patients with pathologic stages III and IV prostate cancer without metastases (Jewett stages C and D1). Diploid tumors have a more favorable outcome than either tetraploid or aneuploid tumors. The use of flow cytometry techniques and histogram analysis to determine prognosis will require standardization.

Often, baseline rates of PSA changes are thought to be markers of tumor progression. Even though a tumor marker or characteristic may be consistently associated with a high risk of prostate cancer progression or death, it may be a very poor predictor and therefore of very limited utility in making therapeutic decisions. For example, baseline PSA and rate of PSA change were associated with subsequent metastasis or prostate cancer death in a cohort of 267 men with clinically localized prostate cancer who were managed by watchful waiting in the control arm of a randomized trial comparing radical prostatectomy to watchful waiting. Nevertheless, the accuracy of classifying men into groups whose cancer remained indolent versus those whose cancer progressed was poor at all examined cut points of PSA or PSA rate of change.

Several nomograms have been developed to predict outcomes either prior to or after radical prostatectomy with intent to cure. Preoperative nomograms are based on clinical stage, PSA, Gleason score, and the number of positive and negative prostate biopsy cores. Postoperative nomograms add pathologic findings, such as capsular invasion, surgical margins, seminal vesicle invasion, and lymph node involvement. The nomograms, however, were developed at academic centers and may not be as accurate when generalized to nonacademic hospitals, where the majority of patients are treated. In addition, the nomograms use nonhealth (intermediate) outcomes such as PSA rise or pathologic surgical findings and subjective endpoints such as the physician's perceived
need for additional therapy. In addition, the nomograms may be affected by changing methods of diagnosis or neoadjuvant therapy.

Definitive treatment is usually considered for younger men with prostate cancer and no major comorbid medical illnesses because younger men are more likely to die of prostate cancer than older men or men with major comorbid medical illness. Elevations of serum acid phosphatase are associated with poor prognosis in both localized and disseminated disease. PSA, an organ-specific marker with greater sensitivity and high specificity for prostate tissue, is often used as a tumor marker. After radical prostatectomy, detectable PSA levels identify patients at elevated risk of local treatment failure or metastatic disease; however, a substantial proportion of patients with elevated or rising PSA levels after surgery may remain clinically free of symptoms for extended periods of time.

Biochemical evidence of failure on the basis of elevated or slowly rising PSA alone therefore may not be sufficient to alter treatment. For example, in a retrospective analysis of nearly 2,000 men who had undergone radical prostatectomy with curative intent and who were followed for a mean of 5.3 years, 315 men (15%) demonstrated an abnormal PSA of 0.2 ng/mL or higher, which is evidence of biochemical recurrence. Of these 315 men, 103 men (34%) developed clinical evidence of recurrence. The median time to development of clinical metastasis after biochemical recurrence was 8 years. After the men developed metastatic disease, the median time to death was an additional 5 years.

After radiation therapy with curative intent, persistently elevated or rising PSA may be a prognostic factor for clinical disease recurrence; however, reported case series have used a variety of definitions of PSA failure. Criteria have been developed by the American Society for Therapeutic Radiology and Oncology Consensus Panel. It is difficult to base decisions about instituting additional therapy on biochemical failure. The implication of the various definitions of PSA failure for overall survival (OS) is not known, and as in the surgical series, many biochemical relapses (rising PSA alone) may not be clinically manifested in patients treated with radiation therapy.

Using surrogate endpoints for clinical decision making is controversial. Preliminary data from a retrospective cohort of 8,669 patients with clinically localized prostate cancer treated with either radical prostatectomy or radiation therapy suggested that short post treatment PSA doubling time (<3 months in this study) fulfills some criteria as a surrogate endpoint for all-cause mortality and prostate cancer mortality after surgery or radiation therapy. Likewise, a retrospective analysis has shown that PSA declines of 20% to 40% (but not 50%) at 3 months and 30% or more at 2 months after initiation of chemotherapy for hormone independent prostate cancer, fulfilled several criteria of surrogacy for OS. These observations should be independently confirmed in prospective study designs and may not apply to patients treated with hormonal therapy. In addition,
there are no standardized criteria of surrogacy or standardized cutpoints for adequacy of surrogate endpoints, even in prospective trials.

After hormonal therapy, reduction of PSA to undetectable levels provides information regarding the duration of progression-free status; however, decreases in PSA of less than 80% may not be very predictive. Yet, because PSA expression itself is under hormonal control, androgen deprivation therapy can decrease the serum level of PSA independent of tumor response. Clinicians, therefore, cannot rely solely on the serum PSA level to monitor a patient’s response to hormone therapy; they must also follow clinical criteria.

4.3.2.3 Statistics

Estimated new cases and deaths from prostate cancer in the United States in 2008:
New cases: 186,320.
Deaths: 28,660.

4.3.2.4 Recent Studies

The New England Journal of Medicine published two studies recently on prostate cancer screening. Before presenting their results for analysis let me first show what the NY Times said. Their headline was: "Prostate Test Found to Save Few Lives"

First the NY Times author, one Gina Kolata, states:

"The PSA test, which measures a protein released by prostate cells, does what it is supposed to do — indicates a cancer might be present, leading to biopsies to determine if there is a tumor. But it has been difficult to know whether finding prostate cancer early saves lives. Most of the cancers tend to grow very slowly and are never a threat and, with the faster-growing ones, even early diagnosis might be too late."

The PSA test is not just one test. It is not a black and white thing. It is a process that has evolved over time. There is not a good and bad PSA per se. Admittedly if you are 65 and have a PSA of 60 you are in some trouble. But as we now know a PSA of 2.1 when you are 50 is of concern. But more critically the rate of change in PSA is almost diagnostic. Thus a 25% rate of increase per year should be followed up.

In July 2003 Punglia et al in the New England Journal of Medicine published a study which demonstrated that the then current set point for PSA missed many cancers. They stated:
“Adjusting for verification bias significantly increased the area under the ROC curve (i.e., the overall diagnostic performance) of the PSA test, as compared with an unadjusted analysis (0.86 vs. 0.69, P<0.001, for men less than 60 years of age; 0.72 vs. 0.62, P=0.008, for men 60 years of age or older). If the threshold PSA value for undergoing biopsy were set at 4.1 ng per milliliter, 82 percent of cancers in younger men and 65 percent of cancers in older men would be missed. A digital rectal examination that is abnormal but not suspicious for cancer does not affect the overall performance characteristics of the test….A lower threshold level of PSA for recommending prostate biopsy, particularly in younger men, may improve the clinical value of the PSA test.”

They presented the following Figure:

The PSA test has been refined over the period of these studies, the PLCO Study, "Prostate, Lung, Colon, Ovary".
Now to issue two, Let us assume that a biopsy is performed. If a Gleason score of 7 is noted then you best have some attention paid, even a 6 is a problem. You have cancer! It will grow. It may very well kill you! That is if you do not die of something else. The problem is twofold; first, the doubling time of the cancer cells may be short, and second, the metastatic potential could be great. For Prostate cancer has the habit of metting to the bones, especially the spine. Does one want to take that risk?

The European study states the following protocol:

"We identified 182,000 men between the ages of 50 and 74 years through registries in seven European countries for inclusion in our study. The men were randomly assigned to a group that was offered PSA screening at an average of once every 4 years or to a control group that did not receive such screening. The predefined core age group for this study included 162,243 men between the ages of 55 and 69 years. The primary outcome was the rate of death from prostate cancer. Mortality follow-up was identical for the two study groups and ended on December 31, 2006..."

The European trial is akin to a Fire House which uses an answering machine which it checks every three days to see if there is a fire. They then study the town with this Fire House and a town without a Fire House and discover that there is no difference in destroyed houses. Well one would perhaps think that having someone there to answer the phone when it rings and then immediately dispatching a fire engine would improve things.

Let me explain. PSA screening once every year, this is based upon a tumor doubling time of 3 months, a DRE and PSA are performed. If the PSA is measured as per Punglia statistic then we would use 2.6 for men under 60. Punglia states:

"These findings, as well as recent data from a randomized trial showing that prostate-cancer treatment improves disease-free survival, indicate that reduction of the threshold PSA level at which biopsy is recommended to 2.6 ng per milliliter, at least in men under 60 years of age, may be reasonable."

Subsequent studies indicate that the added measurement of velocity or rate of change per year is also critical. Thus a 25% per year rate of change should be used as a way to seek an examination.

The American Group provides the following results:

"From 1993 through 2001, we randomly assigned 76,693 men at 10 U.S. study centers to receive either annual screening (38,343 subjects) or usual care as the control (38,350 subjects). Men in the screening group were offered annual PSA testing for 6 years and digital rectal examination for 4 years. The subjects and health care providers received
the results and decided on the type of follow-up evaluation. Usual care sometimes included screening, as some organizations have recommended. The numbers of all cancers and deaths and causes of death were ascertained....In the screening group, rates of compliance were 85% for PSA testing and 86% for digital rectal examination. Rates of screening in the control group increased from 40% in the first year to 52% in the sixth year for PSA testing and ranged from 41 to 46% for digital rectal examination. After 7 years of follow-up, the incidence of prostate cancer per 10,000 person-years was 116 (2820 cancers) in the screening group and 95 (2322 cancers) in the control group (rate ratio, 1.22; 95% confidence interval [CI], 1.16 to 1.29). The incidence of death per 10,000 person-years was 2.0 (50 deaths) in the screening group and 1.7 (44 deaths) in the control group (rate ratio, 1.13; 95% CI, 0.75 to 1.70)."

This American group was one with PSA at 4.0 and a second where PSA may or may not have been used as was a DRE. This is NOT a comparison of two distinct samples. The control group is a mix of anything and everything. Thus there are in my opinion two major faults;

First, the PSA numbers were set too high since we now know they should be set lower.

Second, the Control group was not the untested group as may be inferred, it was unlike the European study which alleges no treatment, and it was tested but just haphazardly.

Thus we have four groups:

Group 1 (American): PSA at 4.0 and DRE annually

Group 2: (American) PSA at 4.0 and DRE haphazardly

Group 3: (European) PSA at 4.0 but only once every 4 years

Group 4: (European) No screening

What is missing is what we now know to be the case. A PSA at 2.0 and an age dependent PSA with velocity measurements.

Thus our conclusion is that the Bayesian analysis, namely determining the probability of death given PSA measurements is or is not independent of the PSA measurement. We believe that the Bayesian approach of using screening at 2.0 under 60 and then testing and addressing a malignancy will reduce the a posteriori mortality. The data assessing that hypothesis appears to bear that out.

The NY Times headline is confusing, and frankly in error. The study proved at best that the specific screening protocol did not result in longer lives. That has been known now for six years! The question is what protocol will prolong life. It is not that PSA does not
work; it just does not work as it was being used ten years ago. This study only shows that.

The Times further states:

"In the European study, 48 men were told they had prostate cancer and needlessly treated for it for every man whose death was prevented within a decade after having had a PSA test. Dr. Peter B. Bach, a physician and epidemiologist at Memorial Sloan-Kettering Cancer Center, says one way to think of the data is to suppose he has a PSA test today. It leads to a biopsy that reveals he has prostate cancer, and he is treated for it. There is a one in 50 chance that, in 2019 or later, he will be spared death from a cancer that would otherwise have killed him. And there is a 49 in 50 chance that he will have been treated unnecessarily for a cancer that was never a threat to his life. Prostate cancer treatment can result in impotence and incontinence when surgery is used to destroy the prostate, and, at times, painful defecation or chronic diarrhea when the treatment is radiation."

Again that is not what the data says. The data shows that men were treated and did not die in either case. The two US cases are so overlapping that a bright line is not there and the European cases due to the longer time between screenings also merge to being identical. The statement about impotence and the like are scare statements since we know that if you have cancer and if we do not know the true level of malignancy then we just remove it, we don't want to be sued.

However the question that should have been posed in the testing is:

"What PSA level should lead to further testing such that there is a material reduction in mortality from Prostate Cancer?"

A corollary question would also be posed:

"What level of PSA and what velocity of PSA should lead to further evaluation and remediation so as to materially reduce prostate cancer mortality and/or significantly reduce the burden on the health care system subject to a constraint on a quality of life standard?"

Apparently all of this work assumed a PSA limit of 4.0 to be a golden standard. That seems not to be the case. However, as interpreted, this appears to have been common knowledge as far back as 2003 but was neglected to be included in the study albeit referred to in the American study.

This leads to the final issue, genetic evaluation. Namely as we have discussed elsewhere we believe that genetic testing for predisposition, presence, staging, and prevention is slowly making progress. It is this effort which will eventually bear fruit.
In a 2005 paper in Science by Tomlins et al they state:

"A central aim in cancer research is to identify altered genes that play a causal role in cancer development. Many such genes have been identified through the analysis of recurrent chromosomal rearrangements that are characteristic of leukemias, lymphomas, and sarcomas (1). These rearrangements are of two general types. In the first, the promoter and/ or enhancer elements of one gene are aberrantly juxtaposed to a proto-oncogene, thus causing altered expression of an oncogenic protein. This type of rearrangement is exemplified by the apposition of immunoglobulin (IG) and T cell receptor (TCR) genes to MYC, leading to activation of this oncogene in B and T cell malignancies, respectively (2). In the second, the rearrangement fuses two genes, resulting in the production of a fusion protein that may have a new or altered activity..."

Their conclusion is:

"The existence of recurring gene fusions of TMPRSS2 to the oncogenic ETS family members ERG and ETV1 may have important implications for understanding prostate cancer tumorigenesis and developing novel diagnostics and targeted therapeutics. Several lines of evidence suggest that these rearrangements occur in the majority of prostate cancer samples and drive ETS family member expression."

The following Table is from Tomlin:

Table 1. Cancer outlier profile analysis (COPA). Genes known to undergo causal mutations in cancer that had strong outlier profiles. “X” indicates literature evidence for the acquired pathognomonic translocation. “XX” indicate that samples in the study were characterized for the indicated translocation. “Y” indicates consistent with known amplification. Double asterisks indicate ERG and ETV1 outlier profiles in prostate cancer. A complete listing of genes known to undergo causal mutations ranking in the top 10 of all studies in Oncomine, along with the relevant references, is included as table S1.
Thus gene expression will be essential as a diagnostic tool. In a recent 2008 NEJM article by Zheng et al they state:

"Multiple SNPs in each of the five regions were associated with prostate cancer in single SNP analysis. When the most significant SNP from each of the five regions was selected and included in a multivariate analysis, each SNP remained significant after adjustment for other SNPs and family history. Together, the five SNPs and family history were estimated to account for 46% of the cases of prostate cancer in the Swedish men we studied. The five SNPs plus family history had a cumulative association with prostate cancer ... In men who had any five or more of these factors associated with prostate cancer, the odds ratio for prostate cancer was 9.46 ..., as compared with men without any of the factors. The cumulative effect of these variants and family history was independent of serum levels of prostate-specific antigen at diagnosis...SNPs in five chromosomal regions plus a family history of prostate cancer have a cumulative and significant association with prostate cancer."

This further indicates that significant gene progress is being made.

4.3.3 Breast Cancer

Breast cancer is a highly aggressive cancer which can be managed and potentially cured if detected early. Breast cancer also has a strong genetic relationship in several cases.

4.3.3.1 Genetic Characteristics and Risk Factors
Several well-established factors have been associated with an increased risk of breast cancer, including family history, nulliparity, early menarche, advanced age, and a personal history of breast cancer (in situ or invasive).

Age-specific risk estimates are available to help counsel and design screening strategies for women with a family history of breast cancer. Of all women with breast cancer, 5% to 10% may have a germ-line mutation of the genes BRCA1 and BRCA2. Specific mutations of BRCA1 and BRCA2 are more common in women of Jewish ancestry. The estimated lifetime risk of developing breast cancer for women with BRCA1 and BRCA2 mutations is 40% to 85%. Carriers with a history of breast cancer have an increased risk of contralateral disease that may be as great as 5% per year. Male carriers of BRCA2 mutations are also at increased risk for breast cancer.

Mutations in either the BRCA1 or BRCA2 gene also confer an increased risk of ovarian cancer. In addition, mutation carriers may be at increased risk of other primary cancers. Genetic testing is available to detect mutations in members of high-risk families. Such individuals should first be referred for counseling.

4.3.3.2 Screening

Clinical trials have established that screening with mammography, with or without clinical breast examination, may decrease breast cancer mortality.

4.3.3.3 Patient Evaluation

Patient management following initial suspicion of breast cancer generally includes confirmation of the diagnosis, evaluation of stage of disease, and selection of therapy. At the time the tumor tissue is surgically removed, estrogen receptor (ER) and progesterone receptor (PR) status should be determined.

4.3.3.4 Prognostic Factors

Breast cancer is commonly treated by various combinations of surgery, radiation therapy, chemotherapy, and hormone therapy. Prognosis and selection of therapy may be influenced by:

- The age and menopausal status of the patient.
- The stage of the disease.
- The histologic and nuclear grade of the primary tumor.
- The ER and PR status of the tumor.
- The measures of proliferative capacity of the tumor.
- HER2/neu gene amplification.
Although certain rare inherited mutations such as those of *BRCA1* and *BRCA2* predispose women to develop breast cancer, prognostic data on mutation carriers who have developed breast cancer are conflicting. Since criteria for menopausal status vary widely, some studies have substituted age older than 50 years as a surrogate for the postmenopausal state. Breast cancer is classified into a variety of histologic types, some of which have prognostic importance. For example, favorable histologic types include mucinous, medullary, and tubular carcinoma.

4.3.3.5 Statistics

Estimated new cases and deaths from breast cancer (women only) in the United States in 2008:

New cases: 182,460.
Deaths: 40,480.

4.3.4 Melanoma

Melanoma is a malignant tumor of melanocytes, which are the cells that make the pigment melanin and are derived from the neural crest. Although most melanomas arise in the skin, they may also arise from mucosal surfaces or at other sites to which neural crest cells migrate. Melanoma occurs predominantly in adults, and more than 50% of the cases arise in apparently normal areas of the skin. Early signs in a nevus that would suggest malignant change include darker or variable discoloration, itching, an increase in size, or the development of satellites. Ulceration or bleeding is later signs. Melanoma in women occurs more commonly on the extremities and in men on the trunk or head and neck, but it can arise from any site on the skin surface.

The pathology slide on the left depicts a malignant melanoma. The cells proliferate from a clonal melanocytes in the basal layer of the skin and then enter the blood stream for rapid hematological spread. There are metastases to the brain and elsewhere. From Miller, Melanoma, NEJM, 2006; 355:51-65.

4.3.4.1 Diagnosis

A biopsy, preferably by local excision, should be performed for any suspicious lesions, and the specimens should be examined by an experienced pathologist to allow for microstaging. Suspicious lesions should never be shaved off or cauterized. Studies show that distinguishing between benign pigmented lesions and early melanomas can be
difficult, and even experienced dermatopathologists can have differing opinions. To reduce the possibility of misdiagnosis for an individual patient, a second review by an independent qualified pathologist should be considered.

Prognosis is affected by clinical and histological factors and by anatomic location of the lesion. Thickness and/or level of invasion of the melanoma, mitotic index, presence of tumor infiltrating lymphocytes, number of regional lymph nodes involved, and ulceration or bleeding at the primary site affect the prognosis. Microscopic satellites in stage I melanoma may be a poor prognostic histologic factor, but this is controversial. Patients who are younger, female, and who have melanomas on the extremities generally have a better prognosis.

4.3.4.2 Genetic Analysis of Melanoma

A great deal of research has been done on the genetic fabric of melanoma. There is no simple answer as to the genetic initiation but the recent work by Curtin et al details the many genetic underpinnings of the malignancy. Specifically Curtin et al concluded in their recent paper:

"Knowledge of the genetic differences among melanomas could be valuable in the design of therapeutic strategies. Our results lead us to make a prediction. The group of tumors on skin without chronic sun-induced damage, which represent the most common type of melanoma, frequently had a mutation in BRAF together with a loss of PTEN or mutations in N-RAS alone. Thus, they would be expected to be responsive to therapeutic interventions targeting the RAS–RAF–ERK and PI3K pathways. In contrast, the majority of melanomas in the other three groups did not have mutations in BRAF or N-RAS but instead had increased numbers of copies of the downstream gene CCND1 or CDK4.

Thus, these three groups of melanomas would be less likely to respond to therapeutic interventions that target upstream components of the mitogen-activated protein kinase pathway including BRAF, such as sorafenib. Our study provides genetic support for the existence of distinct molecular pathways to melanoma, each with a unique relationship to exposure to ultraviolet light. This finding should affect the design of future studies involving the treatment and prevention of melanoma and suggests the existence of as yet- unidentified susceptibility factors."

The results of Curtin seem to imply that the sun damaged generation of melanoma may be more difficult to treat than the non-sun damaged variety, specifically due to the origin from differing genetic pathways. Second, the approach taken by Curtin et al may raise the question as to the MPM syndrome.

As to the MPM and genetic markers relationship, Ferrone has stated:
"Several risk factors associated with the development of MPM have been identified. These include a positive family history of MPM and a personal history of dysplastic nevi (DN); atypical moles that are risk markers but non-obligate precursors of melanoma. Among patients with MPM, 18% to 38% are reported to have a positive family history of melanoma and 38% to 46% are reported to have a history of dysplastic nevi. However, few longitudinal cohort-defined databases have prospectively recorded known risk factors for all patients with melanoma to assess the impact of these risk factors on the development of MPM."

Thus, as to our Case patient, we were not able to determine a full family history and thus this leaves the consideration of this being an MPM syndrome open to question. Specifically family history as well as dysplastic nevus syndrome, clearly ascertained by pathological analysis, is an essential in a proper diagnosis as well as treatment.

4.3.4.3 Statistics

Estimated new cases and deaths from melanoma in the United States in 2008:

New cases: 62,480.
Deaths: 8,420.

4.3.5 Ovarian Cancer

Several malignancies arise from the ovary. Epithelial carcinoma of the ovary is one of the most common gynecologic malignancies and the fifth most frequent cause of cancer death in women, with 50% of all cases occurring in women older than 65 years. Approximately 5% to 10% of ovarian cancers are familial and three distinct hereditary patterns have been identified: ovarian cancer alone, ovarian and breast cancers, or ovarian and colon cancers. The most important risk factor for ovarian cancer is a family history of a first-degree relative (e.g., mother, daughter, or sister) with the disease. The highest risk appears in women with two or more first-degree relatives with ovarian cancer. The risk is somewhat less for women with one first-degree and one second-degree relative (grandmother or aunt) with ovarian cancer.

Transvaginal ultrasound is the initial gold standard for the detection of ovarian lesions. The ultrasound lesion shown to the left shows an ovary with a solid mass interior and is most likely a carcinoma.
4.3.5.1 Genetics

In most families affected with the breast and ovarian cancer syndrome or site-specific ovarian cancer, genetic linkage has been found to the BRCA1 locus on chromosome 17q21. BRCA2, also responsible for some instances of inherited ovarian and breast cancer, has been mapped by genetic linkage to chromosome 13q12. The lifetime risk for developing ovarian cancer in patients harboring germline mutations in BRCA1 is substantially increased over the general population. Two retrospective studies of patients with germline mutations in BRCA1 suggest that these women have improved survival compared with BRCA1-mutation-negative women. The majority of women with a BRCA1 mutation probably have family members with a history of ovarian and/or breast cancer; therefore, these women may have been more vigilant and inclined to participate in cancer screening programs that may have led to earlier detection.

4.3.5.2 Treatment

For women at increased risk, prophylactic oophorectomy may be considered after the age of 35 if childbearing is complete. In a family-based study among women with BRCA1 or BRCA2 mutations, of the 259 women who had undergone bilateral prophylactic oophorectomy, two of them (0.8%) developed subsequent papillary serous peritoneal carcinoma, and six of them (2.8%) had stage I ovarian cancer at the time of surgery. Of the 292 matched controls, 20% who did not have prophylactic surgery developed ovarian cancer. Prophylactic surgery was associated with a higher than 90% reduction in the risk of ovarian cancer (relative risk = 0.04; 95% confidence interval , 0.01–0.16), with an average follow-up of 9 years; however, family-based studies may be associated with biases resulting from case selection and other factors that may influence the estimate of benefit.

After a prophylactic oophorectomy, a small percentage of women may develop a primary peritoneal carcinoma, similar in appearance to ovarian cancer. The prognostic information presented below deals only with epithelial carcinomas. Stromal and germ cell tumors are relatively uncommon and comprise less than 10% of cases.

Ovarian cancer usually spreads via local shedding into the peritoneal cavity followed by implantation on the peritoneum and via local invasion of bowel and bladder. The incidence of positive nodes at primary surgery has been reported to be as much as 24% in patients with stage I disease, 50% in patients with stage II disease, 74% in patients with stage III disease, and 73% in patients with stage IV disease. In this study, the pelvic nodes were involved as often as the para-aortic nodes. Tumor cells may also block diaphragmatic lymphatics. The resulting impairment of lymphatic drainage of the peritoneum is thought to play a role in development of ascites in ovarian cancer. Also, transdiaphragmatic spread to the pleura is common.
4.3.5.3 Prognosis

Prognosis in ovarian cancer is influenced by several factors, but multivariate analyses suggest that the most important favorable factors include:

- Younger age.
- Good performance status.
- Cell type other than mucinous and clear cell.
- Lower stage.
- Well-differentiated tumor.
- Smaller disease volume prior to any surgical debulking.
- Absence of ascites.
- Smaller residual tumor following primary cytoreductive surgery.

For patients with stage I disease, the most important prognostic factor is grade, followed by dense adherence and large-volume ascites. DNA flow cytometric analysis of stage I and stage IIA patients may identify a group of high-risk patients. Patients with clear cell histology appear to have a worse prognosis. Patients with a significant component of transitional cell carcinoma appear to have a better prognosis.

4.3.5.4 Detection

Although the ovarian cancer-associated antigen, CA 125, has no prognostic significance when measured at the time of diagnosis, it has a high correlation with survival when measured 1 month after the third course of chemotherapy for patients with stage III or stage IV disease. For patients whose elevated CA 125 normalizes with chemotherapy, more than one subsequent elevated CA 125 measurement is highly predictive of active disease, but this does not mandate immediate therapy.

Most patients with ovarian cancer have widespread disease at presentation. This may be partly explained by relatively early spread (and implantation) of high grade papillary serous cancers to the rest of the peritoneal cavity. Conversely, symptoms such as abdominal pain and swelling, gastrointestinal symptoms, and pelvic pain, often go unrecognized, leading to delays in diagnosis. As a result of these confounding factors, yearly mortality in ovarian cancer is approximately 65% of the incidence rate. Long-term follow-up of suboptimally debulked stage III and stage IV patients showed a 5-year survival rate of less than 10% with platinum-based combination therapy prior to the current generation of trials including taxanes.

By contrast, optimally debulked stage III patients treated with a combination of intravenous taxane and intraperitoneal platinum plus taxane achieved a median survival of 66 months in a Gynecologic Oncology Group trial. Numerous clinical trials are in
progress to refine existing therapy and test the value of different approaches to postoperative drug and radiation therapy.

4.3.5.5 Statistics

Estimated new cases and deaths from ovarian cancer in the United States in 2008:

New cases: 21,650.
Deaths: 15,520.

4.3.6 Lung Cancer

Small cell lung cancer (SCLC) accounts for approximately 15% of bronchogenic carcinomas. The overall incidence and mortality rates of SCLC in the United States have decreased during the past few decades. Without treatment, SCLC has the most aggressive clinical course of any type of pulmonary tumor, with median survival from diagnosis of only 2 to 4 months. Compared with other cell types of lung cancer, SCLC is more responsive to chemotherapy and radiation therapy; however, a cure is difficult to achieve because SCLC has a greater tendency to be widely disseminated by the time of diagnosis. It is the cancer most commonly associated with paraneoplastic syndromes, including the syndrome of inappropriate antidiuretic hormone secretion, paraneoplastic cerebellar degeneration, and Lambert-Eaton myasthenic syndrome.

4.3.6.1 Limited-Stage Disease

At the time of diagnosis, approximately 30% of patients with SCLC will have tumors confined to the hemithorax of origin, the mediastinum, or the supraclavicular lymph nodes. These patients are designated as having limited-stage disease (LD), and most 2-year disease-free survivors come from this group. For patients with LD, median survival of 16 to 24 months and 5-year survivals of 14% with current forms of treatment have been reported. Patients diagnosed with LD who smoke should be encouraged to stop smoking before undergoing combined-modality therapy because continued smoking may compromise cure rates.

Improved long-term survival has been shown with combined modality therapy. Although long-term survivors have been reported among patients who received either surgery or chemotherapy alone, chemotherapy combined with thoracic radiation therapy (TRT) is considered the standard of care. Adding TRT increases absolute survival by approximately 5% over chemotherapy alone. The optimal timing of TRT relative to chemotherapy has been evaluated in multiple trials and meta-analyses with the weight of evidence suggesting a small benefit to early TRT. Prophylactic cranial radiation prevents central nervous system (CNS) recurrence and can improve survival in patients who have had a complete response to chemoradiation.
4.3.6.2 Extensive-Stage Disease

Patients with tumors that have spread beyond the supraclavicular areas are said to have extensive-stage disease (ED) and have a worse prognosis than patients with LD. Median survival of 6 to 12 months is reported with currently available therapy, but long-term disease-free survival is rare.

4.3.6.3 Prognostic Factors

The pretreatment prognostic factors that consistently predict for prolonged survival include good performance status, female gender, and LD. Patients with involvement of the CNS or liver at the time of diagnosis have a significantly worse outcome. A number of biochemical factors including serum sodium, alkaline phosphatase, and lactate dehydrogenase have also been found to independently correlate with outcome. Regardless of stage, the current prognosis for patients with SCLC is unsatisfactory despite improvements in diagnosis and therapy made during the past 25 years. All patients with this type of cancer may appropriately be considered for inclusion in clinical trials at the time of diagnosis.

4.3.6.4 Statistics

Estimated new cases and deaths from lung cancer (small cell lung cancer and non-small cell lung cancer combined) in the United States in 2008:

New cases: 215,020.
Deaths: 161,840.

4.3.7 Cervix

The prognosis for patients with cervical cancer is markedly affected by the extent of disease at the time of diagnosis. Because a vast majority (>90%) of these cases can and should be detected early through the use of the Pap smear, the current death rate is far higher than it should be and reflects that, even today, Pap smears are not done on approximately 33% of eligible women.

4.3.7.1 Prognosis

Among the major factors that influence prognosis are stage, volume and grade of tumor, histologic type, lymphatic spread, and vascular invasion. In a large surgicopathologic staging study of patients with clinical stage IB disease reported by the Gynecologic Oncology Group (GOG), the factors that predicted most prominently for lymph node metastases and a decrease in disease-free survival were capillary-lymphatic space involvement by tumor, increasing tumor size, and increasing depth of stromal invasion, with the latter being most important and reproducible. In a study of 1,028
patients treated with radical surgery, survival rates correlated more consistently with tumor volume (as determined by precise volumetry of the tumor) than clinical or histologic stage.

A multivariate analysis of prognostic variables in 626 patients with locally advanced disease (primarily stages II, III, and IV) studied by the GOG revealed that periaortic and pelvic lymph node status, tumor size, patient age, and performance status were significant for progression-free interval and survival. The study confirms the overriding importance of positive periaortic nodes and suggests further evaluation of these nodes in locally advanced cervical cancer. The status of the pelvic nodes was important only if the periaortic nodes were negative. This was also true for tumor size.

Bilateral disease and clinical stage were also significant for survival. In a large series of cervical cancer patients treated by radiation therapy, the incidence of distant metastases (most frequently to lung, abdominal cavity, liver, and gastrointestinal tract) was shown to increase as the stage of disease increased, from 3% in stage IA to 75% in stage IVA. A multivariate analysis of factors influencing the incidence of distant metastases showed stage, endometrial extension of tumor, and pelvic tumor control to be significant indicators of distant dissemination.

Whether adenocarcinoma of the cervix carries a significantly worse prognosis than squamous cell carcinoma of the cervix remains controversial. Reports conflict about the effect of adenosquamous cell type on outcome. One report showed that approximately 25% of apparent squamous tumors have demonstrable mucin production and behave more aggressively than their pure squamous counterparts, suggesting that any adenomatous differentiation may confer a negative prognosis. The decreased survival is mainly the result of more advanced stage and nodal involvement rather than cell type as an independent variable. Women with human immunodeficiency virus have more aggressive and advanced disease and a poorer prognosis. A study of patients with known invasive squamous carcinoma of the cervix found that overexpression of the C-myc oncogene was associated with a poorer prognosis. The number of cells in S phase may also have prognostic significance in early cervical carcinoma.

4.3.7.2 Human papillomavirus infection and cervical cancer

Molecular techniques for the identification of human papillomavirus (HPV) DNA are highly sensitive and specific. More than 6 million women in the United States are estimated to have HPV infection, and proper interpretation of these data is important. Epidemiologic studies convincingly demonstrate that the major risk factor for development of preinvasive or invasive carcinoma of the cervix is HPV infection, which far outweighs other known risk factors such as high parity, increasing number of sexual partners, young age at first intercourse, low socioeconomic status, and positive smoking history. Some patients with HPV infection appear to be at minimal increased risk for development of cervical preinvasive and invasive malignancies, while others appear to
be at significant risk and are candidates for intensive screening programs and/or early intervention.

HPV DNA tests are unlikely to separate patients with low-grade squamous intraepithelial lesions into those who do and those who do not need further evaluation. A study of 642 women found that 83% had one or more tumorigenic HPV types when cervical cytologic specimens were assayed by a sensitive (hybrid capture) technique. The authors of the study and of an accompanying editorial concluded that using HPV DNA testing in this setting does not add sufficient information to justify its cost. Whether HPV DNA testing will prove useful in patients with atypical squamous cells of undetermined significance is being studied by the same group. Patients with an abnormal cytology of a high-risk type (Bethesda classification) should be thoroughly evaluated with colposcopy and biopsy.

Other studies show patients with low-risk cytology and high-risk HPV infection with types 16, 18, and 31 are more likely to have cervical intraepithelial neoplasia (CIN) or microinvasive histopathology on biopsy. One method has also shown that integration of HPV types 16 and 18 into the genome, leading to transcription of viral and cellular messages, may predict patients who are at greater risk for high-grade dysplasia and invasive cancer. Studies suggest that acute infection with HPV types 16 and 18 conferred an 11- to 16.9-fold risk of rapid development of high-grade CIN, but there are conflicting data requiring further evaluation before any recommendations may be made.

Patients with low-risk cytology and low-risk HPV types have not been followed long enough to ascertain their risk. At present, studies are ongoing to determine how HPV typing can be used to help stratify women into follow-up and treatment groups. HPV typing may prove useful, particularly in patients with low-grade cytology or cytology of unclear abnormality. At present, how therapy and follow-up should be altered with low-versus high-risk HPV type has not been established.

4.3.7.3  Statistics

Estimated new cases and deaths from cervical (uterine cervix) cancer in the United States in 2008:

New cases: 11,070.
Deaths: 3,870.

4.3.8  Testis

Testicular cancer is a highly treatable, often curable, cancer that usually develops in young and middle-aged men. Testicular cancer is broadly divided into seminoma and nonseminoma types for treatment planning because seminomas are more sensitive to
radiation therapy. For patients with seminoma (all stages combined), the cure rate exceeds 90%. For patients with low-stage disease, the cure rate approaches 100%. Tumors that have a mixture of seminoma and nonseminoma components should be managed as nonseminomas. Nonseminomas include embryonal carcinomas, teratomas, yolk sac carcinomas, choriocarcinomas, and various combinations of these cell types. Tumors that appear to have a seminoma histology but that have elevated serum levels of alpha-fetoprotein (AFP) should be treated as nonseminomas. Elevation of the beta subunit of human chorionic gonadotropin (hCG) alone is found in approximately 10% of the patients with pure seminoma.

Risk of metastases is lowest for teratoma and highest for choriocarcinoma, with the other cell types having intermediate risk.

4.3.8.1 Prognosis

A number of prognostic classification schema are in use for metastatic nonseminomatous testicular cancer and for primary extragonadal nonseminomatous germ cell cancers treated with chemotherapy. Most incorporate some or all of the following factors, which may independently predict worse prognosis:

- Presence of liver, bone, or brain metastases.
- Very high serum markers.
- Primary mediastinal nonseminoma.
- Large number of lung metastases.

Even patients with widespread metastases at presentation, including those with brain metastases, may be curable and should be treated with this intent.

4.3.8.2 Treatment

Radical inguinal orchiectomy with initial high ligation of the spermatic cord is the procedure of choice in treating a malignant testicular mass. Transscrotal biopsy is not considered appropriate because of the risk of local dissemination of tumor into the scrotum or its spread to inguinal lymph nodes. A retrospective analysis of reported series in which transscrotal approaches had been used showed a small but statistically significant increase in local recurrence rates compared with the recurrence rates when the inguinal approach was used (2.9% vs. 0.4%). Distant recurrence and survival rates, however, were indistinguishable in the two approaches. Local recurrence was similar in patients who did not have scrotal violation, regardless of whether or not additional treatments, such as hemiscrotal radiation therapy, hemiscrotal resection, or inguinal lymph node dissection, were used.
An important aspect of the diagnosis and follow-up of testicular cancer is the use of serum markers. Serum markers include AFP, hCG (measurement of the beta subunit reduces luteinizing hormone cross-reactivity), and lactate dehydrogenase. The serum markers may detect a tumor that is too small to be discovered on physical examination or x-rays. In patients younger than 15 years, approximately 90% of testicular germ cell cancers are yolk sac tumors. In these types of patients, the AFP is elevated at diagnosis and is an excellent indicator of response to therapy and disease status. Serum markers plus chest x-rays are important parts of the monthly checkups for patients after definitive therapy of testicular cancer as well as periodic abdominal computed tomographic (CT) scans for 2 to 3 years. The absence of markers does not mean the absence of tumor. After diagnosis and treatment, patients typically receive follow-up monthly for the first year and every other month for the second year. While the majority of tumor recurrences appear within 2 years, late relapse has been reported, and lifelong marker, radiologic, and physical examination is recommended.

Evaluation of the retroperitoneal lymph nodes, usually by CT scanning, is an important aspect of treatment planning in adults with testicular cancer. Patients with a negative result however, have a 25% to 30% chance of having microscopic involvement of the lymph nodes. For seminoma, some physicians think that knowing the results of both the lymphangiogram and the CT scan is important for treatment planning. For nonseminoma, the inaccuracy of both is a problem, and frequently surgical staging is required. About 25% of patients with clinical stage I nonseminomatous testicular cancer will be upstaged to pathologic stage II with retroperitoneal lymph node dissection (RPLND), and about 25% of clinical stage II patients will be downstaged to pathologic stage I with RPLND. In children, the use of serial measurements of AFP has proven sufficient for monitoring response after initial orchiectomy. Lymphangiography and para-aortic lymph node dissection do not appear to be useful or necessary in the proper staging and management of these patients.

4.3.8.3 Comorbidity

Patients who have been cured of testicular cancer have approximately a 2% to 5% cumulative risk of developing a cancer in the opposite testicle during the 25 years after initial diagnosis. Within this range, men with nonseminomatous primary tumors appear to have a lower risk of subsequent contralateral testis tumors than men with seminomas.

HIV-infected men are reported to be at increased risk for developing testicular germ cell cancer. Depending on comorbid conditions such as active infection, these men are generally managed similarly to non-HIV-infected patients. Because the majority of testis cancer patients who receive chemotherapy are curable, it is necessary to be aware of possible long-term effects of platinum-based treatment, such as the following:
1. Fertility: Many patients have oligospermia or sperm abnormalities prior to therapy. Virtually all become oligospermic during chemotherapy. Many recover sperm production, however, and can father children, often without the use of cryopreserved semen. In a population-based study, 70% of patients actually fathered children. The likelihood of recovering fertility is related to the type of treatment received. The children do not appear to have an increased risk of congenital malformations.

2. Secondary leukemias: Several reports of elevated risk of secondary acute leukemia, primarily nonlymphocytic, have appeared. In some cases, the risks were associated with the prolonged use of alkylating agents or with the use of radiation. Etoposide-containing regimens are also associated with a risk of secondary acute leukemias, usually in the myeloid lineage, and with a characteristic 11q23 translocation. Etoposide-associated leukemias typically occur sooner after therapy than alkylating agent-associated leukemias and often show balanced chromosomal translocations on the long arm of chromosome 11. Standard etoposide dosages (<2 g/m² cumulative dose) are associated with a relative risk of 15 to 25, but this translates into a cumulative incidence of leukemia of less than 0.5% at 5 years. Preliminary data suggest that cumulative doses of more than 2 g/m² of etoposide may confer higher risk.

3. Renal function: Minor decreases in creatinine clearance occur (about a 15% decrease, on average) during platinum-based therapy, but these appear to remain stable in the long term and without significant deterioration.

4. Hearing: Bilateral hearing deficits occur with cisplatin-based chemotherapy, but the deficits generally occur at sound frequencies of 4 kHz to 8 kHz, which is outside the range of conversational tones; therefore, hearing aids are rarely required if standard doses of cisplatin are administered.

Although bleomycin pulmonary toxic effects may occur, it is rarely fatal at total cumulative doses of less than 400U. Because life-threatening pulmonary toxic effects can occur, the drug should be discontinued if early signs of pulmonary toxic effects develop. Although decreases in pulmonary function are frequent, they are rarely symptomatic and are reversible after the completion of chemotherapy. Reportedly, men treated curatively for germ cell tumors with cisplatin-based regimens have had elevations in total serum cholesterol. This could not be confirmed, however, in another study.

Radiation therapy, often used in the management of pure seminomatous germ cell cancers, has been linked to the development of secondary cancers, especially solid tumors in the radiation portal, usually after a latency period of a decade or more. These include melanoma and cancers of the stomach, bladder, colon, rectum, pancreas, lung,
pleura, prostate, kidney, connective tissue, and thyroid. Chemotherapy has also been associated with an elevated risk of secondary cancers.

Oligospermia or sperm abnormalities prior to therapy are common. Radiation therapy, used to treat pure seminomatous testicular cancers, can cause fertility problems because of radiation scatter to the remaining testicle during radiation therapy to retroperitoneal lymph nodes as evidenced in the SWOG-8711 trial, for example. Depending on scatter dose, sperm counts fall after radiation therapy but may recover over the course of 1 to 2 years. Shielding techniques can be used to decrease the radiation scatter to the remaining normal testicle. As with treatment with chemotherapy, some men have been reported to father children after radiation treatment of seminoma, and the children do not appear to have a high risk of congenital malformations.

4.3.8.4 Therapy

Radiation therapy and/or chemotherapy for patients with testicular cancer may be associated with an increase in cardiovascular morbidity. In a retrospective series of 992 patients treated for testicular cancer at the Royal Marsden Hospital between 1982 and 1992, cardiac events were increased approximately 2.5-fold in patients treated with radiation therapy and/or chemotherapy compared with those who underwent surveillance after a median of 10.2 years. The actuarial risks of cardiac events were 7.2% for patients who received radiation therapy (92% of whom did not receive mediastinal radiation therapy), 3.4% for patients who received chemotherapy (primarily platinum-based), 4.1% for patients who received combined therapy, and 1.4% for patients who underwent surveillance management after 10 years of follow-up. A population-based retrospective study of 2,339 testicular cancer survivors in the Netherlands, treated between 1965 and 1995 and followed for a median of 18.4 years, found that the overall incidence of coronary heart disease (i.e., myocardial infarction and/or angina pectoris) was increased 1.17 times (95% confidence interval, 1.04–1.31) compared with the general population. Patients who received radiation therapy to the mediastinum had a 2.5-fold (95% CI, 1.8–3.4) increased risk of coronary heart disease, and those who also received chemotherapy had an almost 3-fold (95% CI, 1.7–4.8) increased risk. Patients who were treated with infradiaphragmatic radiation therapy alone had no significantly increased risk of coronary heart disease. In multivariate Cox regression analyses, the older chemotherapy regimen of cisplatin, vinblastine, and bleomycin (PVB), used until the mid 1980s, was associated with a significant 1.9-fold (95% CI, 1.2–2.9) increased risk of cardiovascular disease (i.e., myocardial infarction, angina pectoris, and heart failure combined).

The newer regimen of bleomycin, etoposide, and cisplatin (BEP) was associated with a borderline significant 1.5-fold (95% CI, 1.0–2.2) increased risk of cardiovascular disease.
Although testicular cancer is highly curable, all newly diagnosed patients are appropriately considered candidates for clinical trials designed to decrease morbidity of treatment while further improving cure.

4.3.8.5 **Statistics**

Estimated new cases and deaths from testicular cancer in the United States in 2008: 1
New cases: 8,090.
Deaths: 380.

4.4 **Cost Impact**

In this section we analyze the costs of the eight cancers we have targeted. The costs are divided into two areas: Initial Treatment, which is the surgical and chemotherapy treatment required at the time of recognition, and second, Ongoing Treatment, the costs associated with treating the remaining set of patients, those surviving over a five year period.

4.4.1 **Methodology**

The process is as follows:

1. Incidence Patients: We use the data base from NCI to determine the incidence and then project going forward on a census basis the total number of cases per year of the eight cancers.

2. We then assign costs for surgery, hospital based, then medications, generally chemotherapy, and then for ongoing physician care. We have not included radiation therapy but that may be factored into a loaded pharmaceutical base.

3. We then calculate the costs for the first year incidence patient base.

4. We then use the mortality rates and then linearize a Kaplan Meir survival curve. Using that we determine over the year 2 through year 5 the number of patients requiring ongoing care.

5. We then assume that we have a similar costs base of physician care and pharmaceuticals over this period.

6. We then combine the results into a total cost profile using constant 2008 dollars and a growing population base. The costs of procedures and pharmaceuticals are derived from the data we have presented in the Health Care Chapter in January 2009.
4.4.2 Cost Elements

The cost elements in 2008 dollars are contained in the following Table. We include full surgical and surgical related costs for the first year only. We assume ongoing care by a physician trained to deal with the specific cancer and we also assume that some form of chemotherapy is used.

We also assume that in the ongoing years we require medical and chemotherapy help.

<table>
<thead>
<tr>
<th></th>
<th>Prostate</th>
<th>Female Breast</th>
<th>Lung and Bronchus</th>
<th>Colon and Rectum</th>
<th>Melanomas of the Skin</th>
<th>Ovary</th>
<th>Cervix</th>
<th>Testis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgery</td>
<td>$55,000</td>
<td>$75,000</td>
<td>$105,000</td>
<td>$125,000</td>
<td>$55,000</td>
<td>$95,000</td>
<td>$55,000</td>
<td>$75,000</td>
</tr>
<tr>
<td>Medication</td>
<td>$15,000</td>
<td>$25,000</td>
<td>$18,000</td>
<td>$20,000</td>
<td>$15,000</td>
<td>$45,000</td>
<td>$15,000</td>
<td>$55,000</td>
</tr>
<tr>
<td>Physician</td>
<td>$12,000</td>
<td>$22,000</td>
<td>$25,000</td>
<td>$20,000</td>
<td>$15,000</td>
<td>$25,000</td>
<td>$15,000</td>
<td>$30,000</td>
</tr>
<tr>
<td>Total</td>
<td>$82,000</td>
<td>$122,000</td>
<td>$148,000</td>
<td>$165,000</td>
<td>$85,000</td>
<td>$165,000</td>
<td>$85,000</td>
<td>$160,000</td>
</tr>
</tbody>
</table>

4.4.3 Specific Cost Analyses

We now present the financial data for costs. The Figure below is the costs for just new incidences of the eight cancers from 2010 to 2030 in 2008 dollars.

The Figure below shows the total first year costs growing from $105 billion in 2008 and reaching $125 billion in 2030. This may be further increased by age adjustments in the population. However the age changes are problematic because we also see major ethnic changes as well and this distribution in the incidences may see a considerable mix when all of these factors are combined. The Figure below thus represents a reasonable projection going forward.
The Table shown below is a detailed breakout for each of the cancers in each of the years in question.

As we have stated earlier it is necessary to have female and male populations since many of the cancers are sex related. The incidences are the incidences in the related affected group and do not represent incidences over the total population. We have assumes a static male and female ratio. Any changes there would be expected to be immaterial over this time horizon.

We have also assumed that the treatments do not change in this twenty year period for better or worse. That frankly is a massive assumption as we have discussed earlier. This is the problem with all projections of this nature. In our report on Diabetes it may be reasonable to assume that there will be some genetic work here as well. Yet the understanding of many of these cancers may be quite impressive over this time frame.
<table>
<thead>
<tr>
<th>Year</th>
<th>Male</th>
<th>Female</th>
<th>Total</th>
<th>Prostate</th>
<th>Female Breast</th>
<th>Lung and Bronchus</th>
<th>Colon and Rectum</th>
<th>Melanomas of the Skin</th>
<th>Ovary</th>
<th>Cervix</th>
<th>Testis</th>
</tr>
</thead>
<tbody>
<tr>
<td>2008</td>
<td>148,762,847</td>
<td>154,834,799</td>
<td>303,597,646</td>
<td>211,838</td>
<td>182,241</td>
<td>205,536</td>
<td>146,638</td>
<td>56,166</td>
<td>19,200</td>
<td>12,542</td>
<td>8,033</td>
</tr>
<tr>
<td>2009</td>
<td>150,073,474</td>
<td>156,198,921</td>
<td>306,272,395</td>
<td>213,705</td>
<td>183,846</td>
<td>207,346</td>
<td>147,930</td>
<td>56,660</td>
<td>19,369</td>
<td>12,652</td>
<td>8,104</td>
</tr>
<tr>
<td>2011</td>
<td>152,684,431</td>
<td>158,916,449</td>
<td>311,600,880</td>
<td>217,423</td>
<td>187,045</td>
<td>210,954</td>
<td>150,503</td>
<td>57,646</td>
<td>19,706</td>
<td>12,872</td>
<td>8,245</td>
</tr>
<tr>
<td>2012</td>
<td>153,997,738</td>
<td>160,283,360</td>
<td>314,281,098</td>
<td>219,293</td>
<td>188,654</td>
<td>212,768</td>
<td>151,798</td>
<td>58,166</td>
<td>19,875</td>
<td>12,983</td>
<td>8,316</td>
</tr>
<tr>
<td>2013</td>
<td>155,316,028</td>
<td>161,655,457</td>
<td>316,971,485</td>
<td>221,170</td>
<td>190,028</td>
<td>214,590</td>
<td>154,399</td>
<td>59,139</td>
<td>20,045</td>
<td>13,094</td>
<td>8,387</td>
</tr>
<tr>
<td>2014</td>
<td>156,637,123</td>
<td>163,030,475</td>
<td>319,667,598</td>
<td>223,051</td>
<td>191,887</td>
<td>216,415</td>
<td>157,005</td>
<td>60,139</td>
<td>20,216</td>
<td>13,205</td>
<td>8,458</td>
</tr>
<tr>
<td>2015</td>
<td>157,959,236</td>
<td>165,781,943</td>
<td>322,741,179</td>
<td>224,934</td>
<td>193,507</td>
<td>218,242</td>
<td>159,703</td>
<td>60,635</td>
<td>20,386</td>
<td>13,317</td>
<td>8,530</td>
</tr>
<tr>
<td>2017</td>
<td>161,917,492</td>
<td>168,526,539</td>
<td>330,443,031</td>
<td>228,934</td>
<td>198,356</td>
<td>223,710</td>
<td>162,900</td>
<td>61,635</td>
<td>20,727</td>
<td>13,540</td>
<td>8,672</td>
</tr>
<tr>
<td>2019</td>
<td>164,544,228</td>
<td>171,260,318</td>
<td>335,804,546</td>
<td>231,311</td>
<td>201,573</td>
<td>227,340</td>
<td>166,194</td>
<td>62,621</td>
<td>21,067</td>
<td>13,761</td>
<td>8,815</td>
</tr>
<tr>
<td>2020</td>
<td>165,859,855</td>
<td>172,629,645</td>
<td>338,489,500</td>
<td>232,184</td>
<td>203,185</td>
<td>229,157</td>
<td>167,849</td>
<td>63,121</td>
<td>21,236</td>
<td>13,872</td>
<td>8,885</td>
</tr>
<tr>
<td>2021</td>
<td>167,185,597</td>
<td>174,009,498</td>
<td>341,195,095</td>
<td>233,072</td>
<td>204,809</td>
<td>230,989</td>
<td>169,797</td>
<td>63,625</td>
<td>21,406</td>
<td>13,983</td>
<td>8,956</td>
</tr>
<tr>
<td>2022</td>
<td>168,521,475</td>
<td>175,399,903</td>
<td>343,921,378</td>
<td>234,975</td>
<td>206,464</td>
<td>232,835</td>
<td>171,644</td>
<td>64,134</td>
<td>21,577</td>
<td>14,095</td>
<td>9,028</td>
</tr>
<tr>
<td>2023</td>
<td>169,867,835</td>
<td>176,801,217</td>
<td>346,669,052</td>
<td>236,825</td>
<td>208,095</td>
<td>234,695</td>
<td>173,441</td>
<td>64,646</td>
<td>21,750</td>
<td>14,207</td>
<td>9,100</td>
</tr>
<tr>
<td>2024</td>
<td>171,225,208</td>
<td>178,213,991</td>
<td>349,439,200</td>
<td>238,253</td>
<td>210,758</td>
<td>236,570</td>
<td>175,879</td>
<td>65,162</td>
<td>21,923</td>
<td>14,321</td>
<td>9,173</td>
</tr>
<tr>
<td>2025</td>
<td>172,592,106</td>
<td>179,636,682</td>
<td>352,228,788</td>
<td>240,771</td>
<td>214,432</td>
<td>238,459</td>
<td>178,127</td>
<td>65,660</td>
<td>22,275</td>
<td>14,551</td>
<td>9,320</td>
</tr>
<tr>
<td>2027</td>
<td>175,352,231</td>
<td>182,509,464</td>
<td>357,861,695</td>
<td>244,972</td>
<td>218,814</td>
<td>242,272</td>
<td>184,847</td>
<td>66,604</td>
<td>22,831</td>
<td>14,834</td>
<td>9,469</td>
</tr>
<tr>
<td>2028</td>
<td>176,748,213</td>
<td>183,962,425</td>
<td>360,710,638</td>
<td>246,189</td>
<td>221,524</td>
<td>244,201</td>
<td>187,223</td>
<td>67,131</td>
<td>22,993</td>
<td>14,901</td>
<td>9,544</td>
</tr>
<tr>
<td>2029</td>
<td>178,156,373</td>
<td>185,428,062</td>
<td>363,584,435</td>
<td>248,293</td>
<td>223,865</td>
<td>246,147</td>
<td>189,611</td>
<td>67,623</td>
<td>23,183</td>
<td>15,020</td>
<td>9,620</td>
</tr>
</tbody>
</table>
The following Figure is a detailed close-up of the separate costs of the first year incidence. The key observation is that lung has the highest amount but it also has the lowest survival. This maintenance should be expected to be somewhat lower.

![Costs for First Year Cancer Incidence](image)

We have the maintenance costs here. What is both surprising are the costs or four year maintenance of lung cancer. Here we have the costs for all people who have had the disease for 2, 3, 4, 5, years. This includes taking into account the losses due to deaths.
The following Figure is thus the sum of the two for 2008 by disease. Lung cancer dominates at $80 billion direct costs. This has always been a known fact. The incidence of this may decrease in the event of continued downward pressure on cigarette smokers.
Finally we present in the following Figure the total costs for treatment of these eight cancers. Note than in 2008 it is $250 billion and this is more than 10% of all health care costs. As we have said previously, by controlling these, type 2 Diabetes, and secondary effects of cigarettes smoking we can reduce health care by almost 25% from its current run rate.
Thus from the above summary chart we see that these eight cancers which we argue are controllable contribute more than 10% of the total expenditures for health care. As we had shown in the Type 2 Diabetes paper that constitutes another 10-12% and cigarette smoking effects aside from lung cancer, such as heart and emphysema add another 6-7%. This in total is almost 25% of the total amount. We find it amazing how the totality of plans fails to address the demand issue which we have been looking at. They all seem to worry about how to pay for it not how to reduce the demand.

4.4.4 Impact of Controllability

We can now consider the impact of controllability. We assume that if we can remediate by taking the actions in diagnosing early and reducing any substantial surgery or by diagnosing early and having minimal surgery that we can reduce the costs dramatically. We have performed that analysis herein.

In this analysis we phase in a system of screening and remedial treatment for screened patients and phase it in over this period linearly. We used standard 2008 dollar costs for screening and then we use remediation costs as discussed.

The following Figure depicts the costs per year as we vary pre-screening compliance. It must be remembered that there are still surgical costs because of breast surgery, skin
excisions and the like but that the costs are lower and the ongoing maintenance is also substantially lower due to low rates of metastases. There is a substantial savings in all of these plans. The most likely scenario is a phased introduction on compliance and thus we would expect the high amount early on and then the lowering to the lower scales.

The following looks at 2030. This makes clear the impact in that year of the use of compliance, a factor of 15% reduction in costs despite the increase in population by 40%. However this analysis still assumes that no medical advances are made in this twenty year period, no genetic therapies are achieved. We recognize that that assumption is at its core false and thus we would anticipate even further savings.
Finally we look at three scenarios. They are for 0%, 40%, 100% remediation linearly over 2010 to 2030. The result is shown below.
We then show it as a percent of total costs in that year. Note the decrease as we screen.
Note that the no remediation grows from $250 billion to over $300 billion. The 40% plan shows some reduction in rate of growth. The 100% compliance plan shows almost a flat profile in cost despite a 40% increase in population.

The following Figure shows an example of the costs per disease and by percent for each part, treatment, screening or remediation.
Note in the above that the ratio of screening to remediation is a metric of interest. We show that detail below.
Here we see that the prostate, colon and breast cancers have a good screening to remediation ratio. That is there is a high incidence and high costs per incidence. Screening is done over all the population and remediation on this with incidence. In contrast treatment is done only on those with incidence and frequently since screening is not performed the treatment is considerably more costly than remediation. This is a bit more complex. For example in melanoma screening can recognize a lesion at low costs and result in a low cost of removal. Thus the high screening cost percent is really a low screening cost in total. The ovary cancers are by far more costly since remediation requires surgery, albeit less complicated. The cervical case is more akin to melanoma.

4.4.5 Remediation Plan

The next question is how do we achieve this controllable position. Namely what will motivate a patient to seek out the controllable options necessary to achieve the reductions? This is an economic as well as psychological issue.

Economically we can propose that we compensate a patient for having sought a controllable disease evaluation by having some form of rebate. The opposite which is a penalty on health care premiums is a negative approach. Either way it results in a sloping demand curve.
The second issue is that of psychological control. The major problem, even in universal health care, is patient participation. For example, colonoscopies can be life saving yet patient at high risk, say having multiple first degree relatives with colon cancer, refrain from being tested. This is due to fear, dislike of the test procedure, embarrassment and many other factors which are independent of cost or availability. It may also be cultural. Thus besides a financial motivator, a pure economic solution, some form of persuasion or education is essential.

4.5 Conclusions and Recommendations

This study has focused on potentially remediable cancers which can be caught early and that the risk of mortality and severe morbidity can be reduced. However this study has raised several key issues, and there are recommendations related thereto.

1. Medical practice is a continuing evolving process and the prediction of the future based solely on the past is fraught with errors and distortion. The preponderance of health care plans and analyses fail to account for anticipated changes in the practice of medicine and this failure results in significant projection errors in costs as well as significant errors in the structures used for the servicing of the patients.

2. Genetic techniques for determining susceptibility, existence, staging, and prevention may very well be the key advances over the next twenty years and as such their effects may dramatically outweigh the impacts of cost reduction. As such the allocation of funds into these areas and the use of highly focused research in these areas will have payoffs which could be highly exceptional in the long run.

3. The patient’s willingness to accept responsibility for their own care is fundamentally at the core of improving health care in the United States. Whether from fear, ignorance, or whatever the reason, patient compliance with medical advice and control of life style as well as the patient’s adherence to screening regimes will be an essential part of any plan achieving its goal.

4. There is a changing set of paradigms in the delivery of medicine with the expansion of genetic based care. This paradigm shift will require changes in the way health care can and should be provided and may likely result in the distribution of health care delivery assets.

5. There are a set of controllable cancers which can be managed with the tools that exist today and which are highly likely to be addressed by the genetic techniques which are evolving. The set of such cancers today represent a significant number of all cancers in totality. It is anticipated that this will continue to expand.
6. Physician education must be expanded on a continuing basis to motivate patients to be screened using current techniques as well as being prepared to more widely disseminate the genetic techniques as they evolve.

7. Government spending should focus on a strategic set of genetic medical goals in the areas of screening, staging and prevention, and this focus should be a broadly based approach on the most impacted cancers to demonstrate that the genetic applications are the most efficacious.

8. The changes in the practice of medicine for this class of disease using genetic methods may alter the nature of the relationships between the existing players; physicians, hospitals, drug manufacturers, and Government. There is a natural tendency to maintain the status quo in a set of power relationships. If genetic treatments can be performed extra a hospital based environment than the hospitals may be reduced to institutions to deal with chronic care, and acute care for those requiring immediate support only provided by that environment. There may very well be strong institutional resistance to these changes.

9. Genetic medicine will suffer great regulatory lag. The FDA and other regulatory entities generally have a slow and aged process to deal with drugs and lack fundamental understandings of the new genetic treatments. This will result is massive regulatory lag in releasing treatments.

10. The proposed Comparative Clinical Effectiveness, Evidence Based Medicine, and similar movements will also create a slowness in adoption of new therapeutic measures. They will create methods and processes that will demand long duration testing and evaluation of any new procedure and process thus prolonging introduction, increasing and sustaining costs and causing increased mortality and morbidity.

11. The use or remedial screening of patients for targeted cancers can have a dramatic effect on overall health care costs, reducing them by a factor of 3 or even more. However those numbers assume the practice of medicine on an as is basis and does not factor in any new diagnostic or treatment options as would be anticipated with the inclusion of genetic methods and techniques.

12. With the introduction of genetic medicine to diagnosis, treat and prevent large sets of what can be controllable diseases, using the cancer set discussed herein, the impact of this new treatment regimen will result in a significant structural change in the delivery of healthcare. As psychiatric hospitals went through massive shifts in the late 1960s and early 1970s with the introduction of psychiatric drugs such as haloperidol and the like, setting out many patients into the outside world now controlled by drugs, it is possible that the current hospital system may go through a similar shift.
4.6 Appendix A World View

We spend a few thoughts in this appendix on the concept of architecture and world view. The "architecture" of health care is the set of "instruments" which are used to diagnosis and treat disease. The western world has evolved a view of medicine as composed of the diagnostic and treatments tools, methods, procedures and their interrelationships which in their totality constitute what we call the health care system. These elements and their inter-relationships are the architecture.

They are predicated on paradigms or examples which we rely upon for validating this collection of interconnecting elements in our minds as a holistic and believable effort with the end goal of providing good the people treated in its confines. However it is often worthwhile to step back and examine these elements and to reassess what is being done is being done in a manner which meets the overall goals and is evolutionary can changes to permit new methods, techniques, elements and processes. Furthermore by stepping back we may have the opportunity to glimpse at the possibility of creating and introducing new and more efficacious elements into the world.

We will argue that comparative clinical effectiveness and evidence based medicine are nominal extensions of the current architecture of medicine based on existing paradigms and embedded in the well established world views. The problem that these two approaches may have is that they may tend to reinforce this existing and possibly soon to be outmoded viewpoint.

Politicians and policy makers all too frequently, and in my opinion almost always, look backward, repairing the inefficiencies of the past if possible and promoting the interests of the present. They do not, and more than likely lack the ability to, look forward. However it is incumbent upon the medical profession to do so. The introduction of genetic methods and techniques as related to diagnosis and treatment will be earth shattering. This section lays a bit of a philosophical framework for that effort.

The concept of an architecture of the disease process has been an unarticulated but inherent cornerstone in the development of medical care. That medical architecture has a set of elements, beliefs, preconceptions, processes, procedures, rituals and the like. It is to some degree scientifically and evidenced based. It has the diagnostic criteria, along with the tests and procedures, and the treatment protocols. It also includes how these are developed and vetted. However, the structural elements of these architectures have often not played a role in the development of policies. In this section we will briefly look at the concept of an architecture as a means to understand the issue of health care and will provide a new set of perspectives for viewing health care in terms of a new paradigms and world views.
An architecture, first, requires that the underlying system be treated in terms of a set of commonly understood elements and that these elements have a clearly demarcated set of functions and interfaces that allow for the combining of the basic set of elements. The way the elements then can be combined, reflected against the ultimate types of services provided, determine the architecture. In health care these elements are the diagnostic tools and procedures and the treatment protocols.

An architecture, secondly, is driven by two factors; technology and world view. Technology places bounds on what is achievable, however those bounds are typically well beyond the limits that are self-imposed by the designer or architect in their view of the user in their world. This concept of architecture and the use of design elements are critical in understanding the paradigms used in the structure of information systems. World view is the more powerful driver in an architecture. We argue in this paper that it is essential to develop a philosophical perspective and understanding of how to view networks. We argue with Winograd and Flores, and in turn with Heidegger, that we must be thrown into the network, to understand the needs of the users, and to understand the structure of the paradigms that are used to construct the world view.

To better understand the importance of an architecture we develop the concept of the historicity of architectures based upon the work of Kuhn and ten that of McLuhan. Kuhn begins his thesis of how scientific revolutions occur by the introduction of the concept of paradigms. Kuhn defines these as;"...the term paradigm is used in two different senses. On the one hand, it stands for the entire constellation of beliefs, values, and techniques, and so on shared by the members of a given community. On the other, it denotes one sort of element in that constellation, the concrete puzzle-solutions which, employed as models or examples, can replace explicit rules as a basis for the remaining puzzles of normal science, The first sense of the term, call it sociological, ..., “

The concept of a paradigm is in essence the collection of current technologies that we have at hand for the network and the ways we put these elements together. New paradigms result from new technologies. New technologies allow for the placing of the elements together in new ways. Kuhn, then goes on to demonstrate that the world view, that is how we view ourselves and our environment is based upon the our acceptance of these paradigms, as either collections of techniques and technologies or as collections of embodiments of these techniques and technologies in "examples". We then end to accept this as the way things are and should be.

Then Kuhn argues, as the technologies change, changes in the paradigms do not occur in a continuous fashion but almost in quantum leaps. The new paradigms build and congeal until they burst forth with new world views. It is this model that we agree applies to the evolution of broadband.

It is this philosophical view, almost Hegelian in form that is essential in understanding the underlying and formative changes in paradigms that will change our world view.
As a second perspective of the impact of technology as a dominant driver, we can refer to McLuhan and his development of the concept of media. Drucker has referred to the presentation of McLuhan's doctoral thesis and McLuhan is quoted as follows (See Drucker, p. 250):

"Movable type, rather than Petrarch, Copernicus, or Columbus was the creator of the modern world view..."Did I hear you right," asked one of the professors as McLuhan had finished reading, "that you think printing influenced the course the universities taught and the role of the university, altogether?" "No, sir," said McLuhan, "it did not influence; printing determined both, indeed, printing determined henceforth what was going to be considered knowledge."

This concept later evolved into the medium being the message. In our context it is the fact that both Kuhn and McLuhan recognized, albeit in differing fields and in differing ways, that fundamental changes in technology and technique, call it paradigm or the medium, will change the world view, also the message.

It is the importance of understanding the change in the technology, its function and evaluates the possible change that this will have in the world view. It will be argued, that much of the thinking in the current diagnostic and staging areas, staging in particular, is based upon possibly outmoded techniques and structures, and that a differing world view will evolve as we introduce genetic based methods and methodologies. We shall develop this construct more fully as we proceed.

The concept of a world view is an overlying concept that goes to the heart of the arguments made in this paper. To better understand what it implies, we further examine several common views and analyze the implications of each. If we view our world as hierarchical, then the diagnostic methods as well as treatment protocols may very well reflect that view. If we further add to that view a bias towards gross physical measurements and realities as compared to genetic elements, these two elements will be reflected in all that we do. The very observations that we make about our environment and the needs of the users will be reflected against that view. As an external observer, we at best can deconstruct the view and using the abilities of the hermenutic observer, determine the intent of the builder.
5 THE ELECTRONIC MEDICAL RECORD

Medical costs continue to rise faster than inflation but less than higher education. There is a commitment from the Obama Administration for some form of Universal Healthcare and control over it by the Federal Government. The articulation is not as clear as the Hillary Plan of almost twenty years ago, Obama and others seem to recognize that such an outright takings of the healthcare of the country by the Federal Government was a bit too overreaching, but it is nationalization in many ways. The entry point seems to me through what is called the Electronic Medical Record, the EMR.

We have spent a great deal of effort over the past twenty years looking at and working with electronic medical record systems. They are like puzzles, you can sole one parts while the others just sit there like unassembled pieces. They defy solution, for a variety of reasons. Our first efforts started in 1988 with a joint effort with the Harvard Teaching Hospital and Tufts Medical Center. This was an attempt to use broadband, as fast as it was then, 45 Mbps, and integrate imaging and other medical modalities into an electronic medical record. This was a holistic approach recognizing at one extreme the importance of multimedia elements and at the other the mundane issue of billing and administrative overhead.

In 1993 we prepared a detailed paper looking at the massive deficiencies of the Hilary Health Care Proposal, HHCP, and we proposed at that time what is now know as the Electronic Medical Records system. That was more than fifteen years ago. In this paper we re-look at these issues and address them in the context of the proposed Obama efforts. In the Obama case he is proposing using EMR as an economic stimulus. Albeit there has been a great deal of work performed in developing the EMR over the past fifteen years it is still far from complete. In fact we can argue that there are more issues now than ever before. It is far from a panacea and in fact if rushed and used as an economic stimulus it will have massive unintended consequences and set back good EMR efforts decades.

In this Chapter we review the Obama proposal, and discuss what EMRs are and what their deficiencies are. We also talk about how then can be used in the evidence based medicine, EBM, world as it is being introduced into medical practice. We look briefly at the iPatient paradigm, namely what has actually occurred when a large Medical Center introduces elements of EMR and how this can dramatically change the practice of the profession of medicine, most likely for the worse. Finally we assess the detailed strengths and weakness of EMR and then propose some recommendations. We believe that EMR is highly valuable, whatever it is, but that it must evolve, in a context to meet the needs of quality healthcare to the patient, not just turning the physician into a health care player of an electronic game. We deeply desire to avoid the iPatient result.
The incoming Obama Administration has focused on its stimulus package as one which will invest in various forms of infrastructure improvements. As Larry Summers has stated in the Washington Post 16:

"The Obama plan represents not new public works but, rather, investments that will work for the American public. Investments to build the classrooms, laboratories and libraries our children need to meet 21st-century educational challenges. Investments to help reduce U.S. dependence on foreign oil by spurring renewable energy initiatives (many of which are on hold because of the credit crunch). Investments to put millions of Americans back to work rebuilding our roads, bridges and public transit systems... Investments to modernize our health-care system, which is necessary to improve care in the short term and key to driving down costs across the board."

It is here that we see that healthcare "modernization" has a focus in the plan. He further states:

"We expect to evaluate and to be evaluated rigorously to ensure that Washington is held accountable for how tax dollars are spent."

Of course Washington has never wanted to be held responsible for any of its decisions. It is not clear what Mr. Summers means here. With there being no definition of success or failure then there will never be a way to decide if the day or reckoning should ever arrive.

The Obama Administration has also linked broadband and healthcare. The WSJ has stated 17:

"If that broadband network is built, Mr. Obama already knows one thing he wants flowing through the fibers: digitized, uniform medical records. On the campaign trail, Mr. Obama proposed a health care plan in two parts: Universal access to health insurance and a health care information technology program budgeted at $50 billion over five years. Obama aides assembling the stimulus plan wanted to use it to further the president-elect's policy goals. That health care IT program "perfectly fit the bill," an aide said. Unlike most industries, the country's $2 trillion health care system is clogged with paper, folders and plenty of clipboards.

Some 90% of U.S. doctors and at least two-thirds of hospitals still rely on paper patient records, and many of those who have gone digital can't exchange the information with

---


outside providers. The result is billions of dollars each year in administrative waste, duplicate tests and medical errors. Fixing the problem has seemed the low-hanging fruit of health reform, largely because everyone agrees going digital will improve care. But legal questions, privacy issues and the country’s fragmented system of 700,000 physicians have stymied progress. Doctors have been reluctant to invest $40,000 to $60,000 on an electronic record system that may not be interoperable with other systems, especially when much of the savings goes to insurers and other payers.

Mr. Obama has said digitizing health care could save as much as $77 billion and pay for a lot of other health care reform. The $77 billion figure comes from a Rand Corp. study, however, that adds that kind of savings wouldn’t likely be achieved until 2019 -- and only if 90% of hospitals and doctors are online by then."

Thus we see that the incoming Administration has proposed massive expenditures in broadband and healthcare, two areas which are dramatically different than highways and bridges. We all know how to build a bridge and the same for a highway. We have been doing these things since well before the Romans perfected them. Current bridges have a lifetime of fifty to seventy-five years; Roman bridges still function over two thousand years later. So much for progress. But broadband and healthcare information improvements are moving targets. There are no clear consensus on what the best technology should be, how to deploy it, what it will provide and the like. Thus lumping of these two with the more classic highways and bridges can lead to ultimate disasters. The law of unintended consequences will play havoc on the industries not to mention our economy.

5.1.1 Electronic Medical Record (EMR)

Before continuing it is necessary to give some structure to the EMR. This presentation is but a single view of what it can be in a clinical setting. There are many and it is certain that there will be thousands of other embodiments but they all will have some reflection of the issues contained in this one. Specifically we can characterize an EMR as follows:

1. The Electronic Medical Record is an abstraction with many current realities

2. The principle is that the “Record” follows the patient, in hyper-space, namely an Internet based scheme available at any point of medical service.

3. However the EMR must be a highly adaptive system providing multimedia capabilities in the extreme; images, text, data, voice, and the ability to look at the patient “over time”

4. The EMR must not turn the patient into the iPatient, some abstraction in hyper space.
The above is a concept. But it has been implemented in bits and pieces for the past thirty to forty years, with slow but growing success. In 1988 I developed the first broadband based integrated health information system jointly with Harvard Medical School, Mass General, Brigham and Women's and Children's Hospital, as well as Tufts Medical Center. The principals at the Harvard Hospital included Dr. David Margulies and Dr. Ted Treves. The system was designed, implemented and deployed, using a 45 Mbps network to interconnect facilities as well as physician offices. A common record format was developed, email capabilities, storage capabilities and data retrieval was also integrated. The architecture as developed in 1988 is shown below. This is what was implemented. This is twenty years ago, using Sun and DEC work stations rather than PCs and using earlier versions of screen access and control before html and the like.

---


19 David Margulies, MD, was at the time the CIO of Children's Hospital as well as an attending physician in Internal Medicine. Ted Treves MD was and remains a Professor at Harvard Medical and head of Nuclear Medicine at Children's Hospital Margulies left and became the CTO of Cerner one of the largest electronic medical record companies in the world for managing lab results.
This was a four layer system; transport, network, systems and applications. It was a fully integrated architecture with an open design. It migrated to a fully IP based platform as well. It recognized that medicine is a multimedia world, having text, images, path slides, blood work results, and the like.

The system was implemented but it ran across many problems. The greatest was institutional blockage. There classic turf wars in any institution where one group is perceived as telling another what is best and other groups feeling that they are losing control. It ran across the problem of insurance and payment. The systems attempted to effect pre-approval of procedures and thus cut down on insurance costs. The insurance companies just balked, they wanted to apply their classic "passive aggressive" approach to health care cost containment. Then there were the legal issues; that is malpractice suits could explode if one made these records readily available. Or perhaps as some lawyers said the patient record could become fungible and changeable being in a digital form rather than in the hand of physician.

In addition there was a change in the provision of health care which this system could adapt to but
5.1.1.1 Examples

We provide here three simple examples of the potential complexity and usefulness of an EMR.

5.1.1.1.1 Example 1:

Several physicians have been following this patient for five years. They have had access to the patient's daily blood sugar tests, which have been electronically shared in a common EMR, and specialist to seek a consult on whether he should consider medication. His fasting blood sugar has been consistently peaking above 100 but his HbA1c is 5.2%. The concern is a pattern of increase in FBS.
The problem presented above is that the patient must take blood sample twice a day, every day, and the results must be recorded in the patient record and reviewable by the physician. It also must become an input into what we see as the bases for Evidence Based Medicine. The patient has treated his Diabetes by diet and exercise and has for a period of six years kept the HbA1c well below 7. However there appears to be an increasing trend and should the primary physician look more closely to see if this is addressable by stronger diet and exercise controls or is this evidence of the recurrence of T2 Diabetes returning, which is assumed to be a matter of course in the long term.

This patient presents a case where real time data collection can assist. T2 Diabetes can be "cured" in over 90% of the cases by diet and exercise alone. In fact the use of drugs like metformin and insulin may exacerbate other conditions. The positive feedback of daily results may provide a behavior modification which effects better compliance without drug use. The result is dramatically lower costs by not using drugs and not resulting in any secondary effects such a kidney failure or heart disease.

5.1.1.2 Example 2:

A patient whose father died of a very aggressive form of prostate cancer at 79 has been followed by several physicians for fifteen years. The PSA has gone from 0.6 to 1.45 over that period and there have been several years with percent jumps which have well exceeded the 25% per annum change which would normally warrant a biopsy. Should
this patient proceed to an ultrasound and subsequent biopsy, which percent guideline recommends or should the patient have watchful waiting\textsuperscript{20}.

![PSA Values and Velocity graph](image)

This example demonstrates the usefulness of having long terms data available on a patient and having the changes also available. Prostate cancer is most often noticed in changes in PSA, namely change per annum in percent. A 25-30\% change is what most of concern is. In this patient there is a large change in the mid 90s but that may have been the result of a change in test methodology. Since the patient was young and since the PSA value was low, this was neglected. It showed a reduction the following year. However it has been increasing somewhat on a trend since 1996 going from a 0.6 to the current 1.4. However it has been relatively stable for four years.

5.1.1.3 Example 3:

A fifty year old female patient arrives at the Emergency Room with lower right quadrant pain, afebrile, and is in no other distress. She has been a patient at this Hospital before

\textsuperscript{20} See http://content.nejm.org/cgi/content/full/359/24/2605 for an interesting study of three treatment options.
so that when she arrives the attending physical calls up a recent CAT scan as shown below along with the report of the radiologist taken at that time.

The patient has blood drawn and the attending wants to look more closely at the morphology of the red cells, he is concerned that there may be blood loss and some anemia. The cells are shown in contrast below. The attending can manipulate this image to obtain better resolution with the facilities on the terminal in the ER. He then looks at the data on the patient count as well. He records his findings.

This is an example of a multimedia diagnosis using past and current data. It will assist the physician in targeting a closer examination of the lower abdomen of the patient.

The above three examples show several important things about the EMR. First none of them contain a physician's comments. They are all images. The first example shows how an EMR can result from patient generated data and can then be used to feedback to the
patient for patient adjustment to meet the goals of the management of the disease. The second example shows the criticality of presenting long term data. All too often the physician files reflect at best the last data point. As with the first example, fasting blood sugar is useless as a single measurement, unless severely off from the norm. It is like taking the blood pressure of a patient awaiting a potential diagnosis of cancer; it will be high! The third example is a case where having images taken at a prior time and a different location is critical. Also it shows the correlation in modalities as an integral part of the EMR. Again, there is not a single word written.

5.1.1.2 The Disadvantages of EMR

There are many disadvantages with the EMR. We recount a few here. They are not at all insurmountable, and it is just a matter of time and working with evolving versions of them that will effect positive change. However one would be wrong to assume that we are at a point that just throwing money at the EMR issue will result in its solution. I am certain that there are many companies who would sell their wares claiming solutions but as we all know these solutions are as culturally based as they are technically. Frankly there are very few if any technical problems. There are however almost insurmountable cultural one at this time. Let us examine a few.

5.1.1.2.1 Patient Histories are Complicated

The first thing a Medical Student learns after the course work is taking a patient's history. This is a ritual of passing, from learning to listening, not just asking questions and getting rote answers, but seeking out from the patient what the real problem is. The patient typically arrives with a sense of dread, no matter what the problem is, they have most likely aggrandized the problem into the potential of a serious one, and the physician is seeking to look through this detail and obtain a better understanding of what the true problem is. Thus the eliciting of information in this manner is not always readily amenable to a computerized system.

5.1.1.2.2 Electronic File Cabinet versus A Searchable Data Base

One approach to the EMR is just taking the patient record and storing it in an electronic file cabinet. That is possibly a pdf file and then keeping it so that at some future time it may be extracted and reviewed. The second approach is if the searchable file database is available. In this case one asks the patient questions and enters a pre selected set of answers. In fact the patient may very well not need a physician to even go this far. At one extreme we keep what has been done all along and just digitize the result and at the other extreme we enter the data in a digital form ab initio.

5.1.1.2.3 Data Versus Patient Information
Having access to the patient, looking at, talking to, listening to, performing certain maneuvers on the patient to test for certain response is critical. Using the EMR terminal by itself after ordering tests and making all decisions at the point of the terminal, most likely because of its apparent efficiency, can result in diminished patient care caused by not seeing certain artifacts of the patient and the disease evident only through observation. Neurological disorders are typical. The neurologist looks at a patient differently than an internist. The Internist looks at a patient using the eyes of a differential diagnosis; what are the possible disorders given the presenting symptoms and then eliminate those that do not fit. It is a process of elimination. The neurologist looks at the patient to ascertain where the neurological fault is, the spine, the limbs, the mid brain, the hypothalamus, the cerebellum, the frontal lobe. Then and only then does the neurologist tries to find out what may be causing the defect. Information on the patient is not all found in the data record.

5.1.1.2.4 Multimedia Issues

There are in medicine many multimedia studies which are complex but critical to the patients diagnosis and care. Many of these are imaging such as CAT, PET, MRI and all variants thereof. We have shown the multimedia elements in some of our previous examples. Imaging and hematological results can be accessed directly but they must also be processed, enhanced, compared, correlated, and commented upon, and then they in this form must be actionable in terms of patient care. Finally the multimedia world will result in massive volumes of storage. Consider the following examples:

<table>
<thead>
<tr>
<th>Modality</th>
<th>Technical Driver</th>
</tr>
</thead>
<tbody>
<tr>
<td>Multi-Slice CT or Volume MR</td>
<td>&gt;1000 images, 1024<em>1024</em>2Bytes, &gt;2 gigabytes/Study</td>
</tr>
<tr>
<td>User-Friendly Ultrasound - Volume</td>
<td>Laptop/Handheld/PDA, 3D, 128 x128 x 32, But... &gt;20 images/sec</td>
</tr>
<tr>
<td>PET/CT, SPECT/CT</td>
<td>More agents (C11, O15, NH3 -&gt; function, staging, guide Rx</td>
</tr>
<tr>
<td>Multimodality Image Fusion</td>
<td></td>
</tr>
<tr>
<td>Optical Imaging</td>
<td></td>
</tr>
<tr>
<td>CAD</td>
<td>Extend techniques from Mammo, Lung, Vascular, Neuro</td>
</tr>
</tbody>
</table>

There are trends seen in these systems21:

21 From Dr Ted Treves, Children's Hospital, Boston, and Harvard Medical School. Personal Communications January 2008.
• Workstations will become intuitive customizable multimodality platforms
• Individual imaging specialists will be “served” with more information automatically based on the individual examination
  – Clinic or ER information
  – Results of relevant lab tests
  – Current and Prior relevant images presented according to preferred display protocols
  – Images already fused

• Images and reports will become a routine and integral part of the electronic medical record
• On-line decision support will be easily available to the imaging specialist
• Reporting will become richer
  – Voice
  – Text
  – Text overlays
  – Pointers

Applications include

• Reporting
• Consultation
  – Rounds Image annotations including voice objects
  – Interactive consultation (i.e.: sharing a pointer and voice with another physician on-line (or off-line by means of multimedia objects: image voice and text)
  – Joint reporting by more than one imaging specialist

However meeting the challenges of these trends is quite difficult. Many entities are working on the complexity of the multimedia challenge and have been doing so for two decades. I taught the first course on Multimedia Communications in 1989 at MIT. It was a first step and the main concern was the philosophy of what we were doing more than the technology. I started out assuming it was a simple technical problem but after some thought it was clear that the old Marshall McLuhan phrase that "The Medium is the Message" would clearly play its part. One must be careful than what the message becomes in an EMR system.

5.1.1.3 The Use of the "Commons" for EMR

Eric Schmidt, the CEO of Google, and a major Obama backer, has started a Google offering of Google Health which is Goggle's view of what a physician should do. One may admit that Google is a good search engine and dominates that space but one must question whether they are the true answer for this problem. The Google Health concept
is one of the many which employ what is called the Commons, using the capabilities already in hyperspace to follow the patient.

It comes as no surprise then that Google, its executives being major Obama supporters, have positioned Google Health as a major player in this new Market.

The first Figure below depicts the current structure of Google Health. It has the patients Health Record, allows for importing medical data, connects to online health information and then allows for finding physicians.

Many have tried out the Health Record and frankly any first year Medical Student would probably fail their course on history taking with what is available any physician worth their salt would most likely go elsewhere. But this is a start. It is cumbersome with all the manual entries. This it is even more complicated for the physician.

The Record contains the demographic data, conditions and history, procedures performed, test results, immunizations. It does not permit ready comparison of HbA1C for example to monitor Type 2 Diabetes or ESR or CA 125 or a wide variety of tests which a physician wants to see change readily. It also lacks any multimedia ability to incorporate CAT, MRI, pathology slides, and ultrasounds.

One attraction may be, however, that as a Commons, the Google approach may allow other entities to connect through it. The next Figure depicts some of the current connections available. It is patient directed and the patient or physician may access lab
results, hospital tests and the like. This is attractive yet as we have stated they lack the multimedia and temporal analyses capabilities which are critical. They also lack the ability to be readily used for studies.

The External Medical Records function is displayed below. It can get distant records and import them into a common form and it can convert records, although in a limited manner, and it can share them. This in many ways is a limited version of what we designed twenty years ago.
The structure of the final EMR is shown in the following Figure. The import of medical records is attractive since it allows the patient to import lab tests say from Quest or records from your hospital or from other sources. It is a patient oriented system and functions well for a cumbersome initial attempt.

The medical records can be imported, copies, shared, converted and thus have a potential for wide accessibility. The problem again is that they are so rudimentary that they are virtually useless in any real medical environment. They also lack any Evidence Based Medicine inputs which we believe will be critical. They also seem at this stage to lack pharmaceutical interaction and of course there is no pricing or costs information, thus billing and awareness of costs is totally lacking.

The final chart below shows the details of the medical record we have discussed above.

Finally, one wonders of this is a Trojan Horse for the EMR push that is in the new Budget. Clearly Google has the technology and political connections. It seems to lack the "business side" of the equation however. It lacks what Vint Cerf and Bob Kahn assembled in the days of the Internet's beginning, an IETF type organization, an entity of involved practitioners. That, in our opinion, is an essential and critical element in getting this effort moving and accepted. It must have that ground up effort.
5.1.1.4 Integration of Data Elements

Integrating text, time data, images, lab results, and pathology results, electro testing (cardiology, neurology and the like) into a single searchable and presentable record is no mean task. The EMR is not just an electronic file cabinets. If that is the paradigm then the result is useless.

5.1.1.4.1 Retrieval and Correlations

How the data is stored, retrieved and correlated is a non trivial problem. First is the amount of storage and it accessibility. The second and truly most critical issue is the searchability of these records. How does the EMR deal with searching across complex multimedia objects? Take a CAT scan; it may consist of 75-90 slices, each containing some information. The disease process may be best articulated on slice 57, for example. That may be on the radiologists report. That is most likely searchable, but it

Of course one could try the Data Warehousing approach which is just dumping all the data in one heap and then sorting thru it after the fact as suggested by Teradata, see [http://www.nytimes.com/2008/12/29/technology/29hewlett.html?_r=1&adxnnl=1&ref=business&pagewanted=print&adxnnlx=1230558491-g2vD5ie88HtwfdwEakudxQ](http://www.nytimes.com/2008/12/29/technology/29hewlett.html?_r=1&adxnnl=1&ref=business&pagewanted=print&adxnnlx=1230558491-g2vD5ie88HtwfdwEakudxQ) Yet if one has the opportunity to start afresh then one should at least try to get it right from the beginning.
must readily tie into the CAT scan images and the remaining images must also be searchable.

5.1.1.4.2 Networking and Sharing

Sharing the data is a very complex networking problem. There is the intra-institutional and the inter-institutional issues. Within a teaching hospital, for example, there is the attending and consults, the labs, the path, the imaging, and added to this is the admin and the billing, not to mention all the residents wandering through the process. Thus there are many forms of multi-media data; image, slides, new and old, voice and text, scanned paper, EKG, and ultrasounds, and the list goes on. Physicians want to see the CAT as well as read the report. They want to see the CAT and ultrasound and have the lab work and not just rely on the reports.

5.1.1.4.3 Histories and Profiles

Physicians also want to see the history. Disease is a process of change from a norm. The first part understands the norm and the second part is managing the change. Spots on the lung may not mean anything is they have been there for twenty years. PSA of 4.5 may also not be a serious concern if it has been that for twenty years, assuming the same test procedures are used. Thus networking and sharing in a spatio-temporal context will be a key element. This means inter-institutional and stored for indeterminate periods of time.

5.1.1.4.4 Security and Privacy

The HIPPA laws place great restrictions on patient data. For example it requires faxing and prohibits email\textsuperscript{23}. Now that may have been fine in 19965 but it is absurd in 2009. There is the strain between patient medical records privacy and the need to share information between medical professionals and even back to the patient them. Finally, the HIPPA rules have become a straitjacket on the development of medical information systems, because all such systems must be HIPPA compliant. Patient information privacy is a true essential if there is to be any trust in the medical system. Yet access to information by those studying the efficacy of drugs, the performance of medical institutions and professionals, the expansion of an evidence based medicine, all rely on having a broad based access to records, devoid of patient information. Yet there is the conflict that a patient's medical file, exclusive of the patients direct personal information, may in and of itself be enough information to identify patients, it may be akin to a fingerprint in its uniqueness. There will always be a conflict between privacy and the need for more open access to non-patient identified information.

\textsuperscript{23} See http://www.hhs.gov/ocr/hipaa/
5.1.1.4.5 Litigation

There is still the problem if litigation. The physician has now a massive amount of information before them and in addition the physician may also have, or should have, then EBM information as well. Has the physician taken the correct next steps, and if not and if harm ensues to the patient, there now exists a detailed trail in electronic documents and actions that may or may not reflect the actual process. It opens many new doors for mal practice litigation, based upon what the physician should have done, given the time available.

5.1.1.4.6 Time Constraints

Data must be both current and immediate. Lab results when requested must be made available in a timely manner. Imaging studies must also fit that example. Pathology results likewise must fit.

5.1.1.5 Evidenced Based Medicine and The EMR

Evidenced Based Medicine, EBM, is a recently new approach wherein each procedure used in diagnosis and treatment is now given an assessment based upon the degree to which it has been shown in standardized medical trial to be efficacious or not.24 Thus based upon various clinical trials the techniques used for example to determine if a patient has appendicitis are examined and then are classified as to how effective they may be in determining whether it is truly appendicitis. Considerations such as the specificity and accuracy of certain procedures and then the effectiveness of certain treatments and even the effectiveness of certain preventive measure are considered.

Younger physicians are now more frequently trained in the EBM approach and they all too often may question an experienced physician as to what basis they have used to make the diagnosis or assert a treatment. EBM is in a sense a more scientific method of practicing medicine and in certain ways it is a way to practice which may help to avoid litigation. However it can become a straight jacket if applied excessively for many problems have yet to be studied using this approach.

However the use of the EMR can potentially create a massive data base which in turn adds to the underlying elements of EBM. The EMR if statistically valid and if applied appropriately can become the main drive in an EBM paradigm.

5.1.1.6 The iPatient Syndrome

---

However, with the combination of a workable EBM using EMR on a national basis and adding to this the demand to interact with the data, qua data, and actually qua disease, the physician may lose contact with the patient. A hundred years ago, when physicians visited patients and when physicians walked the wards of hospitals, such things as looking at the patient, listening to the patient, even smelling the patients urine were common place. The old adage was “If all else fails listen to the patient....” for sooner or later the patient will let you know what is wrong. However the EMR and EBM approach sets the patient to the background, tests are processed, results are entered, and the summary and even detail are made available on the monitors. These monitors reside in the physicians room on the floor and in many ways the new young physicians sit and look at the data, look up references in the medieval literature, scan for the use of other tests and data and in many ways reduce the patient to a far off element of this process, like a router in a large IP network supporting the Internet, distant, possibly malfunction, but it can be pinged with various tests to see what is wrong with it. The patient has been turned into an iPatient.

Dr. Verghese, from Stamford, has recently written a superb piece in the New England Journal of Medicine, NEJM, on the use of EMR at the Stanford Hospitals. In many ways it is most likely the same at other Tier 1 Medical Centers, albeit with some changes. From the NEJM Verghese states the following25:

"On my first day as an attending physician in a new hospital, I found my house staff and students in the team room, a snug bunker filled with glowing monitors. Instead of sitting down to hear about the patients, I suggested we head out to see them. My team came willingly, though they probably felt that everything I would need to get up to speed on our patients — the necessary images, the laboratory results — was right there in the team room. From my perspective, the most crucial element wasn’t.....

Still, the demands of charting in the electronic medical record (EMR), moving patients through the system, and respecting work-hour limits led residents to spend an astonishing amount of time in front of the monitor; the EMR was their portal to consultative teams, the pharmacy, the laboratory, and radiology. It was meant to serve them, but at times the opposite seemed true.....

The other way — call it the expedient way — is not formally taught, and yet residents seem to have learned it no matter where in the United States they trained. The patient is still at the center, but more as an icon for another entity clothed in binary garments: the “iPatient.” Often, emergency room personnel have already scanned, tested, and diagnosed, so that interns meet a fully formed iPatient long before seeing the real patient. The iPatient’s blood counts and emanations are tracked and trended like a Dow Jones Index, and pop-up flags remind caregivers to feed or bleed. iPatients are handily

discussed (or “card-flipped”) in the bunker, while the real patients keep the beds warm and ensure that the folders bearing their names stay alive on the computer.

The problem with this chart as surrogate-for-the-patient approach is — to quote Alfred Korzybski, the father of general semantics — that the map is not the territory. If one eschews the skilled and repeated examination of the real patient, then simple diagnoses and new developments are overlooked, while tests, consultations, and procedures that might not be needed are ordered."

He uses the term iPatient, because the use of the technology moves the physician more and more in front of the screen, making the patient at best a small part in the process of providing medicine.

5.2 Past Policy Positions

In our 1993 paper regarding the issue of the Hillary Health Care Plan, we laid out five issues we felt were important in developing policy. We restate them here since frankly little has changed in sixteen years.

"To develop the policy issue we pursue a five point analysis. Specifically;

Epidemiological: First we review the epidemiological factors in this process. The demographic base of health care consumers if one of these elements. The second element is the distribution of diseases in this population. The argument made in this paper is that is the demographic and disease profile that drives the entire process and not the unit costs. The unit costs are a reflection of internal operational efficiencies or inefficiencies.

Measurement and Management: Having established the basis of diseases and demographics as the ultimate driver, we then demonstrate how this can be measured on a micro basis and how this measurement process can be tied to quality of care delivery. We argue that price control is not the issue. Efficiency, productivity, and quality of care are the factors. We further argue that to better understand the direction to go in restructuring the HealthCare establishment it is necessary to do so in a fashion that ensures quality care. To provide quality care and in turn gains in productivity requires a paradigm shift in measurements regarding the results. This is a critically new mode of observation.

Technology Factors: Technology is the enabling agent for introducing productivity changes. The current approach to HealthCare is highly fragmented and there is a great deal of criticism of the technology that is applied. We develop a technology policy direction and provide three cases for study of how a totally integrated technology system and approach can achieve significant productivity gains.
Operating Cost Elements and Control: The epidemiological elements of the study show where the drivers are for the HealthCare field. The cost elements show where the expenses are going. The approach is to drive down the drivers as inputs to the HealthCare system, and to then also reduce the unit costs through productivity. Having shown the impact of technology, we then, in this area, develop a broad set of rules for the management of the cost side. Again, measurements and management of the quality of care and the process of care is the key element.

Policy Implications: Herein lays the most difficult choice to proceed. Policy relates to who gets what and who pays for what. We first develop a philosophical alternative base for the delivery of HealthCare. It is essential to understand what the underlying world view is that we are using in approaching HealthCare and from that see if committing world views lead to the same results. We develop an approach to policy development that uses the deconstructionist approach taken in other areas. To develop the policy issue we pursue a five point analysis. Specifically;

Epidemiological: First we review the epidemiological factors in this process. The demographic base of health care consumers if one of these elements. The second element is the distribution of diseases in this population. The argument made in this paper is that it is the demographic and disease profile that drives the entire process and not the unit costs., The unit costs are a reflection of internal operational efficiencies or inefficiencies.

Measurement and Management: Having established the basis of diseases and demographics as the ultimate driver, we then demonstrate how this can be measured on a micro basis and how this measurement process can be tied to quality of care delivery. We argue that price control is not the issue. Efficiency, productivity, and quality of care are the factors. We further argue that to better understand the direction to go in restructuring the HealthCare establishment it is necessary to do so in a fashion that ensures quality care. To provide quality care and in turn gains in productivity requires a paradigm shift in measurements regarding the results. This is a critically new mode of observation.

Technology Factors: Technology is the enabling agent for introducing productivity changes. The current approach to HealthCare is highly fragmented and there is a great deal of criticism of the technology that is applied. We develop a technology policy direction and provide three cases for study of how a totally integrated technology system and approach can achieve significant productivity gains.
shown the impact of technology, we then, in this area, develop a broad set of rules for the management of the cost side. Again, measurements and management of the quality of care and the process of care is the key element.

**Policy Implications:** Herein lays the most difficult choice to proceed. Policy relates to who gets what and who pays for what. We first develop a philosophical alternative base for the delivery of HealthCare. It is essential to understand what the underlying world view is that we are using in approaching HealthCare and from that see if committing world views lead to the same results. We develop an approach to policy development that uses the deconstructionist approach taken in other areas.

5.3 Conclusions and Recommendations

The following are several conclusions and recommendation based upon the analysis performed above.

5.3.1 **EMRs have Value**

Cleary the EMR, in its broadest sense, has and will continue to have substantial value. It can be a mechanism for ensuring patient health, collecting data on procedures and drug efficacy, looking at real time epidemiological trends, and monitoring and managing the patient.

5.3.2 **EMRs Must be Designed to Ensure Patient Care**

The tale of the iPatient at Stanford is a telling description of how the EMR can take the physician away from the patient and hinder patient care rather than improve it. It dehumanizes the patient and makes the patient an elements in some data collection network which then needs the full time care and attention of the physician, feeding the system with mouse clicks and key board entries.

5.3.3 **EMRs Must be Developed Over Time; They Must Evolve**

The EMR is at this point still a gestalt. It has embodiments in many forms, most meeting the needs of specific institutions and practices. There is nothing wrong with this approach; in fact given the complexity of the problem there most likely is no other reasonable approach.

5.3.4 **Throwing Money at EMRs is Just Wasting Money**

The proposal by the Obama Administration to effectively throw money at the EMR issues is just a waste of money. It is akin to buying a fully restored 1965 Ford Cobra for a nine month old. The infant cannot walk and more than likely is not toilet trained. At
worst the child will crash the vehicle if the child can even make it work and at worst the child will just soil the seats. The EMR is not defined, it is not mature, there is no accepted common architecture, not way to deal with all the issues and the isolated use may very well add burdens to the process of medical care to ensure that the iPatient become the norm.

5.3.5 Improper Use of EMR and Too Rapid a Deployment May Increase Costs and Increase Mortality and Morbidity

Rushing anything, especially something which has the ability to change a great deal about the way medical is practiced and delivered should be paced and measured. The law of unintended consequences continues to hang over our heads. It is clear that if the physician becomes a slave to the screen then the patient will be given short shrif. This in turn will lead to increased morbidity and mortality.

5.3.6 The US Government Should Play No Role

Just think of the FAA and the continual mess that the Air Traffic Control system has been in for decades. The US Government has never demonstrated any great competence in developing any high technology systems Even DoD has abandoned a great deal to buy "off the shelf" equipment except when it is for a specific weapon system, and then is takes ages and costs trillions. Can the Healthcare community handle this on their own, perhaps, but this is clearly a problem that has tremendous human factors issues. It is reliant upon employing a great deal of what has been developed in the commercial market and then putting it together into an architecture to meet the needs. It is iterative, and the timing on the iterative process must remain short.
6 QUALITY: THE HEALTH CARE PRINCIPLE

The single most repeated mantra spouted by all sides in the health care debate is that they want quality health care at an affordable price. We can determine what the latter means but the problem is defining the former, quality, in a manner which makes sense for the patient, not the Government, and not even the provider.

6.1.1 What is Quality

Quality is a difficult word. The current Administration ensures us we will have a quality health care system. The IOM report on Comparative Clinical Research guarantees us quality results. Is it the same word. Well I suggest we recall Alice in Through the Looking Glass:

"Humpty Dumpty took the book, and looked at it carefully. 'That seems to be done right - - ' he began.

'You're holding it upside down!' Alice interrupted.

'To be sure I was!' Humpty Dumpty said gaily, as she turned it round for him. 'I thought it looked a little queer. As I was saying, that SEEMS to be done right -- though I haven't time to look it over thoroughly just now -- and that shows that there are three hundred and sixty-four days when you might get un-birthday presents -- '

'Certainly,' said Alice. 'And only ONE for birthday presents, you know. There's glory for you!'

'I don't know what you mean by "glory,"' Alice said.

Humpty Dumpty smiled contemptuously. 'Of course you don't -- till I tell you. I meant "there's a nice knock-down argument for you!"'

'But "glory" doesn't mean "a nice knock-down argument,"' Alice objected.

'When _I_ use a word,' Humpty Dumpty said in rather a scornful tone, 'it means just what I choose it to mean -- neither more nor less.'

'The question is,' said Alice, 'whether you CAN make words mean so many different things.'

'The question is,' said Humpty Dumpty, 'which is to be master - - that's all.'
Does a word mean whatever we want it to mean, is quality something we can define and hold true to. Quality is not objective, for what one person considers important another rejects. It is not subjective, for when we collect a group of people we can ask them does A have quality and for an overwhelming majority it does or does not. Perhaps quality is akin to pornography, we know it when we see it.

Quality health care may mean we just are treated like humans, respected and considered. Quality health care is not there when you wait to see a physician and the office help shout out your formal given "Abraham" instead of Abe or Mr. Smith. You may recall that the only time you were called by your formal first name was when your mother was seeking to reprimand you for some infraction. But alas for poor quality medical office help.

Now Pirsig, the author of Zen and Motorcycle Maintenance, ZMM, has in his writings looked closely at quality. It is not that I am a fan of the Metaphysics of Quality, his fan club if you will, but he clearly laid out issues of quality and its problems.

Pirsig says:

"The definition was: "Quality is a characteristic of thought and statement that is recognized by a nonthinking process. Because definitions are a product of rigid, formal thinking, quality cannot be defined." The fact that this “definition" was actually a refusal to define did not draw comment. The students had no formal training that would have told them his statement was, in a formal sense, completely irrational. If you can’t define something you have no formal rational way of knowing that it exists. Neither can you really tell anyone else what it is. There is, in fact, no formal difference between inability to define and stupidity. When I say, "Quality cannot be defined," I’m really saying formally, "I’m stupid about Quality.""

This was his beginning of the non-definition. But an important beginning. For quality health care is not measured in QALYs and the like, it is how a person feels. A difficult task.

Pirsig goes on:

"He singled out aspects of Quality such as unity, vividness, authority, economy, sensitivity, clarity, emphasis, flow, suspense, brilliance, precision, proportion, depth and so on; kept each of these as poorly defined as Quality itself, but demonstrated them by the same class reading techniques. He showed how the aspect of Quality called unity, the hanging-togetherness of a story, could be improved with a technique called an outline. The authority of an argument could be jacked up with a technique called footnotes, which gives authoritative reference."
"There’s an entire branch of philosophy concerned with the definition of Quality, known as esthetics. Its question, What is meant by beautiful?...he saw that when Quality is kept undefined by definition, the entire field called esthetics is wiped out—completely disenfranchised—kaput. By refusing to define Quality he had placed it entirely outside the analytic process. If you can’t define Quality, there’s no way you can subordinate it to any intellectual rule. The estheticians can have nothing more to say. Their whole field, definition of Quality, is gone."

Indeed esthetics, and aesthetics does read onto to what quality is, it is a perception, not a measurable quantity.

Pirsig ends with:

""What moves the Greek warrior to deeds of heroism," Kitto comments, "is not a sense of duty as we understand it...duty towards others: it is rather duty towards himself. He strives after that which we translate ‘virtue’ but is in Greek areté, ‘excellence’—we shall have much to say about areté. It runs through Greek life." ...Quality! Virtue! Dharma! That is what the Sophists were teaching! Not ethical relativism. Not pristine "virtue." But areté. Excellence.

Dharma! Before the Church of Reason. Before substance. Before form. Before mind and matter. Before dialectic itself. Quality had been absolute. Those first teachers of the Western world were teaching Quality, and the medium they had chosen was that of rhetoric. He has been doing it right all along...Plato hadn’t tried to destroy areté. He had encapsulated it; made a permanent, fixed Idea out of it; had converted it to a rigid, immobile Immortal Truth. He made areté the Good, the highest form, the highest idea of all. It was subordinate only to Truth itself, in a synthesis of all that had gone before. ..That was why the Quality that Phædrus had arrived at in the classroom had seemed so close to Plato’s Good. Plato’s Good was taken from the rhetoricians."

Quality in health care is indeed the arete of Pirsig, yet indefinable, yet we know it when we engage it. The biggest problem in health care will be quality not cost. A dying patient will respect the "quality" of his health care provider based on the respect he obtains in those final moments, not by how long he survives as a result of chemicals and operations. Death with dignity means a quality death. Life with dignity is a quality life.

Aesthetics is how we see the world looking outward. Quality is how we perceive the effects of the world on ourselves. An ethical person is one who deals with others in goodness and fairness. A quality physician is one who is perceived by the patient as having been dealt with dignity and respect.

I do not sense that anyone in Congress has the slightest idea about what quality care is, cost and political gain are their sole motives. Pity!
6.1.2 Outcomes and Quality

Michael Porter has written an article in NEJM presenting his views on health care reform., calling it "Towards a Value Based System". As we have argued elsewhere the use of the vague term "value", never defined by Porter, may sound good but he owes the reader at some point a definition. It is lacking.

It is worth a brief analysis since he is the oft proclaimed guru of strategic thinking from the renowned Harvard Business School, the place which brought our economy the minds that got us where we are now.

He begins by saying:

"True reform will require both moving toward universal insurance coverage and restructuring the care delivery system."

The issue of universal coverage is a critical point as we have been arguing for over twenty years. Allowing individuals to opt out is really allowing individuals a free ride. We no longer permit that in auto insurance, at least in most states so why do so in health insurance. So, point well taken. He then poses the following:

"How can we achieve universal coverage in a way that will support, rather than impede, a fundamental reorientation of the delivery system around value for patients?"

Porter first lays out what he believes the six principles of an ideal health care system should be:

"First, we must change the nature of health insurance competition. Insurers, whether private or public, should prosper only if they improve their subscribers’ health."
This is a wonderful goal but first one must ask how this is measured and second what is the responsibility of the patient, consumer. If you cannot stop someone from smoking, from obesity, just look at some in the White House, failure to address a condition before it becomes deadly, and the failure to maintain hypertension to a reasonable level, then what can a physician do. No matter how Porter tries he fails to define this and fails to incorporate the patient as a truly controlling agent.

"Second, we must keep employers in the insurance system."

On this I really believe his is far from seeing a new way. The employers create pools which may be low cost to them and the result is that it shifts the costs to those who are in smaller pools or individuals. My argument has been the auto insurance market. If I purchased my plan through say Verizon as compare through my own way, then the Verizon plan would be cheaper than mine and in fact the costs the insurer would be burdened within the Verizon contract would shift to me as a sole purchaser! Does Porter not understand the economics of the process? Only if everyone bought their own insurances, sans pooling, would there be a level playing field. The whole employer based system was an artifact to get around a Government wage cap in the 1940s, it was a system born of Government control and now Porter glorifies it a sine qua non. How pathetic!

"Third, we need to address the unfair burden on people who have no access to employer-based coverage, who therefore face higher premiums and greater difficulty securing coverage..."

Yes, indeed, that is just what was argued above. Why do they face higher premiums, because these poor people are subsidizing the large pools and those without? The risk pools are the same, the same statistics. Pooling people does not change risk if universal coverage is required.

"Fourth, to make individual insurance affordable, we need large statewide or multistate insurance pools, like the Massachusetts Health Insurance Connector, to spread risk and enable contracting for coverage and premiums equivalent to or better than those of the largest employer-based plans."
The Federal pools or State pools are required only if we were to keep the employer subsidized pools!

"Fifth, income-based subsidies will be needed to help lower-income people buy insurance."

Obviously! But what of those who are here illegally. What does universal mean and who is really NOT covered? Is it the 20 million illegal aliens of the 40 million uninsured? How is this problem solved?

"(Sixth) ... once a value-based insurance market has been established, everyone must be required to purchase health insurance so that younger and healthier people cannot opt out."

Well universal is universal...so why repeat it.

Porter then describes what must be changed about the current system. He starts with a preface:

"The current delivery system is not organized around value for patients, which is why incremental reforms have not lived up to expectations....In order to achieve a value based delivery system, we need to follow a series of mutually reinforcing steps."

The problem with the Porter pitch is that he nowhere ever defines "value". It is like quality and all the other HBS catch phrases. We all want quality, we all want value, but they are all too often in the eye of the beholder. Porter then lays out his six points for improving health care. They are as follows:

"First, measurement and dissemination of health outcomes should become mandatory for every provider and every medical condition."

We agree. Today we measure diagnosis and procedure. The problem is how we define an outcome for a chronic disease. It would be great to have an outcome. In most cases it is that things just do not get worse. Take Hashimoto's thyroiditis. What is the outcome, management? When is the outcome measured? The list goes on.

"Second, we need to radically reexamine how to organize the delivery of prevention, wellness, screening, and routine health maintenance services."

I agree and that is why we have to do two things. Introduce the classic public health system as was common here in the US before health insurance became so prevalent and institute taxes to control demand by taxing bad behavior, such as tobacco and carbs.

"Third, we need to reorganize care delivery around medical conditions."
I really do not know what world he is speaking of. If I see a primary physician I do so for my annual needs or possibly a chronic condition. If I have the gene for melanoma then I should see a qualified dermatologist. My primary physician no matter how qualified will not be able to deal with this one. I see an ophthalmologist for my glaucoma, and gynecologists about whatever problems a woman may have. I do not expect my primary physician to deal with ovarian cysts! Nor do I expect my primary physician to read the MRI on a hip replacement! The system is organized in this manner today and it generally works smoothly!

"Fourth, we need a reimbursement system that aligns everyone’s interests around improving value for patients."

Here Porter supports Bundled Payments. We have argued extensively against this concept. It removes patient choice, it institutionalizes the archaic hospital centric system and disenfranchises the entry of new and innovative genetic medical applications and it sustains the dramatic and inefficient overheads that hospital brings to the table. On this point Porter appears to be totally clueless. Perhaps he should consider at least talking to real physicians instead of the ivy tower types who develop policy.

"Fifth, we must expect and require providers to compete for patients, based on value at the medical-condition level, both within and across state borders."

Again I have no idea what value means but this happens today with informed patients. Yes indeed some patients select a physician from the yellow pages, some by referral and a very few seek out the best for their specific problem.

"Sixth, electronic medical records will enable value improvement, but only if they support integrated care and outcome measurement."

We have discussed this at length. Yes electronic medical records will change things, slowly. If it were possible I would say they should occur instantly. However they will time manufacturing systems which took twenty five years.

"Finally, consumers must become much more involved in their health and health care. Unless patients comply with care and take responsibility for their health, even the best doctor or team will fail."

I agree and I have argued this from the demand perspective. The problem is that as a physician you can tell your patient time and time again to stop smoking cigarettes or take off those seventy pounds but only one in a hundred will comply. Consumers, aka patients, are often in denial as to their health and tend to deal with the problem if and only if it becomes a crisis. Type 2 Diabetes becomes a concern when the foot is
removed. The typical patient after twenty years on metformin, sulfonylureas and then insulin and years of cajoling by the physician then wonders why they are having a failing kidney, or the smoker why they have small cell carcinoma and the like. Getting patients to take responsibility is difficult unless motivated by some exogenous acts such as a tax.

6.2 Quality as a Measurement

There has been a great deal of work regarding quality in health care. As one would have suspected the work attempts to quantify quality and then to assign costs to such quantified qualities. Anyone familiar with the least bit of Aristotelian philosophy recognizes that quality and quantity are two separate attributes, they are orthogonal, they cannot project upon one another. Thus there may be an inherent conflict in this very process.

We focus in this section on the QALY approach which is used extensively in the UK and appears to be penetrating the current debate in the US as well. A simple example is the use of imatinib in CML. It prolongs life a year or so in a fairly normal manner but blast phases are still present. It extends life but does not change the ultimate outcome. It is costly. Since the outcome is the same should we pay for the drug? What is two years of a human life worth? Can we even ask that question? The present discussion on health care does just that, again and again!

6.2.1 A Case Study: Prostatectomy

Let us begin with a simple but realistic example. We consider the case of prostate cancer and consider two treatments; do nothing (euphemistically called "watchful waiting") and radical prostatectomy. We assume that the cancer is confined so that the two are pari passu the same.

We approach this example by using a paper from by Teineck in NEJM in 2002. The following Tables are from the NEJM article and list adverse factors and their incidence by treatment.26 The first Table lists physical factors as shown below.

<table>
<thead>
<tr>
<th>CATEGORY OF FUNCTION</th>
<th>DEFINITION OF OUTCOME</th>
<th>RADICAL PROSTATECTOMY</th>
<th>WATCHFUL WAITING</th>
<th>UNADJUSTED RELATIVE RISK (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Emptying capacity</td>
<td>Sensation of not emptying the bladder</td>
<td>34/165 (21)</td>
<td>46/152 (30)</td>
<td>0.7 (0.5–1.0)</td>
</tr>
<tr>
<td></td>
<td>Need to urinate less than two hours after urinating</td>
<td>53/164 (32)</td>
<td>58/152 (38)</td>
<td>0.8 (0.6–1.1)</td>
</tr>
<tr>
<td></td>
<td>Involuntary stoppages during urinating</td>
<td>20/165 (12)</td>
<td>32/152 (21)</td>
<td>0.6 (0.3–1.0)</td>
</tr>
<tr>
<td></td>
<td>Weak urinary stream</td>
<td>46/164 (28)</td>
<td>68/153 (44)</td>
<td>0.6 (0.5–0.9)</td>
</tr>
<tr>
<td></td>
<td>Need for push or strain to begin urination</td>
<td>17/163 (10)</td>
<td>22/157 (14)</td>
<td>0.7 (0.4–1.3)</td>
</tr>
<tr>
<td>Storing capacity</td>
<td>Typical frequency of urinating at night</td>
<td>72/164 (44)</td>
<td>90/159 (57)</td>
<td>0.8 (0.6–1.0)</td>
</tr>
<tr>
<td></td>
<td>Urgency</td>
<td>38/163 (23)</td>
<td>44/157 (28)</td>
<td>0.8 (0.6–1.2)</td>
</tr>
<tr>
<td>Global features</td>
<td>Distress</td>
<td>34/164 (21)</td>
<td>34/157 (22)</td>
<td>1.0 (0.6–1.5)</td>
</tr>
<tr>
<td></td>
<td>Lower urinary tract symptom score</td>
<td>11/164 (7)</td>
<td>9/157 (6)</td>
<td>1.2 (0.5–2.7)</td>
</tr>
<tr>
<td></td>
<td>American Urological Association Symptom</td>
<td>55/164 (35)</td>
<td>74/150 (49)</td>
<td>0.7 (0.5–0.9)</td>
</tr>
<tr>
<td></td>
<td>Severe symptoms (20–35 points)</td>
<td>16/159 (10)</td>
<td>10/150 (7)</td>
<td>1.5 (0.7–3.2)</td>
</tr>
<tr>
<td>Urinary leakage</td>
<td>Frequency of leakage between episodes of urinating</td>
<td>80/164 (49)</td>
<td>33/155 (21)</td>
<td>2.3 (1.6–3.2)</td>
</tr>
<tr>
<td></td>
<td>Subjective estimation of the degree of leakage</td>
<td>101/163 (62)</td>
<td>53/152 (35)</td>
<td>1.8 (1.4–2.3)</td>
</tr>
<tr>
<td></td>
<td>At least some leakage</td>
<td>30/163 (18)</td>
<td>3/152 (2)</td>
<td>9.3 (2.9–29.9)</td>
</tr>
<tr>
<td></td>
<td>Distress from urinary leakage</td>
<td>47/164 (29)</td>
<td>15/158 (9)</td>
<td>3.0 (1.8–5.2)</td>
</tr>
<tr>
<td></td>
<td>Moderate or great distress</td>
<td>14/164 (9)</td>
<td>5/158 (3)</td>
<td>2.7 (1.0–7.3)</td>
</tr>
<tr>
<td>Aids against leakage</td>
<td>Regular dependence on some form of protective aid</td>
<td>Yes</td>
<td>71/165 (43)</td>
<td>16/154 (10)</td>
</tr>
<tr>
<td></td>
<td>Regular dependence on diaper or urine bag</td>
<td>Yes</td>
<td>23/165 (14)</td>
<td>1/154 (1)</td>
</tr>
<tr>
<td></td>
<td>Urinary problems affecting sexual life</td>
<td>Moderately or severely</td>
<td>15/159 (9)</td>
<td>5/158 (3)</td>
</tr>
<tr>
<td></td>
<td>Overall distress from all urinary symptoms</td>
<td>Moderate or great distress</td>
<td>44/163 (27)</td>
<td>28/157 (18)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Great distress</td>
<td>15/163 (9)</td>
<td>8/157 (5)</td>
</tr>
</tbody>
</table>

Note that there is a relative occurrence column which gives the ratio of one to the other. Take for example regular dependence on aids for leakage. 43% of those with a prostatectomy had that problem whereas only 10% of those with no treatment did. Perhaps the 10% is a baseline so that the increase above baseline should be calculated. This is one of the many types of questions one may have regarding this analysis.

The following Table relates the psychological factors regarding the treatments. As we see from above, we consider men having the symptoms in the two treatment cases.
<table>
<thead>
<tr>
<th>CATEGORY OF FUNCTION</th>
<th>DEFINITION OF OUTCOME</th>
<th>RADICAL PROSTATECTOMY</th>
<th>WATCHFUL WAITING</th>
<th>UNADJUSTED RELATIVE RISK (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical function</td>
<td>The lowest five of seven possible categories</td>
<td>89/164 (54)</td>
<td>89/157 (57)</td>
<td>1.0 (0.8–1.2)</td>
</tr>
<tr>
<td>Low or moderate physical well-being</td>
<td>The lowest five of seven possible categories</td>
<td>68/164 (41)</td>
<td>78/157 (50)</td>
<td>0.8 (0.7–1.1)</td>
</tr>
<tr>
<td>Psychological function</td>
<td>The highest five of seven possible categories</td>
<td>64/164 (39)</td>
<td>71/157 (45)</td>
<td>0.9 (0.7–1.1)</td>
</tr>
<tr>
<td>Worry (moderate or high)</td>
<td>The highest five of seven possible categories</td>
<td>37/164 (23)</td>
<td>48/157 (31)</td>
<td>0.7 (0.5–1.1)</td>
</tr>
<tr>
<td>Anxiety (moderate or high)</td>
<td>The highest five of seven possible categories</td>
<td>15/159 (9)</td>
<td>16/157 (10)</td>
<td>0.9 (0.5–1.8)</td>
</tr>
<tr>
<td>Anxiety (high)</td>
<td>A score above the 90th percentile on the State–Trait Anxiety Inventory</td>
<td>10/153 (7)</td>
<td>16/151 (11)</td>
<td>0.6 (0.3–1.3)</td>
</tr>
<tr>
<td>Depression (moderate or high)</td>
<td>The highest five of seven possible categories</td>
<td>57/164 (35)</td>
<td>60/157 (38)</td>
<td>0.9 (0.7–1.2)</td>
</tr>
<tr>
<td>Depression (high)</td>
<td>A score above the 90th percentile on the Center for Epidemiological Studies Measure of Depression</td>
<td>57/164 (35)</td>
<td>57/158 (36)</td>
<td>1.0 (0.7–1.3)</td>
</tr>
<tr>
<td>Low or moderate psychological well-being</td>
<td>The lowest five of seven possible categories</td>
<td>64/159 (40)</td>
<td>68/151 (45)</td>
<td>0.9 (0.7–1.2)</td>
</tr>
<tr>
<td>Low or moderate subjective quality of life</td>
<td>The lowest five of seven possible categories</td>
<td>64/159 (40)</td>
<td>68/151 (45)</td>
<td>0.9 (0.7–1.2)</td>
</tr>
</tbody>
</table>

Note from above that well being and quality of life were comparable. High depression was greater in the no treatment group, perhaps due to the dread.

### 6.2.2 Measurement of Quality

In preparation for the discussion on the QALY we first define a measurement of quality, Q. We will use the above example to do this. Before doing so we first review the methodology used in the UK system.

Consider a disease and consider several treatments. We desire to assign a quality measure, Q, to the treatment A or treatment B at any one time. We want to assign a quality by determining a quantity, a single number. Yes that is what they do in the UK. Scores for the are generated from the ability of the individual to function in five dimensions. See Phillips, C., G. Thompson, What is a QALY www.evidence-based-medicine.co.uk
2 Pain/discomfort

2.1. No pain or discomfort.
2.2. Moderate pain or discomfort.
2.3. Extreme pain or discomfort.

3 Self-care

3.1. No problems with self-care.
3.2. Some problems washing or dressing.
3.3. Unable to wash or dress self.

4 Anxiety/depression

4.1. Not anxious or depressed.
4.2. Moderately anxious or depressed.
4.3. Extremely anxious or depressed.

5 E Usual activities (work, study, housework, leisure activities)

5.1. No problems in performing usual activities.
5.2. Some problems in performing usual activities.
5.3. Unable to perform usual activities.

Each of the five dimensions used has three levels (i) no problem, (ii) some problems and (iii) major problems making a total of 243 possible health states, to which "unconscious" and "dead" are added to make 245 in total.

Now we take each of these five factors and assign a valuation to each possible combination. There are $3^5$ possible combinations. We list from Phillips et al a sample set below:
<table>
<thead>
<tr>
<th>Health state</th>
<th>Description</th>
<th>Valuation</th>
</tr>
</thead>
<tbody>
<tr>
<td>11111</td>
<td>No problems walking about; no problems with self-care; some problems with performing usual activities; some pain or discomfort; not anxious or depressed</td>
<td>1.000</td>
</tr>
<tr>
<td>11221</td>
<td>Some problems walking about; some problems with dressing self; some problems with performing usual activities; moderate pain or discomfort; moderately anxious or depressed</td>
<td>0.760</td>
</tr>
<tr>
<td>22222</td>
<td>No problems walking about; some problems washing or dressing self; some problems with performing usual activities; some pain or discomfort; not anxious or depressed</td>
<td>0.516</td>
</tr>
<tr>
<td>12321</td>
<td>Some problems walking about; no problems with self-care; unable to perform usual activities; some pain or discomfort; not anxious or depressed</td>
<td>0.329</td>
</tr>
<tr>
<td>21123</td>
<td>Some problems walking about, unable to wash or dress self; unable to perform usual activities; moderate pain or discomfort; extremely anxious or depressed</td>
<td>0.222</td>
</tr>
<tr>
<td>23322</td>
<td>Confined to bed; unable to wash or dress self; unable to perform usual activities; extreme pain or discomfort; moderately anxious or depressed</td>
<td>0.079</td>
</tr>
<tr>
<td>33332</td>
<td>Confined to bed; unable to wash or dress self; unable to perform usual activities; extreme pain or discomfort; extremely anxious or depressed</td>
<td>-0.429</td>
</tr>
</tbody>
</table>

We have arbitrarily given numbers to these. Note that we have been totally arbitrary and there is also a negative value below dead! That is pain and suffering is so bad you might as well be dead! Does that tell you something. Perhaps they should also add cost, and if you cost too much you might as well be dead.

Now let is return to the same analysis but using the prostate data. In principle a Q of 1 means everything is just fine, a Q of 0 is dead, and a negative Q means you might be better off dead.

To use the numbers above we can define a quality as 1 - the value of any entry since all of the entries are negative factors. Thus we can construct a quality as follows:

$$Q = \frac{\sum_{i=1}^{N} a_i (1 - E_i)}{\sum_{i=1}^{N} a_i}$$

where the Es are the negative effect percents, the average or mean values, and as are some arbitrary weights. If we weight each equally then they are one.

Now before continuing we have shown just two possible Q calculations. But there are several factors we must consider. They are:

1. Qs change with time. People may get sicker or better. It depends.
2. Qs are averages of averages or means of means. They do not speak of any individual, and in fact there may be no human which has the profile of the Q value!

3. Qs are one dimensional. We attempt to reduce all patients to one number. Any physician knows this is impossible.

4. Qs become the basis for treatment requirements, not just recommendations.

Needless to say there are a plethora of problems with the Q analysis. In fact it is our opinion that it is not only worthless but dangerous. It is deadly!

6.2.3 The QALY Concept

Now that we have determined the Qs we can apply it as follows to the QALY concept. From the review paper by Sassi, he states:

"The term ‘quality-adjusted life year’ (QALY) was first used in 1976 by Zeckhauser and Shepard to indicate a health outcome measurement unit that combines duration and quality of life ... But the underlying concept had been formally shaped in the early 1970s in the development of a ‘health status index’ ..., while an earlier study of the treatment of chronic renal disease ... had used a subjective adjustment for quality of life. Early applications of the health status index include one on tuberculin screening ... and one on screening for phenylketonuria ... The underlying assumptions of the QALY model were spelled out by Pliskin et al. (1980), who demonstrated that the QALY maximization criterion is justified in a multi-attribute utility theory framework under the following conditions: utility independence between life years and health status; constant proportional trade-off; and risk neutrality on life years."

He continues:

"The DALY is primarily a measure of disease burden (disability weights measure loss of functioning) but its use in cost-effectiveness analysis is also relatively common, and this paper is concerned with the latter. As a measure of outcome in economic evaluation, the DALY differs from the QALY in a number of aspects. Most importantly, the DALY incorporates an age-weighting function assigning different weights to life years lived at different ages, and the origins of disability and quality of life weights differ significantly."

A simple QALY is defined as over a year as:

QALY=1*Q

where Q is a measure of quality as we have already described and it is assumed that this measure remains constant over the year. We define a QALE, quality-adjusted life expectancy (QALE) at age a can be defined as:
The discounted QALE is defined as:

\[
\text{QALE} = \sum_{t=a}^{a+L} \frac{Q_t}{(1+r)^{t-a}}
\]

where \(r\) is some determinable discount rate.

The QALY gained by use of one treatment over another is defined by the difference in their respective QALE which is defined as follows:

\[
\text{QALY}_{\text{Gained}} = \sum_{t=a}^{a+L'} \frac{Q'_t}{(1+r)^{t-a}} - \sum_{t=a}^{a+L} \frac{Q_t}{(1+r)^{t-a}}
\]

where

\(L' \geq L\)

and

\(Q' \geq Q\)

Thus if we use the treatment \(I\) versus no treatment, the quality may increase as well as the life expectancy and the net result is a greater QALE for the treatment versus no treatment.

Now we can allow for continuous changes in \(Q\) as follows:

\[
\text{QALE} = \int_{t=a}^{t=a+L} Q(t) \exp(-r(t-a))dt
\]

if \(Q(t)=Q\)

then

\[
\text{QALE} = Q \int_{t=a}^{t=a+L} \exp(-r(t-a))dt
\]

\[
\text{QALE} = \frac{1-\exp(-rL)}{r}
\]

Then we can calculate the QALY gained as:

\[
\text{QALY}_{\text{Gained}} = (Q^{\text{TreatmentA}} - Q^{\text{TreatmentB}}) \frac{1-\exp(-rL)}{r}
\]
where we assume that the lifetime is the same and that the only difference is the Q factor for the different treatments.

We can take one more step towards some semblance of a reality. That is we assume that the Q does vary from time to time. The results are in the paper by Sassi.

Now we can attribute costs to this analysis. Name we know a cost C applies to each treatment. Thus the cost per QALY is defined as:

\[
C_{QALY} = \frac{C_{TreatmentA} - C_{TreatmentB}}{QALY_{Gained}}
\]

This then becomes the sole metric for deciding "quality" health care treatment.

We now consider a paper by Nadler which applies this principle to the treatment of cancer. We show this in the Figure below from Nadler:

Nadler shows the above Figure which "depicts the differences in cost and efficacy estimates for bevacizumab exist for oncologists who believe that bevacizumab offers "good value for money" and those who do not believe bevacizumab offers good value for money. Each respondent’s estimate of survival and cost were plotted on the figure. We further distinguished those respondents who believed that bevacizumab offered good value by the plotted symbol. The slope of the lines throughout the figure reference various cost-effectiveness thresholds, with the cost-effectiveness ratios (C/E ratios) increasing from right to left."\(^{28}\)

Nadler then concludes:

"A majority of academic oncologists stated that cost does not influence their clinical practice, nor should it limit access to “effective” care. Yet respondents did not consider all effective drugs to be of good value. Implied cost-effectiveness thresholds were $300,000/QALY—a value higher than the $50,000 standard often cited. A subset of oncologists were sensitive to cost, believing it should factor into clinical decisions. These findings reflect the ongoing controversies within the medical community as expensive new therapies enter the system."

6.2.4 QALY Extension

The National Cancer Institute recently posted a note that Physicians treating cancer patients should (must?) tell the patient how much it will cost and then focus them on

---

28 See Nadler, Do Oncologists Believe New Cancer Drugs Offer Good Value?, The Oncologist, 2006;11:90–95 www.TheOncologist.com
the less expensive path! Imagine just being told you have breast or ovarian cancer, or that your child has leukemia, and then being told about how much it will cost and then why you should select the cheapest treatment! This is the new health care world.

The NCI note states:

"The skyrocketing cost of medical care has been front and center in the current deliberations over how to reform the country’s health care system. A new guidance statement released last week by the American Society of Clinical Oncology (ASCO) tackles one component of the issue head on, urging oncologists to discuss the potential financial costs of care with their patients. These clinician/patient discussions about cost, the guidance statement declares, are “a key component of high-quality care.”"

It continues in classic bureaucratic fashion:

"The new guidance statement, published in the Journal of Clinical Oncology, is intended to help not just oncologists, Dr. Schnipper explained, but also other stakeholders—including patients, insurers, and industry members—better understand how cost can affect care choices and decisions."

I love the word "stakeholder". It is corporate jargon meaning something I have never figured out. It is akin to the statement "walk the talk". Try that on anyone who speaks English as a second language, they try to parse it and get nowhere.

The note continues:

"Oncologists should acknowledge in discussions with patients that treatments may be very expensive and “should seek to identify any specific cost-related barriers to optimal treatment,” the guidance document recommends. To aid in these discussions, oncologists should be “armed with information that will help them ...communicate the value of specific cancer treatments,” including trying to quantify “how much benefit might be expected from a particular therapeutic option.”"

The question is what happened to quality care. Does this mean that if you are seventy that you should not be treated for prostate or colon cancer since you are due to die soon anyhow. Is this the approach that Senator Kennedy used in his decision process, doubtful. But it may very well be the decision process for a ten year old dying with ALL. Are we interested in quality care or low cost care. Apparently we rather do it on the cheap for those who cannot pay.

I fear that this is the first shot across the bow of the destruction of one of the best health care systems in the world.

The final quote is chilling:
"We’re not saying that physicians should be experts on insurance or even have all the direct conversations [with patients]," stressed Ms. Blum, a patient representative on the ASCO task force. “But it has to be some place in the care protocol. Ideally, the physician would talk about the relative costs and benefits of treatment, but the doctor doesn’t have to be the one to help the patient sort out what a situation will allow them to choose.”

6.3 Quality as a Perception

Quality is NOT quantity. Humans are always trying to reduce the quality of something to a quantity. For example a Renoir is reduced to an auction price. The nouveau riche tell everyone how much they paid for an objet d’art and then this gives it value to them, one thinks. The key question is what is quality? It is not how do we reduce it to a single number.

When some retired Cabinet Secretary, White House official, Senator, is dying of a multiple set of mets to the bone, they want what’s good for them. If their grandchild is afflicted with ALL they will want that child cured. There is no use at that time for them a quality measure that is an average of an average. Thus it is necessary to explore what we mean by quality.

6.3.1 What is Quality: Subjective vs Objective

Is quality objective or subjective. Is quality reducible to a single number as some universal objective reality or is it totally in the eye of the beholder. Or perhaps is it akin to that famous quote about pornography, "you know it when you see it".

I believe it is neither objective or subjective, it is something you know when you see it. It is different from everything else which is why Aristotle singled it out. To assist in addressing these issue we look briefly at some philosophical underpinnings.

6.3.2 Kantian Views

We first address the Kantian view of the world. It may appear strange that we invoke Kant as a player and thinker in health care but it is his view and thought process of how we create our world which has merit. One may strongly disagree with his conclusions, as I do in many areas, but his process as a breakthrough has substantial merit.

Let us begin by seeing the world of reason at the time of Kant. He faced to schools of thought. They were:
1. That of Leibniz. He was a Rationalist, and he concluded that reason can attain true knowledge. Derives all knowledge from use of reason and gives absolute description of the world, uncontaminated by experience of observer.

2. That of Hume, the Empiricist: to Hume the external elements determine what is true. Knowledge comes from experience alone, no possibility of separating from experience of the observer.

The issues that Kant was dealing with were as follows:

The “Forms of Thought” govern our understanding and the a priori nature of reality. Both of these are to be in “harmony”. We have what he called Objective Knowledge which consists of (i) sensibility and (ii) understanding. Within this context we have two different constructs, those which are pure concepts of our ability to understand and those elements with which we deal with nature. Specifically these are:

Pure Concepts of Understanding:

1. As to Quantity,
2. As to Quality,
3. As to Relation,
4. As to Modality

Pure Physiological elements of the Universal Principles of the Science of Nature:

1. Axioms of Institution,
2. Anticipations of Perception,
3. Analogies of Experience,
4. Postulates of Empirical Thinking

Again in Kant’s mind, knowledge falls into another set of categories: first: A priori: which not based upon facts, and second A posteriori which is based upon facts. Thus A Priori Truth is Truth which is independent of experience, a necessary truth, whereas A Posteriori Truth is a Truth which is based on experience, and is a contingent truth.

To these Kant adds the dimension of the relationship of subject and predicate. Specifically he states the following. In any statement of fact we have the following two elements; (i) the Subject: The subject of a statement “The dog is...”, (ii) and then the Predicate: The characterizing of a subject, “The dog is brown.” All our statements about something connect subject to predicate. Thus the statement "watchful waiting" is better quality than prostatectomy" connects the subject of "watchful waiting" to the object of comparative quality.
Now Kant takes these two and sees that they fall into two types of subject-predicate statements. These are:

1. **Synthetic**: The Predicate characterizes subject ab initio. “Everybody occupies space.” Space is a characteristic of a body so it already there.

2. **Analytic**: No relationship between subject and predicate. “Trees are 120 feet tall” no connection between two.

Flowing from the synthetic/analytic dualism is the judgments related thereto. Kant defines them as:

1. **Analytic Judgment**: A judgment in which the concept of the predicate term is found in the concept of the subject term. (often called true by definition).

2. **Synthetic Judgment**: A judgment in which the concept of the predicate term in not found in the concept of the subject term.

We can now align these types of judgments into four categories. This is shown below.

We now detail the elements in the following:
The last form of judgment, Synthetic a priori types, are what Kant focuses upon. They are the ones which form the basis of metaphysics and they are what in many ways make us humans. There are propositions which are just true, judgments which are universal, we know them to be so, we recognize their validity, and we do so without having the use of data! We know quality without quantity.

Synthetic a priori judgments are characterized by:

- those which are synthetic because the content of them is supplied by a synthesis of the facts of experience
- a priori, because the form of universality and necessity is imposed on them by the understanding independently of experience.
- an example would be "Every effect must have a cause."

For Kant this opening of synthetic a priori judgments opens the door to what he calls the Fundamental Question of Metaphysics, namely is synthetic a priori knowledge possible? His arguments revolve around the transcendental vs. empirical: the Faculty; intuition vs. concepts. He places our forms of thought in Categories: 1. category of substance, 2. the category of cause, total of 12 categories. He places our Judgments as follows; (i) Judgment of experience: have objective reality, (ii) Judgment of Perception: only subjectively valid, finally (iii) Judgments: 1 As to Quantity, 2. As to Quality, 3. As to Relation, 4. As to modality. But his use of quality differs from what we intend. Substance: that which is able to exist independently and support the properties which depend upon it.
His use of the term transcendental is that it transcends experience. In our analysis we transcend measurements and there lies the analogy. Thus in this transcendental world we have:

**Transcendent Knowledge:** Neither experience nor reason provide knowledge. The first provides content without form and the second form without content. The synthesis of the two transcends and can make legitimate claims on an independent world.

**Transcendental Idealism:** Experience contains within itself the features of space, time and causality; hence in describing my experience I am referring to an ordered world.

Kant states that there cannot be an explanation of a priori knowledge which divorces object known from the perspective of the knower. In Aristotle the categories were modes or inflection of being to which the mind adapted itself. For Kant, the mind already has the categories and things conform to the mind. Start with mind and then interpret nature. Previous philosophers had taken nature as primary and asked how cognitive capacities could lay hold of it...Kant takes these cognitive capacities as primary and then deduce the a priori limits of nature.

Experience contains intellectual structure and is organized in accord with the ideas of space, time, substance and causality. The Kantian world is shown in the Figure below. We have phenomenon, the artifacts of reality, the measurable and quantifiable reality we cling to a rational humans. Then through the mind, and the mind’s use of categories, synapse connections if you will, we obtain noumena, the ideas or abstracts that we cling to as humans.
In the pre Kantian classic world one could argue that the construct was as follows:

This inverts the relationship between what is perceived and what is understood. In both cases we have the elements of the categories.
The Forms of Judgment in Aristotle's logic are the necessary preconditions for any possible thought. From the 12 forms of judgment in Aristotle Kant deduces the Categories of experience.

The Categories are the means by which the human mind organizes percepts of to form objects of experience. In terms of knowledge the most important of the categories are those of Relation: (1) Of Inherence and Subsistence (substance and property) (2) Of causality and Dependence (cause and effect) (3) Of Community (reciprocity between agent and object).

The Categories are the necessary preconditions for the kind of knowledge exemplified by Newton's science. They are both synthetic and a priori, and are the contributions of Speculative Reason to knowledge. Speculative reason is the faculty of knowledge; Practical reason is the faculty of choice (the Will). The Laws of Logic are necessary for any kind of thought. We show these Categories below.

This is a summary of several of the key Kantian precepts which we need to apply to the idea of quality.

Thus the reason for going over Kant in this manner is the construct he creates for assisting in understanding a simple statement such as: "Watchful waiting is a quality alternative form of health care." We argue that this is not a posteriori, we cannot deduce this from a wealth of facts, it is a personal experience. We can deduce this as
the process of treatment continues, as we live our lives. Thus dealing with quality is dealing with a judgment that may very well fit external to a Kantian world view.

6.3.3 Pirsig's View

We now consider a totally different view of quality. That is the view developed by Pirsig in his now classic book, *Zen and the Art of Motorcycle Maintenance*. There may be many assessments of this book but it does raise many issues regarding quality in its broadest and truest philosophical sense. We may not want to take it to the extent that Pirsig does in his Metaphysics of Quality but he has many valuable points to contribute to the current debate. Indeed perhaps it is worth a reread of this wonderful classic again, thinking this time of health care.

Our approach is to seek several key quotes from Pirsig and then to comment.

"Today now I want to take up the first phase of his journey into Quality, the nonmetaphysical phase, and this will be pleasant. It's nice to start journeys pleasantly, even when you know they won't end that way. Using his class notes as reference material I want to reconstruct the way in which Quality became a working concept for him in the teaching of rhetoric. His second phase, the metaphysical one, was tenuous and speculative, but this first phase, in which he simply taught rhetoric, was by all accounts solid and pragmatic and probably deserves to be judged on its own merits, independently of the second phase." 29

This is the first time that Pirsig mentions quality. He does so in what I fell is a Kantian construct, separating the metaphysical from the non-metaphysical. You will see that as he proceeds the simple Kantian dialectic begins to erode. The closer one gets to the reality of quality as seen by Pirsig and as what is essential to health care one sees the dialectic explode.

""How are we supposed to know what quality is?" they said. "You're supposed to tell us!" Then he told them he couldn't figure it out either and really wanted to know. He had assigned it in the hope that somebody would come up with a good answer. That ignited it. A roar of indignation shook the room. Before the commotion had settled down another teacher had stuck his head in the door to see what the trouble was..."It's all right," Phedrus said. "We just accidentally stumbled over a genuine question, and the shock is hard to recover from." Some students looked curious at this, and the noise simmered down." 30

29 see ZMM p 191

30 see ZMM p 205
This is the first confrontation of trying to use the tools at hand to describe quality. This is done in the simple world of rhetoric. A "real question" indeed. Quality is not the simple separation of a dialectic of metaphysical and non-metaphysical. As Pirsig has brilliantly done in ZMM he uses the metaphor of the trip itself, the trip and the interaction of man, machine, and environment.

One can expand this experience of understanding by regarding it in another manner as well. As Gadamer has stated (see Warnke), we understand things in a dialog manner. Specifically:

"If one examines Gadamer's analysis ...all knowledge of the natural and social world...is grounded in traditional orientations. We never come upon situations, issues or facts without already placing them within some context...and interpreting them in some fashion."

"In equating the logic of understanding with the structure of dialogue, Gadamer suggests that the proper answer is that..in genuine conversations ...all participants are led beyond their initial positions towards a consensus."

Thus the process of consensus in a conversational mode is what leads to new understanding. All initial constructs are based upon prior prejudices that can best be formed in the context of metaphors. If our goal in developing new user interfaces is the ability to allow the users to understand, as viewed by Gadamer, then we must do so as to support the conversational modality and to allow the reaching of consensus. This understanding is critical to the relationship between patient and physician. It is absent in the relationship between the citizen and the current Administration.

We can also look at the world view of understanding and creating realities as developed by Heidegger. We refer to the book by Winograd and Flores which brilliantly displays this. Winograd and Flores have noted six effects of accepting the Heidegger world view. These are;

1. **You cannot avoid actions.** Even inaction is a form of action. Physicians interact with their day to day environment, and physicians who act by inaction have the corresponding results. The physician interaction with the patient is always a flow of action. From tests to the space between visits.

2. **You cannot step back and reflect.** Events exogenous to us are continually occurring and any attempt to stop time to best understand the situation is at best specious. At worst, it becomes inaction. The concept of hermeneutics is one that extended to the environment of the end user say that we make interpretation with what is at hand and what is part of our tradition. Health care is a classic hermeneutic experience, there being the patient as the messenger and the physician attempting to interpret the message. The famous Osler was
always advising his students at Hopkins to paraphrase, "If all else fails, listen to the patient."

3. **Effects of actions cannot be predicted.** We can anticipate, we can plan and we can strategize, but the world is filled with uncertainty. As such, we act in an environment where the exact outcome is uncertain. The user must anticipate that but not be fearful of it. The physician sees each patient as an individual, as a person. There may be a great deal of information in Harrison's for the Internist but each presentation has nuance, for each human is different.

4. **You do not have a stable representation of the situation.** Every situation is a representation in flux. When a user accesses a system, there are many factors that impinge on the interaction of the user, their needs and responses. No presentation of symptoms are static, they are changing, the patient is aging, improving, or failing to respond.

5. **Every representation is an interpretation.** X rays are inherently representations of physiological factors. In looking at an x ray a physician is looking at a representation and performing an interpretation. The lab tests are open to interpretation, the CAT scan may require more interpretation with an ultrasound and an MRI. Medicine has evolved into a brilliant patch quilt of methods of assembling and interpreting the puzzle. Some diseases are simple and they present simply. Others are complex and require a great deal of reassembling.

6. **Language is action.** Speech through our language is a spontaneous reaction to a set of situations. In the design of computer interfaces we spend many hours on structuring the presentation of the visual material. Images are carefully scrutinized. Speech, in a multimedia context is fluid and open to instant interpretation that may not be consistent with the other participants in the multimedia session. For example, our tone of voice may make us appear arrogant, our questioning may make us appear petulant and our suggestions may make us appear pedantic. Despite all our structured work on the interface, the instantaneous impacts of the language may override the setting. Thus a physician may tell their patient to lose weight, exercise, and reduce the Type 2 Diabetes. The patient must "hear" and respond.

This concept of the ideal form and the ideal as an achievable entity is as old as Plato and Aristotle. The concept of the ideal form, as a Platonist would state, is that there is a true idea of a daylily. It is an abstraction that is the daylily, and what we see as humans is a mere shadow of its true form. To the art of medicine, we then ask how does a Platonist communicate, namely, does he try to use the abstraction that closely matches the form? Copleston speaks on this with regard to Plato:31

---

31Copleston (Vol I, Part I, p. 175):
"I would point out that the essence of Plato's doctrine of Forms and Ideas is simply this: that the universal concept is not an abstract form devoid of objective content or references, but that to each true universal concept there corresponds an objective reality."

Continuing he states further:32

"In the Republic it is assumed that whatever a plurality of individuals have a common name, they have also a corresponding idea of form. This is the universal, the common nature or quality which is grasped in the concept."

It is the attempt to describe the "nature" or essence of things and to use this as a means to communicate that is the basis of many of our problems in design. An example is the compression of speech or video. We compress to avoid the need for more bandwidth. We compress also because we believe that by doing so we get to the essence of it. We do so in a Shannonesque fashion, assuming that there is an essence of bits, minimal as they may be. This extension is best described by Popper:33

"I use the name methodological essentialism to characterize the view, held by Plato and many of his followers, that the task of pure knowledge or "science" to discover and to describe the true nature of things; their hidden reality or essence. ...All these methodological essentialists also agreed with Plato in holding that these essences may be discovered and discerned with the help of intellectual intuition. A description of the essence of the thing they called the "essence"."

An extreme position to this essence approach is the positivist approach expressed by Ayer when describing the early work of Wittgenstein.34

"..the main theses of the Tractatus can be easily summarized. The world is said to be totally of facts which themselves consist in the existence of what are called.. atomic facts.. or states of affairs. The states of affairs consist of simple objects, each of which can be named. The names can be significantly combined in ways that express elementary propositions. Each proposition is logically independent of all its fellows. They are all positive and each of them depicts a possible state of affair which constitutes

---

32Copleston (Vol I, Part I, p. 175):
33Karl Popper has stated (Hull, Ershefsky ED. p 201):
34Ayer (Witt, p 17)
its sense....The fact that they are logically independent means that in order to give a complete account of reality one has to say which of them is true or false."

The development of medicine is in many ways the development of new metaphors. We have seen medicine evolve through the humours and to the genetic levels we understand today. We understand disease as a process and its causes as a mixture of environment, heredity, and one actions. Physicians have evolved their science and their art by accepting evolving metaphors. MacCormac best describes this change that metaphor can take:35

" Metaphor can be described as a process in two senses: (1) as a cognitive process by which new concepts are expressed and suggested, and (2) as a cultural process by which language itself changes...epiphors are metaphors that express more than they suggest...diaphors suggest more than they express."

He goes on to state:36

"Generations of students who have passed through introductory philosophy courses in colleges and universities have come to believe in the division between the mind and nature. The rise of cognitive psychology in opposition to behaviorism, which denied the existence of the mind, fins comfort in the philosophical efforts to build a foundation for knowledge. The account that I have presented of metaphor as a cognitive process presumes the existence of the mind existing as a deeper level of explanation that of semantics and surface language." 

The essence of the Heidegger philosophy as relates to medicine has been best described by Winograd and Flores:37

"We...present...a...discussion of Heidegger's philosophy,...

(1) Our implicit beliefs and assumptions cannot be all made explicit.

(2) Practical understanding is more fundamental than detached theoretical understanding.

(3) We do not relate to things primarily through having representations of them.

35Mac Cormac (Met, p 5)
36Mac Cormac (Met, p 155)
37Winograd & Flores (UCC p 30-31)
(4) Meaning is fundamentally social and cannot be reduced to the meaning-giving activity of individual subjects."

The final element of Heidegger's approach is the breaking down effort of providing information in a way in which it is broken down or handled by the user.38

"... Heidegger's ...insistence that objects and properties are not inherent in the world, but arise only in an event of breaking-down in which they become present-at-hand...In sum, Heidegger insists that it is meaningless to talk about the existence of objects and their properties in the absence of concernful activity with its potential for breaking-down." 

The latter comment on Heidegger is the essence of medicine. The breaking down if the basis of a diagnosis, of a change in state of the human or humans in the conversation between physician and patient leading hopefully to a cure. It is the rhetoric of medicine and it goes beyond that in that it must have at its core the quality being examined by Pirsig,

We now return to Pirsig. Pirsig continues in his evolving discourse:

"The definition was: "Quality is a characteristic of thought and statement that is recognized by a nontinking process. Because definitions are a product of rigid, formal thinking, quality cannot be defined." The fact that this "definition" was actually a refusal to define did not draw comment. The students had no formal training that would have told them his statement was, in a formal sense, completely irrational. If you can't define something you have no formal rational way of knowing that it exists. Neither can you really tell anyone else what it is. There is, in fact, no formal difference between inability to define and stupidity. When I say, "Quality cannot be defined," I'm really saying formally, "I'm stupid about Quality." "39

Here Pirsig digs deeper into quality. His statement about it being undefinable becomes the basis for his ongoing arguments. His statement of the irrationality of the definition applies aptly to the irrationality of the QALY definition or as we shall see the definition applied in the most recent Congressional health care legislation. Yet as we said above definitions have consequences. These consequences can affect people in a mild way or in the case of health care and a traumatic manner.

"He singled out aspects of Quality such as unity, vividness, authority, economy, sensitivity, clarity, emphasis, flow, suspense, brilliance, precision, proportion, depth and

38Winograd & Flores (UCC p 36-37)

39 see ZMM pp 206-207
so on; kept each of these as poorly defined as Quality itself, but demonstrated them by 
the same class reading techniques. He showed how the aspect of Quality called unity, the 
hanging-togetherness of a story, could be improved with a technique called an outline. 
The authority of an argument could be jacked up with a technique called footnotes, 
which gives authoritative reference." 40

Here Pirsig attempts to deal with the issue through previous lectures by his alter ego, the 
person he was before the breakdown, the Phaedrus of the past. The footnotes reference 
is akin to the many committees and panels that the Government assembles to yield a 
patina of correctness to an undefinable process.

"There’s an entire branch of philosophy concerned with the definition of Quality, known 
as esthetics. Its question, What is meant by beautiful?...he saw that when Quality is kept 
undefined by definition, the entire field called esthetics is wiped out—completely 
disenfranchised—kaput. By refusing to define Quality he had placed it entirely outside 
the analytic process. If you can’t define Quality, there’s no way you can subordinate it to 
your intellectual rule. The estheticians can have nothing more to say. Their whole field, 
definition of Quality, is gone." 41

Here he tries a nexus to aesthetics. Quality as beauty, quality as goodness of 
presentation.

Pirsig now steps across the threshold in the following:

"Because if Quality exists in the object, then you must explain just why scientific 
insitutions are unable to detect it. You must suggest instruments that will detect it, or 
live with the explanation that instruments don’t detect it because your whole Quality 
concept, to put it politely, is a large pile of nonsense. On the other hand, if Quality is 
subjective, existing only in the observer, then this Quality that you make so much of is 
just a fancy name for whatever you like...If he accepted the premise that Quality was 
objective, he was impaled on one horn of the dilemma. If he accepted the other premise 
that Quality was subjective, he was impaled on the other horn. Either Quality is objective 
or subjective, therefore he was impaled no matter how he answered. ..A third rhetorical 
alternative to the dilemma, and the best one in my opinion, was to refuse to enter the 
arena. Phaedrus could simply have said, "The attempt to classify Quality as subjective or 
objective is an attempt to define it. I have already said it is undefinable ," and left it at 
that..." 42

40 see ZMM p 208

41 see ZMM pp 212-213

42 see ZMM pp 228-229
As we discussed in the Kantian world, subjective versus objective, a well accepted dialectic for argument. The dialectic is also the basis for many philosophical debates. Yet what we see here is that quality is neither! Quality is not something we can measure and it is not totally subjective. Quality is no analytic a posteriori, a measurable and quantifiable entity. It is not a true synthetic a posteriori, it is a synthetic a priori.

"And really, the Quality he was talking about wasn’t classic Quality or romantic Quality. It was beyond both of them. And by God, it wasn’t subjective or objective either, it was beyond both of those categories. Actually this whole dilemma of subjectivity-objectivity, of mind-matter, with relationship to Quality was unfair. That mind-matter relationship has been an intellectual hang-up for centuries... And so: he rejected the left horn. Quality is not objective, he said. It doesn’t reside in the material world...Then: he rejected the right horn. Quality is not subjective, he said. It doesn’t reside merely in the mind...And finally: Phædrus, following a path that to his knowledge had never been taken before in the history of Western thought, went straight between the horns of the subjectivity-objectivity dilemma and said Quality is neither a part of mind, nor is it a part of matter. It is a third entity which is independent of the two."43

Quality is truly not in the mind. It is a third entity indeed. Pirsig moves to his revelation:

"The world now, according to Phædrus, was composed of three things: mind, matter, and Quality. The fact that he had established no relationship between them didn’t bother him at first. If the relationship between mind and matter had been fought over for centuries and wasn’t yet resolved, why should he, in a matter of a few weeks, come up with something conclusive about Quality? ... He noted that although normally you associate Quality with objects, feelings of Quality sometimes occur without any object at all. This is what led him at first to think that maybe Quality is all subjective. But subjective pleasure wasn’t what he meant by Quality either. ...Quality decreases subjectivity. Quality takes you out of yourself, makes you aware of the world around you. ...Quality is opposed to subjectivity. I don’t know how much thought passed before he arrived at this, but eventually he saw that Quality couldn’t be independently related with either the subject or the object but could be found only in the relationship of the two with each other. It is the point at which subject and object meet. That sounded warm. ...Quality is not a thing. It is an event."44

Quality is an event! Pirsig in this statement draws out quality as the perception and the process. It is truly the event of what occurs.

43 see ZMM p 237

44 see ZMM p 238
"The first horn of Phædrus’ dilemma was, If Quality exists in the object, why can’t scientific instruments detect it?

This quote I believe destroys the QALY world view. They want to measure and want to measure to a single number.

"This horn was the mean one. From the start he saw how deadly it was. If he was going to presume to be some super-scientist who could see in objects Quality that no scientist could detect, he was just proving himself to be a nut or a fool or both. In today’s world, ideas that are incompatible with scientific knowledge don’t get off the ground."

He remembered Locke’s statement that no object, scientific or otherwise, is knowable except in terms of its qualities. This irrefutable truth seemed to suggest that the reason scientists cannot detect Quality in objects is because Quality is all they detect. The "object" is an intellectual construct deduced from the qualities. This answer, if valid, certainly smashed the first horn of the dilemma, and for a while excited him greatly.

Here he is playing with the many meanings of quality so that he may be drawn back to what he means and indeed what we also mean.

""What moves the Greek warrior to deeds of heroism," Kitto comments, "is not a sense of duty as we understand it...duty towards others: it is rather duty towards himself. He strives after that which we translate ‘virtue’ but is in Greek areté, ‘excellence’—we shall have much to say about areté. It runs through Greek life."...Quality! Virtue! Dharma! That is what the Sophists were teaching! Not ethical relativism. Not pristine "virtue." But areté. Excellence. ... Quality had been absolute. Those first teachers of the Western world were teaching Quality, and the medium they had chosen was that of rhetoric. He has been doing it right all along...Plato hadn’t tried to destroy areté. He had encapsulated it; made a permanent, fixed idea out of it; had converted it to a rigid, immobile Immortal Truth. He made areté the Good, the highest form, the highest idea of all. It was subordinate only to Truth itself, in a synthesis of all that had gone before. ..That was why the Quality that Phædrus had arrived at in the classroom had seemed so close to Plato’s Good. Plato’s Good was taken from the rhetoricians."45

Indeed if Pirsig had written this in light of the Hippocratic Oath then indeed he would have discovered quality, the quality of medicine. That is:

"I swear by Apollo, the healer, Asclepius, Hygieia, and Panacea, and I take to witness all the gods, all the goddesses, to keep according to my ability and my judgment, the following Oath and agreement:

45 see ZMM pp 376-378
To consider dear to me, as my parents, him who taught me this art; to live in common with him and, if necessary, to share my goods with him; To look upon his children as my own brothers, to teach them this art.

I will prescribe regimens for the good of my patients according to my ability and my judgment and never do harm to anyone.

I will not give a lethal drug to anyone if I am asked, nor will I advise such a plan; and similarly I will not give a woman a pessary to cause an abortion.

But I will preserve the purity of my life and my arts.

I will not cut for stone, even for patients in whom the disease is manifest; I will leave this operation to be performed by practitioners, specialists in this art.

In every house where I come I will enter only for the good of my patients, keeping myself far from all intentional ill-doing and all seduction and especially from the pleasures of love with women or with men, be they free or slaves.

All that may come to my knowledge in the exercise of my profession or in daily commerce with men, which ought not to be spread abroad, I will keep secret and will never reveal.

If I keep this oath faithfully, may I enjoy my life and practice my art, respected by all men and in all times; but if I swerve from it or violate it, may the reverse be my lot."

This is the oath which in medicine yields true quality as perceived by Pirsig. It is a duty, a duty of the physician to his patient. It is the bonding of physician and patient in a manner as Spartan as Pirsig had imagined. It is not the hand of Government overseeing all.

6.4 Quality as a Political Mantra

In the wealth of health care bills emanating from Congress, they all contain the word quality but there is not a single point at which the word is defined. For example at the very title page of HR 3200 it states:

"To provide affordable, quality health care for all Americans and reduce the growth in health care spending, and for other purposes."

Yet nowhere is quality ever defined. The closest we get in the Bill is the following:
"(2) QUALITY MEASURE.—The term ‘quality measure’ means a national consensus standard for measuring the performance and improvement of population health, or of institutional providers of services, physicians, and other health care practitioners in the delivery of health care services."

The patient or person is never mentioned. This is a bizarre measure. It measures the process of delivery and NOT what is delivered. What is delivered is what the patient perceives, how the patient is treated, what the end result is for the patient. Frankly who cares what the institutional providers care for. Who cares for a national consensus. It is the individual who counts. The whole of the current health care debate however eliminates the individual, the patient, the very person!

6.4.1 A Current Health Care Bill and Quality

We have written extensively about quality in health care. In reading HR 3200 I see that the Congress too has included quality. In fact the Bill is called:

H. R. 3200 “America’s Affordable Health Choices Act of 2009” "To provide affordable, quality health care for all Americans and reduce the growth in health care spending, and for other purposes."

Now as we have said before quality is truly in the eye of the beholder, in this case the patient. If one has prostate cancer, quality care is not lots of morphine and just letting it met to the bone. Quality is engaging the patient in the process of managing his disease. Each patient is different, each patient has a different world view. Some dread incontinence, some sexual dysfunction, some pain. Thus the treatment of a patient, quality treatment, is a personalized interaction between patient and physician.

In HR 3200 they introduce sections defining as best as a politician can the idea of quality. The HR 3200 Bill, one of the most recent, states (This Act like all such bills from the Congress is divided into divisions, titles, and subtitles) as follows:

H. R. 3200 “America’s Affordable Health Choices Act of 2009”.

DIVISION B—MEDICARE AND MEDICAID IMPROVEMENTS

TITLE IV—QUALITY

Subtitle C—Quality Measurements

SEC. 1441. ESTABLISHMENT OF NATIONAL PRIORITIES FOR QUALITY IMPROVEMENT.

Title XI of the Social Security Act, as amended by section 1401(a), is further amended by adding at the end the following new part:
“PART E—QUALITY IMPROVEMENT “ESTABLISHMENT OF NATIONAL PRIORITIES FOR PERFORMANCE IMPROVEMENT” SEC. 1191.

(a) ESTABLISHMENT OF NATIONAL PRIORITIES BY THE SECRETARY.—The Secretary shall establish and periodically update, not less frequently than triennially, national priorities for performance improvement.

“(b) RECOMMENDATIONS FOR NATIONAL PRIORITIES.—In establishing and updating national priorities under subsection (a), the Secretary shall solicit and consider recommendations from multiple outside stakeholders.

“(c) CONSIDERATIONS IN SETTING NATIONAL PRIORITIES.—With respect to such priorities, the Secretary shall ensure that priority is given to areas in the delivery of health care services in the United States that—

“(1) contribute to a large burden of disease, including those that address the health care provided to patients with prevalent, high-cost chronic diseases;

“(2) have the greatest potential to decrease morbidity and mortality in this country, including those that are designed to eliminate harm to patients;

“(3) have the greatest potential for improving the performance, affordability, and patient centeredness of health care, including those due to variations in care;

“(4) address health disparities across groups and areas; and

“(5) have the potential for rapid improvement due to existing evidence, standards of care or other reasons.”

It then goes on to define quality as follows:

"“(d) DEFINITIONS.—In this part:

“(1) CONSENSUS-BASED ENTITY.—The term ‘consensus-based entity’ means an entity with a contract with the Secretary under section 1890. ‘

“(2) QUALITY MEASURE.—The term ‘quality measure’ means a national consensus standard for measuring the performance and improvement of population health, or of institutional providers of services, physicians, and other health care practitioners in the delivery of health care services...."

This is a deadly definition of quality. It is akin to what the Brits have in their national system where they use the QALY approach to the rationing of health care. The QALY
approach looks at a disease and looks at the average quality of life for a variety of treatments. For example we consider prostate cancer. There are three treatments; do nothing, prostatectomy, radiation therapy. Each of these has an outcome and has a patient result in quality of life measurements. Thus is we consider the quality measures some weighted average of pain, sexual dysfunction and incontinence, then we get a quality measure for each treatment for each period of time after diagnosis. We then obtain the average across the country and see that for example doing nothing may have the least impact, the patient has longer time with no sexual dysfunction and incontinence and they die faster so the time with pain is less. Then we assign a cost. Doing nothing is cheap, just lots of morphine if the Government even allows that. The Brits then rank each treatment by the $/QALY and permit the lowest cost treatment only! That means often doing nothing!

But what is wrong with this you may ask, for Congress has in effect placed this in the new Bill! What is wrong is that every patient is different and we are assuming the average. If you are average then you get the correct treatment. If you are not then you are mistreated.

Parsing the above definition is telling. Let us proceed:

1. "national consensus": this means an average across all and disregard to the individual. Medicine is a profession which deals with persons, individuals, and not large groups. Each person with prostate cancer is different. However the Congress drives this to an average. The Brit's QALY approach is just that, an average. God forbid if your disease is one sigma either way, the plan drives to the mean.

2. "performance and improvement of population health" This is NOT individual health, not individual quality, but the population as a whole, as an average. This takes the practice of Medicine and throws it out the door. Why take patient histories, just do a test, diagnose the disease, and use what is in column A. Why perhaps we do not need physicians, that good old obese GS 10 can handle it all on their own!

3. "or of institutional providers of services, physicians, and other health care practitioners" This again focuses on the delivery, and one suspects the costs of the delivery. If we make them all size 10. I remember the tale a fellow grad student told me at MIT. He lived on a Kibbutz and he was 6" 5" and had a size 14 shoe. The Kibbutz only had size 6 thru 10 shoes. He never got shoes because he was outside the range that was acceptable in the Kibbutz. Thus he move to the States where he could get shoes. In the HR 3200 plan it assumes that the delivery will be those size 6-10 shoes and God forbid if you have a 14 foot, You die!

The Bill then continues:

"SEC. 1192. DEVELOPMENT OF NEW QUALITY MEASURES."
(a) AGREEMENTS WITH QUALIFIED ENTITIES.—

“(1) IN GENERAL.—The Secretary shall enter into agreements with qualified entities to develop quality measures for the delivery of health care services in the United States.

“(2) FORM OF AGREEMENTS.—The Secretary may carry out paragraph (1) by contract, grant, or otherwise.

“(3) RECOMMENDATIONS OF CONSENSUS BASED ENTITY.—In carrying out this section, the Secretary shall—

“(A) seek public input; and

“(B) take into consideration recommendations of the consensus-based entity with a contract with the Secretary under section 1890(a).

“(b) DETERMINATION OF AREAS WHERE QUALITY MEASURES ARE REQUIRED.

—Consistent with the national priorities established under this part and with the programs administered by the Centers for Medicare & Medicaid Services and in consultation with other relevant Federal agencies, the Secretary shall determine areas in which quality measures for assessing health care services in the United States are needed.

“(c) DEVELOPMENT OF QUALITY MEASURES.—

“(1) PATIENT-CENTERED AND POPULATION BASED MEASURES.—Quality measures developed under agreements under subsection (a) shall be designed—

“(A) to assess outcomes and functional status of patients;

“(B) to assess the continuity and coordination of care and care transitions for patients across providers and health care settings, including end of life care;

“(C) to assess patient experience and patient engagement;

“(D) to assess the safety, effectiveness, and timeliness of care;

“(E) to assess health disparities including those associated with individual race, ethnicity, age, gender, place of residence or language;

“(F) to assess the efficiency and resource use in the provision of care;...
Finally the Bill defines the Stakeholders who will assist in the definitions. It states:

"SEC. 1443. MULTI-STAKEHOLDER PRE-RULEMAKING INPUT INTO SELECTION OF QUALITY MEASURES...."

“(6) MULTI-STAKEHOLDER GROUPS.—For purposes of this subsection, the term ‘multi-stakeholder groups’ means, with respect to a quality measure, a voluntary collaborative of organizations representing persons interested in or affected by the use of such quality measure, such as the following:

“(A) Hospitals and other institutional providers.  
“(B) Physicians.  
“(C) Health care quality alliances.  
“(D) Nurses and other health care practitioners.  
“(E) Health plans.  
“(F) Patient advocates and consumer groups.  
“(G) Employers.  
“(H) Public and private purchasers of health care items and services.  
“(I) Labor organizations.  
“(J) Relevant departments or agencies of the United States.  
“(K) Biopharmaceutical companies and manufacturers of medical devices.  
“(L) Licensing, credentialing, and accrediting bodies."

Does anyone notice who is missing from this list? The patient. There should be one and only one advocacy group and that should and must be the patient. The patient along with their physician should decide. Not some gang from Washington or the south side of Chicago!

Who (what) is a patient advocacy group? It is some political organization whose sole purpose is its own continuation. They, the Government, have all of these "stakeholders", entities interested in lining their own nests and pockets, but the poor patient is left out in the cold. Remember this bill looks at the average patient, not even plus or minus one standard deviation. The arrogance of assembling this group of people is an insult to the American patients who as taxpayers are paying for this collections of lobbyists. This Bill is a full employment Bill for Lobbyists!

Finally the Bill advocates the use of these measures as follows:

"SEC. 1444. APPLICATION OF QUALITY MEASURES."

(a) INPATIENT HOSPITAL SERVICES.—Section 1886(b)(3)(B) of such Act (42 U.S.C. 1395ww(b)(3)(B)) is amended by adding at the end the following new clause:...

“(x)."
(I) Subject to subclause (II), for purposes of reporting data on quality measures for inpatient hospital services furnished during fiscal year 2012 and each subsequent fiscal year, the quality measures specified under clause (viii) shall be measures selected by the Secretary from measures that have been endorsed by the entity with a contract with the Secretary under section 1890(a).

“(II) In the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical quality measure has not been endorsed by the entity with a contract under section 1890(a), the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. The Secretary shall submit such a non-endorsed measure to the entity for consideration for endorsement. If the entity considers but does not endorse such a measure and if the Secretary does not phase-out use of such measure, the Secretary"

Finally we have the Secretary of HHS selecting the quality measures! Health care is now a fully political process! You cannot make this up. The poor patient is thrown onto the ash heap of politics and their health care is reduced to political whims!

6.5 Quality as Perceived by the Patient

The NY Times published an article today discussing the current Administration’s approach to health care and in particular prostate cancer. It is a most telling article on how the new process of delivering health care will be approached. They discuss prostate cancer, one which we have spoken of many times in the past few months.

The article states:

"It’s become popular to pick your own personal litmus test for health care reform….My litmus test is different. It’s the prostate cancer test. The prostate cancer test will determine whether President Obama and Congress put together a bill that begins to fix the fundamental problem with our medical system: the combination of soaring costs and mediocre results. If they don’t, the medical system will remain deeply troubled, no matter what other improvements they make....

So let’s talk about prostate cancer. Right now, men with the most common form — slow-growing, early-stage prostate cancer — can choose from at least five different courses of treatment. The simplest is known as watchful waiting, which means doing nothing unless later tests show the cancer is worsening. More aggressive options include removing the prostate gland or receiving one of several forms of radiation. The latest treatment — proton radiation therapy — involves a proton accelerator that can be as big as a football field. ...
“No therapy has been shown superior to another,” an analysis by the RAND Corporation found. Dr. Michael Rawlins, the chairman of a British medical research institute, told me, “We’re not sure how good any of these treatments are.” When I asked Dr. Daniella Perlroth of Stanford University, who has studied the data, what she would recommend to a family member, she paused. Then she said, “Watchful waiting.”"

Now if a man suggested watchful waiting for breast cancer there would be hell to pay. First this is the wrong first issue. The first issue is to determine how aggressive the prostate cancer is and that is a cellular and genetic problem. You learn nothing from a Gleason score other than it most likely is not too bad or bad. Thus the works should focus on performing the research on assessing the nature of a specific prostate cancer and to develop procedure to monitor it in a cost effective manner.

Any physician who has dealt with patients with prostate cancer know that there are men who just will never die of it no matter how long they live and there are men who just seem to fall apart and die in months, each from the same starting point. So watchful waiting from a woman physician may be what we are in for in the future. Perhaps it is some Freudian form of revenge...

The same would be the case, as we have argued, for comparative clinical effectiveness studies. In a CCE study we may be measuring the effects of the different forms of cancer cells and NOT the impact of the treatments. Yet we have never determined the underlying forms of cancer cells. Performing a CCE study we see the results of different procedures on patients and we determine that watchful waiting is best, for example. The fact is that say 80% of the patients this is true and the 20% which die a painful death it was false because they had a different disease.

We now know much of the underlying genetics of breast cancer and we can now stage patients accordingly. We know different treatments work for different subgroups of breast cancer and we treat them accordingly. We must do the same for men as we do for women, not just let them die because some woman says so! Especially if that person is a Government Czar of some sort.

6.6 Conclusions

The National Cancer Institute just posted a note that Physicians treating cancer patients should (must?) tell the patient how much it will cost and then focus them on the less expensive path! Imagine just being told you have breast or ovarian cancer, or that your child has leukemia, and then being told about how much it will cost and then why you should select the cheapest treatment! This is the new health care world.

The NCI note states:
"The skyrocketing cost of medical care has been front and center in the current deliberations over how to reform the country’s health care system. A new guidance statement released last week by the American Society of Clinical Oncology (ASCO) tackles one component of the issue head on, urging oncologists to discuss the potential financial costs of care with their patients. These clinician/patient discussions about cost, the guidance statement declares, are “a key component of high-quality care.”"

It continues in classic bureaucratic fashion:

"The new guidance statement, published in the Journal of Clinical Oncology, is intended to help not just oncologists, Dr. Schnipper explained, but also other stakeholders—including patients, insurers, and industry members—better understand how cost can affect care choices and decisions."

I love the word "stakeholder". It is corporate jargon meaning something I have never figured out. It is akin to the statement "walk the talk". Try that on anyone who speaks English as a second language, they try to parse it and get nowhere.

The note continues:

"Oncologists should acknowledge in discussions with patients that treatments may be very expensive and “should seek to identify any specific cost-related barriers to optimal treatment,” the guidance document recommends. To aid in these discussions, oncologists should be “armed with information that will help them access and communicate the value of specific cancer treatments,” including trying to quantify “how much benefit might be expected from a particular therapeutic option.”"

The question is what happened to quality care. Does this mean that if you are seventy that you should not be treated for prostate or colon cancer since you are due to die soon anyhow. Is this the approach that Senator Kennedy used in his decision process, doubtful. But it may very well be the decision process for a ten year old dying with ALL. Are we interested in quality care or low cost care. Apparently we rather do it on the cheap for those who cannot pay.

I fear that this is the first shot across the bow of the destruction of one of the best health care systems in the world.

The final quote is chilling:

"“We’re not saying that physicians should be experts on insurance or even have all the direct conversations [with patients],” stressed Ms. Blum, a patient representative on the ASCO task force. “But it has to be some place in the care protocol. Ideally, the physician would talk about the relative costs and benefits of treatment, but the doctor doesn’t
have to be the one to help the patient sort out what a situation will allow them to choose.”
7 MEDICARE AND ITS FINANCIAL IMPLICATIONS

The New America Foundation, a left wing think tank in Washington, has published a chapter entitled Realigning US Health Care Incentives. It is an attack on Medicare plain and simple. It also is a concerted effort by the managers of large Hospitals to drive the independent physicians out of business and to get them aligned with the hospitals. It is a move using those covered by Medicare to drive a wedge between their health care providers and their needs as patients. The speech today by the current President re-intensifies this attack.

The report starts by stating:

"Health reform must make quality health care and health insurance affordable and accessible to all. In order to achieve the goal of quality, affordable coverage for all, we support: (i) Health insurance exchanges or new marketplaces to help consumers compare and choose the health plan that is right for them (ii) Reforms that end insurance discrimination based on age, sex, and health status, including: guaranteed issue, community rating, and a ban on pre-existing condition exclusions, (iii) Subsidies financed through broadly shared responsibility to ensure coverage is affordable, (iv) A requirement that individuals obtain coverage, once such coverage is accessible and affordable..."

This appears as a broad statement suggesting that they intend to look at health care in general. However they soon target Medicare. Remember that in our previous analysis we have demonstrated that those receiving Medicare have more than paid for their care. They have contributed to the system for forty years and the contribution exceeds any draw that they will make upon the system. At no point do the authors ever take recognition of this fact. Why should they, they want to remove coverage from the elderly and just allow them to go their way despite having contributed to their care well in excess of any other group.

They start their attack by saying:

"Over the next 10 years, we can reduce system-wide cost growth by far more than many think, enough to save $500 to $600 billion in the Medicare program alone. This level of cost growth reduction can be achieved while simultaneously improving the quality and patient-centeredness of care. Over time, this money could help fund coverage expansions, improvements to Medicare and Medicaid benefits and payment rates, and deficit reduction. We describe reforms that will make these savings possible in the remainder of this paper."

Where is the focus on the obese 30 year olds who will cost many times more with their Type 2 Diabetes and resulting morbidities? Not a word of that. They continue:
"Improving health care quality is consistent with reducing health care costs, which is essential to fund coverage expansion and make Medicare and Medicaid more sustainable for generations to come. To reach these goals, we must develop, pursue, and implement strategies to achieve greater value for the American health care dollar. We will not control health care costs until we create clear incentives for providers – the people who deliver care – to focus on quality and efficiency. Likewise, patients must be encouraged to make healthier choices through changes to their incentives. This will require exemplary and even courageous provider leadership and significant cultural change."

What does this mean? Simply they want quality. Frankly we have no idea what quality is. There is the Demming quality which applies to manufacturing, a term which means that we want to lower costs on production by reducing errors. However quality in health care is akin to pornography in law, you know it when you see it. The patient knows quality care by the way the patient is treated, not by whether they live or die. Death can be a quality experience if the human dignity is preserved.

If as this paper and the current Administration propose the dignity is removed and the costs are reduced. One may never again achieve even death with dignity and thus we would argue that quality is lacking. One view of quality is the Pirsig view, with its warts and all, where quality is a contradistinction to quantity, it is the opposite of the Demming model and akin to the legal world view we proposed. Value is another term for quality in the discussion as well and we have equally rejected the value metric as proposed by Porter.

They then look at the comparative clinical effectiveness model. They state:

"We can identify overuse, underuse, and misuse and implement best practice processes....Comparative effectiveness research, best practice information, and decision support tools will enhance the doctor-patient relationship."

We have argued that the CCE proposed here and elsewhere has the potential of being both a means to ration health care and also to push down costs on the providers in an attempt to eliminate the sole or small group provider.

They then address specific proposals:

"Fee-for-service payment is unsustainable. Medicare will lead a concerted effort to end fee-for-service payments for individual services within five to seven years. Further, Medicare will cooperate and collaborate with private payers to transition the entire delivery system away from fee-for-service payment and toward outcome-driven bundled payments that encourage provider accountability through full and partial risk contracts within 10 years..."
This means that the patient will lose any and all flexibility in selection providers. Thus if one has ovarian cancer or breast cancer and is covered by Medicare then they will tell you who to see and where even if say the best procedures are at Memorial Sloan Kettering rather than your local hospital. You the patient will be shelved and just allowed to die!

They then continue:

"Providers will be held accountable to reasonable cost and quality standards at a specified date...More efficient, value-based incentives will lead to higher-quality, lower-cost care."

The authors use quality and value dozens of times without ever addressing the definition. Is it the Pirsig definition, goodness, or the Demming definition, low failure rate. The patient knows.

They then start with the bundling argument:

"Develop and transition toward bundled payment models. Medicare should begin a concerted and focused effort to develop and implement payment bundles to enable a widespread transition from fee-for-service payment....Eventually, all clinicians will have strong incentives to move toward more integrated models of care that allow them to accept full responsibility and reward for high-quality patient care and patient outcomes...1. Comprehensive services with shared risk....2. Complete chronic care....3. Ambulatory chronic care....4. Acute episode."

These four bundles are discussed. As we have argued before the bundling puts the hospital and the Government in charge It institutionalizes an old paradigm for delivery ensuring lower care quality, here I mean a Pirsigian goodness term, and higher costs. We have argued this in detail with financial models demonstrating the results.

They end with Medicare changes they feel are required:

"Reform Medicare Advantage payments to drive quality and innovation...Improve the quality and patient-centeredness of end-of-life care through advanced planning and palliative care...."

They seem to have difficulty with getting away from the use of quality, without ever defining it. The focus on end of life care is really warehousing the old and dying. Hopefully those on or soon to be on Medicare, and who have paid for what they are due, will understand this fact.
Why the attack on Medicare. Because the Government controls it. What does this mean for non-Medicare patients, well simply if the current Administration gets its way with a Government plan, and then a single payer plan, namely the Government, then Medicare is just the training ground for doing this to everyone! It is the old adage; first they came for the old, and I said they are old anyhow, then they came for the young and I said well no matter they are just young kinds anyhow, and then they came for me, and I had no say at all!

Why is this important, because entities like the New America Foundation are feeders to the White House, they create "policies" and give them a patina of acceptance. What happens when they come for their parents, then their children...but they are them!

7.1 Medicare Demands

Now that I have been over 65 for a while and now that many of my friends are also, I read the paper in today's NEJM on the hospitalization of Medicare recipients with some surprise. The NEJM paper states that there were 13 million Medicare participants enrolled who were hospitalized in the year between 1 October 2003 and 30 September 2004. If one goes to the Medicare Site and look at the Medicare Trustee Report for that period one sees that there were:

"In 2004, 41.7 million people were covered by Medicare: 35.4 million aged 65 and older, and 6.3 million disabled. Total benefits paid in 2004 were $303 billion. Income was $318 billion, expenditures were $309 billion, and assets held in special issue U.S. Treasury securities grew to $289 billion."

This means that 32% of the Medicare participants were hospitalized at least once. That is one in three. That means that of the fifty or so friends in that age who I know and see somewhat frequently, enough so that if they were hospitalized I most likely would know, more than 16 of them should have been hospitalized! I can only think of one, and that one has been a chronic one for years. A closer look shows that of the 41 million only 34 million were 65 and older so it even gets worse, that is 38%! I wonder where all these sick old people are hiding out? The map in the paper shows a story which may or may not be correct. Clearly it reflects the data, no question there, but it may also reflect another tale. The picture is shown below from NEJM:
The question is, does the lack of higher hospitalizations in the low states reflect healthier people, or have the sicker people moved, and why? There is still the lingering question as to where all these chronically ill people are. They are hospitalized not just seeing a physician. Just some food for thought. There are times when these numbers really get confusing....I will look for the old people like me this week when I go to New Hampshire to work the farm, they are probably out tilling the soil!

Just after completing the entry preceding this one I read the speech by the current President on how he would fund his Healthcare plan. Specifically he states:

"Since making this proposal, the Administration has worked with Congress on other ways to offset fully the cost of health care reform through additional savings and revenues. To that end, the Administration is detailing today savings proposals that will contribute another $313 billion over 10 years to paying for health care reform, bringing the total scoreable offsets put forward by the Administration to nearly $950 billion over 10 years. Together, this would extend the solvency of Medicare’s Hospital Insurance Trust Fund by seven years to about 2024, and reduce beneficiary premiums for physician and outpatient services by about $43 billion over the next 10 years."

He specifically will use Medicare in the following manner to reduce expenditures by taking more money from Medicare. Specifically he proposes:

"1. Incorporate productivity adjustments into Medicare payment updates. Productivity in the U.S. economy has been improving over time. However, most Medicare payments have not been systematically adjusted to reflect these system-wide improvements. We should permanently adjust most annual Medicare payment updates by half of the economy-wide productivity factor estimated by the Bureau of Labor Statistics. This
adjustment will encourage greater efficiency in health care provision, while more accurately aligning Medicare payments with provider costs.....

2 Pay better prices for Medicare Part D drugs. In its meeting with the President and subsequent communication, the pharmaceutical industry has committed itself to helping to control the rate of growth in health care spending. There are a variety of ways to achieve this goal. For example, drug reimbursement could be reduced for beneficiaries dually eligible for Medicare and Medicaid. The Administration is working with the Congress to develop the most appropriate policy to achieve these savings.....

3. Reducing Medicare overpayments to private insurers. The establishment of a competitive system where payments are based upon an average of plans’ bids submitted to Medicare would save taxpayers close to $177 billion over 10 years, as well as reduce Part B premiums....

4. Improving Medicare and Medicaid payment accuracy. By strengthening program integrity efforts, the Centers for Medicare and Medicaid Services (CMS) will address vulnerabilities that have led to billions of dollars in overpayments and fraud each year. ...

5. Expanding the Hospital Quality Improvement Program: By linking a portion of Medicare payments for acute in-patient hospital services to hospitals’ performance on specific quality measures, quality of care for beneficiaries will improve, and Medicare will save approximately $12 billion over 10 years...."

I have demonstrated that Medicare more than pays for itself for those who have worked during their lifetime and then seek Medicare after 65. There are those obtaining Medicare who have contributed nothing. Frankly they should be covered by a separate plan. The assumption of the current President is that Medicare is a gift from the taxpayers to those retired. It frankly is not, it has been bought and paid for several times over! Thus the intent is to again burden Medicare and the Medicare recipients with this cost reduction. Perhaps they should just let them all just pass on, as I suggested earlier. After all the gang in the White House will be exempt due to age for another twenty years.

The following data are three further facts on Medicare. We present the CBO estimated costs, the HHS estimates of participants and the cost participant per year.

The CBO Cost Estimates are presented below. We show Parts A, B and D as well as the total. The growth in the total is substantial over the period to 2018 dominated by the inflow of the Baby Boomers.
The total participants are presented below. These are the Baby Boomers referred to above. One should remember that the enrollment starts at 65 and that the average life span for a male is about 75 and a female 79. Thus there will be a dominance of females receiving benefits even if many had not contributed as much as the males, although that is shifting as the younger group of working females is included. What that means is as we approach 2018 the females will have contributed equal to the males so the "free rider" status which may have been attributed before is no longer the case. All Medicare participants will have contributed as we have discussed before.
The cost per participant calculated from the above two is presented below. Given our previous analyses and the above comments regarding contributing participants, we see that the expenditures for the period thru 2018 are still less than the contributions from participants!
We thus argue that the Medicare participants will have contributed substantially in excess of their withdrawals by 2018 and that the excess has been spent by the Government rather than being used as specified. In addition we assumed in our earlier calculation a 20 year life for males and females post 65 and we know that it is substantially lower, only 10 for males and 14 for females. This makes the contribution excess even greater. This clear cold fact must become an element in the debate, and not a victim.

7.2 Medicare Financial Analysis

There has been many arguments that Medicare is broken. We will show here that such a statement is far from the truth. Indeed Congress is broken and is literally stealing money from Medicare. We will do this with a simple example.

1. Assume that a person starts work in 1970 at the salary of $16,000 per year. They get raises of 5% per year until they retire at 65 in 2005. Their final salary is $107,000 per year.

2. Each year they have contributed 3% of their gross salary to the Medicare fund. That is gross with no cap. Assuming the fund invests the contribution at an average 6% rate for that period and it is compounded then in 2005 they have $165,000.
3. Now they retire at 65 and they have an actuarial life of 12 more years. Medicare costs an average of $12,000 per year as we show below. The net present value of these 12 payments of $12,000 is $100,000.

![Cost of Medicare per year per Enrollee $](image)

4. But, and this is an important BUT, they have contributed $65,000 more than they will ever collect! Where did the money go? Congress spent it!

5. This gets worse the more you make. In the following chart we show how the contribution explodes as salary explodes. Remember the costs are the 12 years times the $12,000. They are the same for everyone. The more you make the more the Government collects.
6. We finally show in the following some details on this payout. This is nothing more than the details of the contributions by year.
This is a rather powerful chart. It belies all the "facts" that those who maliciously attack Medicare present. Let us look at a person who works for 40 years. The typical American. This person goes to college and then starts work in 1970 at $16,000 per year and gets annual raises at 5% per annum. This is NOT some corporate executive and NOT some uneducated worker. It is in many ways the typical American. The engineer, the school teacher, the salesperson, the person on the GM factory line, the police officer and the like. They contribute 3% of their gross to Medicare. We assume it is saved and invested at say 6% per annum by the Government, a real bad assumption.

Then at 65 we add all of the savings up and we get a total of $165,143 in a lump sum amount. Now we assume that this person lives another 20 years and we ask what is the payout per assume that this person gets. It is $14,398, well in excess of their personal cost of an insurance plan even at the rate of today's private plans. Furthermore it is substantially less than any Medicare benefits.

Thus what is the problem with Medicare. This simple back-of-the-envelope calculation, which can be performed by any high school student seems to be missed by the economic brains in the current Administration. Any VC, any entrepreneur, any banker, could do this calculation. Also the Medicare recipient pays an additional amount into
the fund on an annual basis and the Medicare payments typically cover at most 60% of the actual costs, thus leaving a substantial amount to be paid by the Medicare recipient.

The conclusions of this simple calculation are as follows:

1. The Medicare recipients who work a lifetime get much less than what they contribute.

2. The money is wasted by the Government, not by the Medicare recipient.

3. Those who run Medicare are doing what they are doing to establish a national single payer plan, which if Medicare is an example will end up costing people more for less and yield poorer health care.

4. Medicare has also become a dumping ground for many who have not reached 65 and have not contributed. It is an SSI dumping and loading ground.

One must ask why those who represent the elderly such as AARP would even allow such a plan to continue. It is outright highway robbery of the elderly. Does one suspect that the good Senator Kennedy gets his healthcare from Medicare, doubtful. It is essential to run the numbers and see the results.

7.3 Bundling

There has been a flurry of proposals for paying and reimbursing under Medicare. One of the strangest proposals is the Bundling approach which seems to have originated out of a Medicare advisor group. We look at that proposal briefly.

MedPAC is a Government policy panel formed under law to do the following:

"The Medicare Payment Advisory Commission (MedPAC) is an independent Congressional agency established by the Balanced Budget Act of 1997 (P.L. 105-33) to advise the U.S. Congress on issues affecting the Medicare program. The Commission's statutory mandate is quite broad: In addition to advising the Congress on payments to private health plans participating in Medicare and providers in Medicare's traditional fee-for-service program, MedPAC is also tasked with analyzing access to care, quality of care, and other issues affecting Medicare."

In a 2008 paper in the New England Journal by Hackbarth and others, all part of MedPAC, the authors propose a "Bundled" payment system. This bundled system simply stated is that
"Under a bundled payment approach, Medicare would pay a single provider entity (comprising a hospital and its affiliated physicians) a fixed amount intended to cover the costs of providing the full range of Medicare-covered services delivered during the episode, which might be defined as the hospital stay plus 30 days after discharge. Bundling payments in this way should provide incentives to increase efficiency, coordinate in-hospital and post-hospital care, and, if combined with pay-for-performance initiatives, improve the quality of care."

MedPAC published a detailed report in 2008 on bundled care. This report is in many ways the blueprint for Bundled payments.

This bundled approach of MedPAC assumes that if one needs medical care in a hospital that the patient in some manner stops dealing with their physician and then enters into some yet to be defined agreement with a hospital which in turn provides the full "team" and a bundled price. Thus if you require an aortic heart valve replacement, or breast cancer surgery, or prostate cancer surgery, you first get the hospital to tell you what bundle you get.

They choose all physicians and surgeons and they tell you the procedures and they set the price, somehow in accord with Medicare. You just show up and pray that the person or persons who treat you have some idea what they are doing. You choice, your responsibility, your freedom as a patient is destroyed for the better good, in this case the hospital, which in turn reports to the Government!

A detailed paper by Fisher et al called Fostering Accountable Health Care states that:

"We then present a specific payment reform proposal for Medicare designed to foster the development of accountable care organizations (ACOs) and provide empirical evidence of the potential impact of this approach..."

They continue:

"We propose a voluntary and incremental program that would foster the development of ACOs. Our proposal builds on the current Physician Group Practice (PGP) Demonstration, a program in which large group practices are rewarded with a share of the savings they achieve in caring for their Medicare patients if they also achieve documented quality improvement. During the first two years of the program, the participating groups achieved major gains in quality and savings for the Medicare program overall."

They conclude:

"But other approaches to reducing the growth of health care spending and fostering integration face serious constraints and even stronger resistance. The political
opposition to requiring all beneficiaries to join capitated health plans would likely be fierce.

Bundled payments reinforce the principle of shared accountability and encourage collaboration and coordination among providers but are unlikely to have much impact on the overall costs of care. Bundled payments will not discourage the provision of unnecessary services outside the context of the episode; nor do they necessarily reduce the provision of unnecessary or questionable episodes of care. And cuts in payment rates will be vigorously opposed as threats to providers’ ability to provide care to Medicare beneficiaries. The tensions that have to be managed include the difficult physician-hospital relationships pervading some markets, the increasing need to slow spending growth, and the widely held perception that cost containment requires income loss for some providers.

A promising middle ground. In this difficult environment, we believe that a voluntary payment reform designed around ACOs and shared savings offers an incremental and promising middle ground that could meet the interests of providers, beneficiaries, and taxpayers better than the competing alternatives. And interest in the approach is growing....."

In effect their proposal is in contradistinction to the bundled plan. The above highlights their view that the bundled plan would not achieve its goals.

There is also a paper called the Long Term Care Quality Alliance which presents a comparison of the following approaches:

1. Accountable Care Organization (Shared Savings or ACO)
2. Primary Care Medical Home
3. Bundled Payments
4. Partial Capitation
5. Full Capitation

This paper views many negative aspects of the bundled care approach. The paper promotes the ACO model which it defines as:

"The Accountable Care Organization (ACO) model establishes a spending benchmark based on expected spending. If an ACO can improve quality while slowing spending growth, it receives shared savings from the payers. This model is well-aligned with many existing reforms, such as the medical-home model and bundled payments, and also offers additional support (and accountability) to the provider organization to enable them to deliver more efficient, coordinated care. This approach has been implemented in programs like Medicare’s Physician Group Practice (PGP) Demonstration, which has shown significant improvements in quality and savings for large group practices."
This paper concludes on a positive note regarding the ACO approach:

"The ACO model is receiving significant attention among policymakers and leaders in the health care community, not only because of the unsustainable path on which the country now finds itself, but also because it directly focuses on what must be a key goal of the health care system: higher value. The model offers a promising approach for achieving this goal without requiring radical change in either the payment system or current referral patterns. Rather, fee-for-service remains in place, and most physicians already practice within natural referral networks around one or a few hospitals. By promoting more strategic and effective integration and care coordination, the ACO model holds substantial promise as a reform that offers a potential win-win for providers, payers, and patients alike."

The unintended consequences of a Bundled approach are many:

1. **The Patient and Provider lose a Nexus: The relationship becomes one with the hospital and not the physician. It breaks the fundamental bond that is the cornerstone of health care.**

The patient and the physician are an important nexus. The only physicians who have little to no contact with a patient are the pathologist, radiologist, and anesthesiologist. The surgeon has contact as does the other specialists. It goes to the heart of practicing medicine. The hospital has the least.

In my experience, hospitals are run by managers who care less about patients and more about their bottom line. They are not professionals as are physicians. The only fear a hospital administrator faces is possible loss of accreditation, which only comes after gross negligence if even then. The hospital is run for the benefit of the management and not the patient.

Teaching hospitals may be different in that they are run to produce new physicians. Thus the teaching hospital may be further out on the risk profile.

By placing the hospital at the focus as is done in a bundled approach one creates a barrier between patient and physician and further places the worst possible party in a position of control, the hospital administrator.

Hackbarth et al state:

"Bundling the payments for multiple providers would create incentives for providers not only to contain their own costs but also to work together to improve their collective efficiency. Providers accepting bundled payments would have the flexibility to develop entirely new approaches to organizing care and allocating payments among themselves
in ways that could help them achieve efficient, high-quality care. They could then share in any savings gained by improving coordination, quality, and efficiency."

There is no basis for this statement. They continue and state that perhaps some adjustments may be made. In fact by placing the hospital in the nexus one creates the most inefficient form as we have shown in our analyses.

2. **It institutionalizes and memorializes the hospital at a time when the role of the hospital may be at a massive turning point with genetic medicine.**

The Bundled approach places the hospital at the center of the model. We have argued that this entity is the most vulnerable to downsizing and change and is also at the heart of the explosion in costs. This is especially true for Medicare patients. Thus we see that placing such an entity at the core creates a tension for continuation of bad practices.

3. **It creates massive problems with the issue of transfer pricing of services and creates the incentive for further padding by hospitals.**

Anyone who has ever been in business, in a large multifunction company, has come to grips with the transfer pricing problem. Many business school doctoral theses have been written on the topic and many a corporate war has been fought over the issue. The price one unit charges another for a good or service is difficult to ascertain. This is difficult even when there is a market for the product. For the buying unit may easily say the internal price is too high and that they will go elsewhere. The hospital could do the same. They may say your physician is too costly so you must accept theirs or no surgery, just go home and die!

4. **It drives good physicians out of the delivery of Medicare services further disenfranchising those on Medicare.**

Physicians are opting out of Medicare in droves, as was reported by the New York Times. As the paper states:

"Many people, just as they become eligible for Medicare, discover that the insurance rug has been pulled out from under them. Some doctors — often internists but also gastroenterologists, gynecologists,... and other specialists — are no longer accepting Medicare, either because they have opted out of the insurance system or they are not accepting new patients with Medicare coverage. The doctors’ reasons: reimbursement rates are too low and paperwork too much of a hassle."

This means that with the system as it is already, it is becoming harder for Medicare patients to find physicians which will take them. If one adds the burden of bundling then it becomes worse.
In our opinion, as we have stated many times in the past, the rearrangement of deck chairs, namely the many plans on how to cut costs via payment and control mechanisms miss the point. First, demand can be modulated, second, costs can be reduced by multiple means, third, genetic medicine will change the paradigm fundamentally and having the agent which will be changed the most in the middle will just delay this change, and finally, and only as the last step is the payment issue.

Let me pose a different issue, however. The plans discussed by Fisher, albeit well posed and meaningful, work for the majority of chronic and acute care problems, such as acute MI, heart valve replacements, and even hysterectomies. However, consider the following. A woman has a BRCA positive breast nodule which upon fine needle aspiration is determined to be a malignancy. She lives somewhere in New Jersey and she has the option, assuming that it still exists, to seek service through one of the Fisher like plans in the local hospital or she goes to Memorial Sloan Kettering in New York. Well, off to New York she would go! She may often have a greater chance of dying from nosocomial infection at some local hospital, I am not saying it would be the one in the town in New Jersey, before the cancer gets to her. The plans proposed by Fisher for Medicare would prevent her from going to a tertiary care facility, even if it could save her life.

My concern is that the on the average approach works on the average. Yet there must always be room for exceptions, yet the exceptions are always what Government seems so unwilling to deal with, it is inherent in any bureaucracy. I strongly believe that as patients become more aware and as medicine has centers of excellence, that patient choice, albeit at a price, must be maintained. The abuse that Fisher in his many writings presents can and must be eliminated but not at the price of patient choice.

7.4 Payment Options

There has been a great deal of talk about schemes for health care payments and the current Administration has used Medicare as the proposed scheme, namely a Government plan. We look briefly at some of the varying options herein.

7.4.1 Medicare

Medicare is generally, but not always, for those over 65. It functions as shown below.
Namely a person spends their entire working life, say 40 years, contributing 3% of their gross pay, with NO cap as is the case for Social Security, and then at 65 they have the option of enrolling in Medicare. They pay about $50 per month per person. But what of the amount they contributed for those 40 years? Well, let us calculate what that may have been. We make some simple assumptions. We assume that they made $80,000 a year for 40 years and that the money gained a simple 6% per annum interest. Thus when they retire at 65 they have accumulated $370,000 which they now deduct a fixed amount for say their remaining 20 years of life. This equals to a payout of $32,400 from what they contributed and added to their current payment it is $33,000 per year! It costs about $8,000 per year to care for them. So what is the problem, First of course is that most people did not make $80,000, but we will account for that shortly. Second, the real problem is the Government already spent the money! Medicare really has no problem, Government does, it spends beyond what it has collected. If Medicare were say an independent fund non attachable by the Government then it would be self supporting.

Now let us look at the sensitivity to this number. We show this in the following Figure.
Note that the number scales simply. That is we can calculate what the amount would be at say $30,000 per year, which would be $12,200 for a 20 year life span plus the $600 per month. This is still well above the cost! You would have to go even lower to get below cost but the average salary per working person is well above that number. Why has no one ever calculate this number? Because it demonstrates that the Government is the problem NOT the way the system works!

7.5 Medicaid

The next system is Medicaid. This is a problem because unlike Medicare there is no contribution. We show this in the following Figure.
This does cost money and this is something which gets supported by those of us who already contributed to Medicare! So don't punish us workers.

7.5.1 Corporate

The next is the Corporate Plans. Remember that this is an artifact from when the Government regulated salaries. It was a way to give workers something when the Government denied pay raises. It is akin to the Wage Czar we have today. We show this below.
The problem with the Corporate model is that for the 40-50% of those insured covered under this the Corporations have leverage and they drive down costs below what it costs to deliver. Thus the insurers will make it up on the individual insured persons and put pressure on the providers as well.

7.5.2 Individuals

This group really gets the burden. The insurers delimit it to low risk persons and then charge exorbitant rates.
7.5.3 Co Op

The above individual model could be improved via the co-op plan which Republican have presented. This avoids a single payer Government plan as well as allowing for buying cooperatives which have some leverage with insurers. The problem is it adds another layer and the costs will reflect that.
7.5.4 Single Payer Government

The Democrats want a single payer plan with the Government being that payer. In many ways it is reminiscent to Medicaid with all of its problems. It does allow for a single buying pool which is a benefit but it also allows and would encourage delimiting service to reduce costs. It also begs the question of price setting and who pays whom in the process. The Government then takes away any market power that either the patient or the provider may have had, little if any now, and with this plan it would be zero.
7.5.5 Cost Comparisons

We now do some cost comparisons on these plans. First we show below a comparison table for all plans with assumptions which reflect the general numbers as are currently observed. Not what is contributed, what the costs are and that providers are almost uniformly getting a loss.

<table>
<thead>
<tr>
<th></th>
<th>Medicare</th>
<th>Medicaid</th>
<th>Corporate</th>
<th>Individual</th>
<th>Uninsured</th>
<th>Averaged</th>
</tr>
</thead>
<tbody>
<tr>
<td>Percent Covered</td>
<td>15%</td>
<td>8%</td>
<td>55%</td>
<td>7%</td>
<td>15%</td>
<td></td>
</tr>
<tr>
<td>Full Cost</td>
<td>$8,000</td>
<td>$7,500</td>
<td>$6,500</td>
<td>$6,500</td>
<td>$8,000</td>
<td>$7,030</td>
</tr>
<tr>
<td>Provider Pay</td>
<td>$5,500</td>
<td>$7,000</td>
<td>$5,800</td>
<td>$5,800</td>
<td>$0</td>
<td>$4,981</td>
</tr>
<tr>
<td>Provider Cost</td>
<td>$7,500</td>
<td>$4,000</td>
<td>$6,500</td>
<td>$6,500</td>
<td>$8,000</td>
<td>$6,675</td>
</tr>
<tr>
<td>Provider Gain/Loss</td>
<td>($2,500)</td>
<td>($500)</td>
<td>($700)</td>
<td>($700)</td>
<td>($8,000)</td>
<td>($2,049)</td>
</tr>
<tr>
<td>Individual Payment</td>
<td>$600</td>
<td>$0</td>
<td>$1,800</td>
<td>$10,000</td>
<td>$0</td>
<td>$1,780</td>
</tr>
<tr>
<td>Third Party Payment</td>
<td>$5,000</td>
<td>$4,000</td>
<td>$4,000</td>
<td>$0</td>
<td>$0</td>
<td>$3,270</td>
</tr>
</tbody>
</table>

We show below the costs by class.
Below we show the costs across all classes. These numbers show we believe that Medicare really is the most healthy based on those who contributed and that Medicaid is the worst. Perhaps a co-op system is better than a single payer for the obvious stated reasons. The Medicare is different in that people already paid and are still paying. One must remember that even Medicare places substantial personal burden on the individual.
The Telmarc Group

Health Care Policy: Politics vs Reality

Cost Elements per Patient Averaged Over All

<table>
<thead>
<tr>
<th>Cost Elements per Patient Averaged Over All</th>
</tr>
</thead>
<tbody>
<tr>
<td>Full Cost</td>
</tr>
<tr>
<td>($1,000)</td>
</tr>
</tbody>
</table>
8 PUBLIC VIEW

In an op-ed in the NY Times, Tyler Cowen writes a piece entitled "Something’s Got to Give in Medicare Spending". This title states his conclusion based on what at best can be said are a confused set of facts. Cowen is a faculty member in economics at George Mason University, one of the Virginia state schools in Arlington, VA. He clearly has done no work regarding Medicare if his analysis is to be believed.

First, as we have stated and we have shown on multiple and repeated occasions, Medicare is a program that supports those who have contributed in excess of what they ever hope to get returned and many more who have contributed nothing.

Now Cowen states:

"It’s not the profits of the drug companies or the overhead of the insurance companies that make American health care so expensive, but the financial incentives for doctors and medical institutions to recommend more procedures, whether or not they are effective. So far, the American people have been unwilling to say no."

Frankly that may be part correct but it is not the provider alone who it fault. Providers perform tests to avoid legal problems. As has been noted, a 70 year old with back pain may have metastasized prostate cancer, breast cancer, multiple myeloma, and a plethora of other problems. This the tests to determine what the problem is. The patient may not sue but oftentimes the family will. Thus to reduce the risk procedures are performed. How are you to control that. Multiple myeloma can be diagnosed by a series of blood tests seeking specific markers, PSA may help with prostate cancers but the CCE may not permit that if the patient if over say 70!

Cowen then continues:

"Drawing upon the ideas of the Harvard economist David Cutler, the Obama administration talks of empowering an independent board of experts to judge the comparative effectiveness of health care expenditures; the goal is to limit or withdraw Medicare support for ineffective ones. This idea is long overdue, and the critics who contend that it amounts to “rationing” or “the government telling you which medical treatments you can have” are missing the point. The motivating idea is the old conservative chestnut that not every private-sector expenditure deserves a government subsidy."

Cutler is a health care mini-czar to the current President. Yes he was at Harvard but he has moved on, thus one should be honest at least with that biased disclosure. CCE has its problems as articulated herein many times. It, as proposed, is a Government, and not
a professional, assessment group and as such it lags trends, delimits options and in the end will ration. Only those not on Medicare such as all Government employees will be free of the rationing. Is there no wonder that there are no objections from Congress, they are not affected. Cowen is missing the point and paying no attention to facts. Just look at how long a new drug takes to get through the FDA. Now compound that many fold and we have CCE procedure approvals. If the Government has its way the unapproved Medicare CCE procedures may be banned totally. Why don't we just burn the medical books, JAMA and NEJM to start!

Cowen then goes on to use the Dartmouth study:

"Scholars have been applying comparative-effectiveness research to Medicare for years, and the verdict is not altogether pretty. It turns out that some regions spend more on Medicare than others — sometimes two or three times as much, as documented by the Dartmouth Atlas Project. Yet the higher-spending regions often fail to produce superior health care results."

The problem here is in the details. Take a colonoscopy for example. If one does a colonoscopy in Florida the overhead costs are low and the patients may be somewhat homogeneous. Then take one done at Columbia Presbyterian in New York at 168th Street. In New York there are say 200 performed per day in a clinic setting which is akin to some industrial type surgery wards I have seen in Russia. People side by side and English not the main language. The staff performs one per 40 minutes and it is a true assembly line. But the costs are higher despite the attempts to be more productive than any other location. Why? Good question. Dartmouth damns New York without asking why. Truth is found by answering the whys and not just mouthing the whats. One should remember that Dartmouth is in Hanover and it does not in any way present the real world. Columbia Presbyterian and other New York Hospitals are a cross section of humanity. Thus the Dartmouth group should really find the whys before they justify themselves on the whats!

Cowen then goes on:

"Suggested ways to lower costs include an emphasis on preventive care, the use of electronic medical records and increased competition among insurers. But even if these are likely to improve the quality of care, they are speculative and uncertain as cost-saving measures. Keep in mind that while computers were remarkably powerful inventions, it took decades before they showed up in the statistics as having improved productivity in the workplace."

Frankly I have no idea where he is going here. It is a bit of on the one hand and then on the other. Yes we all agree the EMR will help, assuming it exists, it works, and it is used. We have addressed that issue in detail before.
Cowen continues:

“One idea embodied in a bill sponsored by Senator Ron Wyden, Democrat of Oregon, and Senator Robert F. Bennett, Republican of Utah, is to finance new health care programs by taxing health insurance benefits. This makes sense in principle: why should insurance benefits be favored over salary by our tax system? But employer-supplied insurance is a mainstay of the current health care system, and there is no adequate replacement immediately in sight.....It sounds harsh to suggest that the Obama administration cut areas of Medicare spending, but, too often, increased expenditures and coverage are confused with good health care outcomes. The reality is that our daily environment, our social status and our behavior — including diet and exercise — have more to do with good health than does health care more narrowly defined....The demand for universal coverage sounds like a moral imperative to “take care of everybody,” but in reality it would make only a marginal difference when it comes to the overall health of the American population. The sober reality is that universal coverage is another way to spend money, which may or may not be a good idea.”

There are many ideas here with little justification. Let me address them in a more logical order:

1. Universal Coverage: Like auto insurance there are externalities. We have to take care of a sick person whether they have insurance or not. Opting out means moving the cost to everyone who is in. The issue is coverage for what? Catastrophic, accident, chronic, acute. That is the debate.

2. Taxing Benefits: This is a question if and only is we assume that employer benefits remain rather than having a system where every person is insured in a manner akin to auto insurance. I recognize that such an approach is antithetical to the way we think but perhaps new thinking is necessary. Multiple providers, and individuals. Perhaps also the patient should pay the physician or provider and the patient should then get reimbursed by the insurer. Again like auto insurance in many cases. The nexus between the patient and the provider in terms of the payment is a critical connection to let both understand costs.

3. Medicare has some problems but they are too often Government based problems. The Medicare reimbursement system if used in global financial trading systems would collapse the world economy in just a few days. It is incompetently organized and operated. No business would have a billing and payment system like this. I remember my days developing and managing the cellular billing system twenty years ago. They were complex and if we had a problem we were soon aware if it and it was fixed. What takes Medicare so long, well it is the Government!
4. Back to Universal: If Universal is to work then all must be in the system, and if one looks at Medicare then that means Unions and Government workers and all politicians. They must have a dog in the hunt!
9 HEALTH CARE POLICY ALTERNATIVES

The current focus on Health Care cost control has been from the perspectives of the inputs to the system; namely physician charges, hospital charges and drug costs. This paper attempts to present an outcome driven analysis of HealthCare costs to show that focusing in the outcomes and then on the Microstructure of procedures allows for the development of significantly different policy alternatives. We first develop a model for the demand side of health care and demonstrate that demand can be controlled by pricing, namely exogenous factors, as well as by endogenous factors relating to the management of the Health Care process in the United States. We then address several issues on the supply side, starting first at the quality issue and then in terms of short and long term productivity issues. Health Care is a highly distributed process that is an ideal candidate for the distributed information infrastructures that will be available in the twenty first century. It is

We have written extensively about many of the current issues in Health Care. This report looks at the various proposals that have been recently put forth and does so in two perspectives. First we take a step backward and ask the question about the question itself. We do that using the work of Ludwik Fleck, a mid 20th century physician from Poland who wrote a book called *Genesis and Development of Scientific Fact*. Fleck presents a way of looking at the process which helps develop clarity in what is being said by many today. Secondly, we look at what can be called the core elements and principles. We argue that these are the issues which should be debated.

Notwithstanding the various presentations and offerings that are floating about in the current environment we argue that there will be substantial change in Health Care as we know it driven by the changes in the way we deliver the care. As we have argued before if we used the 1950 mindset towards psychiatric care we would have been building bigger and bigger psychiatric hospitals, instead we have medications and few hospitals. The same would have been the case in 1920 as regards to building TB hospitals, and in 1980s of AIDS hospitals. We all too frequently fail to understand that medicine changes. The old adage that fifty percent of what you learned in medical school is out of date the day you complete it has a certain ring of truth. Medicine and its practice are in a constant state of flux. Plans to deal with Health Care must recognize this fact and build on it not institutionalize the past.

9.1.1 A Point of View

There is an interesting approach to the understanding of Health Care and its management by looking at the work of Dr Ludwik Fleck. In 1935, Fleck published this work in German and it lingered in the corner of the world resulting from a variety of reasons, World War II being one of them. Fleck was read by Kuhn who is known for his writings on the Scientific Revolution and his introduction of the term paradigm to establish changes in the scientific world. Fleck, however, approached his theory from
the perspective of a physician. This makes his insights of interest because they in many ways presage what we see today. Fleck used the development and introduction of the Wassermann test for syphilis as the core example. When first introduced the test was thought to definitively test for syphilis. In reality, the test is highly non-specific. Yet the underlying facts as described by Fleck justifying the test were accepted as scientific truths at the time the test was developed. Based upon this observation calls into question the entire concept of facts as existing independent of the observers and adherents to a common viewpoint.

At the time of the development of the Wassermann test there was at best a primitive understanding of the immune system, clearly less than what we understand today. Yet around this understanding combined with cultural and societal predispositions of the disease and its imputed causes came the credibility that the test produced an irrefutable fact, namely the presence of absence of the disease. It took decades to determine that the results were problematic at best. For generations the test was a precondition for a marriage license.

The Fleck model consists of the following principles:

1. Facts are not Objective but Reflect the Collective: To Fleck, facts are not objectively ascertained but are the result of a collective process. Thus in a Fleckian world the facts that we all use as the basis of our decision making are all too often massaged and molded by the collective. For the purpose of a Health Care policy this may mean that the facts that are used by the body politic to demand and structure changes and laws may themselves be suspect. These very facts may be the creations of the collective presenting them.

2. Thought Collectives are the carriers of ideas. The thought collectives are groups of individuals who have assemble around a mutually created set of facts and become the carriers and propagators of those facts. Thought styles originate within an elite central group and propagate outward. Creativity is the result of the thought collective not of any individual. In the Medical world there are clear thought collectives. Facts are all too often the result of what those collectives bring to bear. For example in the current view of many medical issues the cause is attributed to some genetic defect, albeit it may be unknown as to how it functions. For decades after Watson and Crick there was a gene-disease paradigm that was sought, now we see multiple gene and disease paradigms, and we even see some processes evolving, such as the Vogelstein model for colon cancer. In Health Care policy we see several thought collectives existing and from those collectives we see them use their collective based facts to present policies to the world. The thought collectives for Fleck were divided into four layers; (i) the inner circle of creators, (ii) the collection of general experts and advisors, (iii) the popularizers of the of what the inner circle creates, and (iv) the followers and the materials used for initiation into the collective. In the area of Health Care policy we can determine many of the collective inner circles. These are the people who state the change and have the power
to assemble about them the advisors. The advisors are all too often the academics and policy types who interpret and popularize the ideas of the core and the press in a broad sense facilitates the dissemination.

3. Thought styles are the special carrier for the historical development of any field of thought as well as for the given stock of knowledge and level of culture. The thought style is a constraint, it is the setoff boundaries in which the thought collective vies reality and in which the thought collective interprets the facts and thus presents any conclusions based upon those facts. Thought styles mean than any member of the thought collective cannot think any other way.

9.1.2 Underlying Principles

As we have presented Fleck, we can now take the prefacing effort a few steps further. Specifically we look into the world and mind of the current Administration. In a manner it has certain elements reminiscent of the Clinton effort but in other ways it is dramatically different. The current Administration’s approach is much more controlled and professional than was the Clinton effort in Health Care; it is much more mature in terms of the Fleck structure, having an elite and closeted core group. It has its minions of advisors and experts interpreting the approach are the most eloquent of terms and it can effect what is so desires in a less confrontational manner. In addition the mindset of the electorate has changed considerably as well and the presentation of the Administration’s efforts are on the one hand vague and unstructured, thus obviating any frontal assault by those opposed and on the other hand are stated when done so in non confrontational a manner. There is no Hillary Health plan taking away from the public what they held dear. In fact the public sees its health care at risk and thus are considerably more compliant.

From what perspective are the elites approaching Health Care. Let me deal with this from an oblique but convergent manner. Fifteen years ago I wrote a paper on universal service in telephony. I compared the Rawlsian system with the Utilitarian school and the Benthamites. Rawls was a philosopher whose view of the world was that people should all receive at the level of the least of us. He calls this a Theory of Justice. If the least of us gets no MRI then no one gets an MRI. In the simplest terms this is the essence of Rawlsian philosophy. In the paper I was commenting on the Baumol-Willig theorem, a tautological proposition crafted by a few economists at the beckon call of AT&T to justify the incumbents control over the network. I stated:

"The Baumol Willig theorem states that we want to maximize the welfare of the populace while keeping the profits of the monopolies high. This is a classical example of an ad hoc propiter hoc theorem. Clearly the result is that we tax the people and subsidize the monopoly.

The other issue is how we measure welfare."
If we are a Rawlsian then we measure welfare as the welfare of the least of us and not the average welfare. Rawls states that if we maximize average welfare then we disadvantage the least of us and this is not just.

Thus as a Rawlsian we demand Universal Service. We must insist that all people have access to all service elements, whether it makes economic senses or not, we do so via wealth transfer. Hopefully, this political theory should now not seem too foreign. Rawlsians favor the implementation of access fees and the implementation of Universal Service. Indeed, the true Rawlsian would impute Universal Service to even computer terminals as has been stated by Vice President Gore.

In contrast is the classic liberal, now called libertarian view. It is more a combination of minimal government involvement and maximizing utility to the consumer. This is the philosophy of the utilitarian. Here we assume that government has a de minimis role and that the market follows of its own accord and that the market, in an Adam Smith fashion, will clear any inefficiency of distribution and pricing mechanisms.

It assumes that each business should stand on its own stand and that utility is maximized on average. The result from the libertarian school, as opposed to the contractarians or Rawlsians, is the elimination of access fees and the elimination of universal Service."

I then went and described the Rawlsian approach; one which I thought would never raise its head again. I stated:

"Rawls has proposed a theory of justice that is a statement of what many proponents of antitrust theory ion the mid-fifties and sixties promulgated. The essence of Rawls’ theory has three elements;

Original Proposition: There exists a means and method for a society to establish a Contract amongst and between them. This Contract thus created in this society of the just is one that maximizes the return on every transaction to the least of the individuals in the society. This approach to Contractarianism is one related to individuals in a non-bargaining environment establishing between and amongst them a “contract” to govern their society.

There are two elements contained herein.

The first is the essence of a contract, and in fact a form of social contract between the members of society and amongst them as a whole.

The second element is that of a view towards man as a constrained and unconstrained view of Human nature."
The unconstrained view states that man, individually and in concert, has the capabilities of feeling other people’s needs as more important than his own, and therefore we all act impartially, even when the individuals own interest are at stake.

The constrained view is to make the best of the possibilities which exist within the constraint.

For example, the constrained view of universal service is one which would state that if it costs a certain amount to provide the service, an there is a portion of the society not able to purchase the service, then there is no overriding need to provide it if such a provision is uneconomical and places a significant burden on the other member of society.

The unconstrained view, as a form of socialism, states that if there is the least of us in want for whatever the telecommunications revolution has in store, then they should have access to it at whatever cost. One can see that the current trend in Universal Service is such an unconstrained view, especially as viewed by the current Vice President in his actions over the past four years.

Rawls approach to this contract is one wherein the individuals in the society collect themselves as individuals, and agree to a plan for the operations of that society.

First Principle of Justice: each person shall have equal rights and access to the greatest set of equal fundamental personal liberties.

Second Principle of Justice: social and economic inequalities are to be arranged so that they both, (i) provide the greatest benefit to the least advantaged, and (ii) attached to positions available to each individual under conditions of fair equality of opportunity."

Thus to my surprise I read in this week's JAMA an article entitled, The Ethical Foundation of American Medicine, In Search of Social Justice. In their view the Rawlsian approach is key to the way in which health care should be provided. They state:

“Rawls’ theory of justice, often referred to as social justice, has gained prominence since the 1970s as a dominant theory of justice. This theory has 2 major principles. The first, that “people should have maximal liberty compatible with the same degree of liberty for everyone,” defines limits of individual liberty by focusing on the liberty of others. The second, that “deliberate inequalities [a]re unjust unless they work to the advantage of the least well off,” focuses on social consequence and responsibility for actions.

Considering the body of research and news reports that describe inequalities in US health care access and quality, and the fact that these inequalities do not work to the advantage of the least fortunate, it is clear that the US health system does not meet these criteria for being just. It seems that the structure of incentives in the current health
system stimulates behavior that marginalizes considerations of social justice, leaving it seldom emphasized, relative to the other 3 core principles of medical ethics."

Unlike other theories of society, the Rawlsians argue that there exists a social contract with all so that all should receive what the least receive and no more. Thus if I have the financial resources to seek medical care for the prevention of colon cancer by annual colonoscopies and the law permits payment only for five year colonoscopies, the Rawlsian would either deny me my annual choice or make it annual for all, and then have all people pay the added costs.

The Rawlsians establish "rights" extra those constitutionally and legally established and then take the position that if the least of a society do not have them fully then none shall have them. It states that those who have been successful should not in any way use that wealth to disenfranchise those who do not. In a manner Cass Sunstein and his works on a Second Bill of Rights fills the bill for the Rawlsians.

The Rawlsian School also removes burdens from people. If you happen to be one of the 30% who are morbidly obese in the US and most likely suffering from Type 2 Diabetes, so be it, it is not your fault, despite the fact that you consume well in excess of 2000 cal per day, you must be dealt with as a faultless and blameless victim. Those who struggle to maintain health must therefore pay for the victims who out of total abject neglect do not.

The article in JAMA continues:

"For example, physicians attempt to maximize income while caring for the needs of their individual patients, but this means that some physicians choose to accept fewer, if any, Medicare and Medicaid recipients, as well as self-pay patients. Some physicians argue that to keep their practice financially viable, they have to see fewer patients for whom they are inadequately reimbursed.

Yet for each of the physicians who decide they can no longer care for these patients, the responsibility of care falls to another clinician. This increases the burden on those other clinicians and exacerbates the income disparities among them. In circular fashion, this increases the focus on revenue and reimbursement, rather than on social justice.

A second factor that may contribute to the imbalance of medical ethics in practice involves the cost of education and level of student debt....

A third important factor is the US culture of “individualism.” While general western philosophy has shaped US culture, the unique history of the United States has created a special emphasis on individualism, entrepreneurial capitalism, and personal responsibility. Specifically regarding health care, many other western nations have some form of universal coverage supported by their government and treat health care as a
The Telmarc Group

HEALTH CARE POLICY: POLITICS VS REALITY

public good. In the United States, health care only intermittently has been treated as a public good and an intense debate regarding the promotion of government health programs vs the philosophy of individual responsibility and allowing market forces to work is ongoing."

The authors recognize the unique character of the United States and then as classic Rawlsians they reject it in a backhanded manner. The US has not only created the special emphasis on individualism, entrepreneurial capitalism, and personal responsibility but has built its culture, society and success on those pillars. They are at the core of our society and they are what make us what we are, they are the success of the United States. The authors as true Rawlsians are vehemently opposed to those core principles. That should be a terrifying thought.

Now there are other schools of thought. For example, there were two recent articles today which reflect on the ultimate cost containment in Health Care. The first is by Boudreaux who is a conservative professor of economics at George Mason. The second was in the NY Times discussion Obama and his grandmother. Boudreaux states the old adage that if several people have dinner and all agree to equally split the cost then this is an inducement for one or more to order the highest priced item on the menu. There are several flaws in that argument but let that stand. The second is the problem of Obama and his grandmother. He was dying of terminal cancer at 86 and she broke her hip. She had the hip repaired and died two weeks later, from either the cancer or broken hip. The issue was should Medicare pay for hip surgery for someone who is going to die anyhow?

These two stories are quite different but reflect in essence the same problem.

First, why do people go to physicians and hospitals?

1. Primarily in youth due to accidents and in old age due to chronic ailments. Broken bones and congestive heart failure. Chronic illness in the aged is frequently life style related; smoking, drinking, overweight, and failure to have preventing care. Some of the chronic old age problems are genetic, but less than half.

2. Many older people do not go to seek medical care until it is a more severe problem. They generally avoid care because they fear the worse. The avoid care during that period when it can be mediated and the impact reduced. It is a deadly cycle. You see that 65 year old widow in the emergency room at 3 AM Sunday with an impacted colon ready to burst because for the last month she feared she had cancer and was afraid to see the doctor. Now, in addition to the neoplasia she has septic shock! How does one stop that, she had Medicare, yet she was terrified. She did not select Boudreaux’s fillet Mignon, she was terrified. Economists have no experience of the emergency room and the fears of the elderly.

Page 290
3. The Obama problem is a simple one, human dignity. If his grandmother needed surgery then he had a moral duty to see that she received care. We as a society have a moral duty to see that such a person is cared for. Yet, at what level for society? If society decides it is palliative, and then a person of substantial means like Obama has an overriding duty, honor thy parents, to see that she is taken care of. The end point is a moral imperative, respect and care. The way to that end point may be open for debate. Who has responsibility, those with the means such as Obama, or society in general? Who gets the fillet Mignon and who gets the chicken?

4. Stuff happens. There is a percent, albeit much smaller than the percent of chronic illnesses, of people who have catastrophic illnesses. These are the brain tumors, the ALS patients, the MS patients, the ones who have gotten various leukemias, melanomas, and the like. Here society also has a moral imperative to assist those people so that their families and the person themselves are not financially destroyed as well as physically. The 39 year old mother with a glioma and three children, with a husband working two jobs is what I am focusing on. This requires the rally round approach, there are few people like this, more than there should be, and yet we as a society have a moral duty to assist them as best we can.

Thus, Boudreaux points to a small group of people who choose the Beef Wellington. There are just not that many. Patients do not choose one surgery over another. A patient with a disorder seeks to be cured or at least regain some quality of life for as long as possible. I have no idea what the Boudreaux argument is based upon. The Obama story is more complicated. Clearly the end point is without doubt, but who pays for that end point is a question. Should multi-millionaires get Medicare at the same cost as say a retired telephone company lineman? That is the way it is today. Most likely that will not be the way it will always be.

To examine the Fleckian world let us examine briefly a book by David Cutler of Harvard who is a major advisor to the current Administration. In many ways this is a classic example of the advisor layer and it presents the thought style and is a true element of the current Administration's thought collective on Health Care.

Cutler deals with the issue via a set of issue oriented vignettes. Let us follow along in that vein:

In Chapter 2 he speaks of pricing. He specifically he speaks of the rich willing to pay more and demand more health care. He states that the rich value health insurance more than the poor. In fact, in today's market for the truly rich, the physicians and hospitals that treat them in the fashion they desire do not accept insurance. Say you are quite wealthy in New York and you have a potential ovarian carcinoma and you desire one of the best referred physicians in the city. When seeking out that person you find that they do not take insurance of any kind. That is what the truly rich deal with. Then for the truly rich they get hospitalized in exclusive floors at the best hospitals and have round
the clock nursing, gourmet food, and all the amenities as they require. That is not covered by insurance. Cutler seems to define rich as anyone having insurance not the rich who have no need of insurance. Further when one looks at the demands placed upon the medical system, the upper middle class and upper class all have health care directives generally stipulating limited measures in extremis. In contrast it is the group without insurance who all too frequently seek and demand in extremis procedures and thus drive up costs. Cutler's thought style is aligned with the thought collective. He is not the creator of this thought style; he is but an advisor promulgating it in an "intellectual" manner.

In Chapter 3 he discusses the extreme costs of dealing with premature infants. Again, for the most part, these are problems arising in a community where the availability of insurance and of pre-natal care is minimal. He argues that the reason for the growth of prenatal costs is twofold; first the lacks of prenatal cares and second the development of medical techniques and technology allowing for the survival of premature births. He fails to state that the reason all too often is individuals not taking personal responsibility. That element of the cause is outside of the basis of the thought style.

Chapter 4 is a discussion of Prozac and the cure of mental disorders. He states that this is a recent phenomenon, the last twenty years, since the early 1990s. In fact this has been growing since 1950 with the introduction of haloperidol and Thorazine. In the 1960s the mass number of psychiatric hospitals were emptied assuming medication could now handle the problems. In many ways it did. Much of the illness considered as a mental health concern can be handled by medication and often via the internist and not requiring psychiatric consultation. Yet it is not new, in fact it has been around for almost sixty years now. Furthermore it is a primal example of how the delivery of health care can change. That seems to be missed as an observation by Cutler.

Chapter 5 is on the use of heart medications. The thought style here is one that assumes that medication can prevent disease and prolong quality of life. One would suspect that the same would be the case if he had written a chapter on Type 2 diabetes. What is lacking is any discussion of individual and personal responsibility to manage lifestyle such as weight and exercise.

Cutler continues on in a variety of other areas discussing quality in a vague manner and then universal service in a similar fashion. He lacks any details to understand what his proposal truly is but one does get a view of the thought styles of the thought collective.

9.1.3 The Problem

Thus, what is the problem? If we look at the following charts we find that for those insured the expenditures are equal for both physicians and hospitals. In addition most of the payments still come from the insurer with a modest out of pocket. In contrast the Government paid portions, consisting of Medicare and Medicaid, are dominated by
Hospital expenses at more than a 2X rate. This seems to imply that the care these patients receive is all too frequently delivered in a hospital. It also implies that the hospitals may very well have the dominant leverage when dealing with the government. This will become clear as we look at the issue of bundling.

The following chart further details Medicare expenses by allocation. Hospital care represents almost 50% of the total Government expenditures, including all in costs. Physicians represent about a quarter and the remainder is spread across prescriptions and nursing homes and medical support services.
The following Table is the full detail which we used for the above two charts.

<table>
<thead>
<tr>
<th></th>
<th>Private</th>
<th>Government</th>
<th>Total</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Insured</td>
<td>Out of Pocket</td>
<td>Other</td>
<td>Subtotal</td>
</tr>
<tr>
<td>Hospital Care</td>
<td>$291</td>
<td>$27</td>
<td>$355</td>
<td>$355</td>
</tr>
<tr>
<td>Physicians and Clinical Services</td>
<td>$264</td>
<td>$55</td>
<td>$34</td>
<td>$353</td>
</tr>
<tr>
<td>Dental and Other Professional Care</td>
<td>$79</td>
<td>$65</td>
<td>$3</td>
<td>$148</td>
</tr>
<tr>
<td>Prescription Drugs</td>
<td>$113</td>
<td>$56</td>
<td>$0</td>
<td>$170</td>
</tr>
<tr>
<td>Home Health and Nursing Home Care</td>
<td>$17</td>
<td>$43</td>
<td>$6</td>
<td>$67</td>
</tr>
<tr>
<td>Medical Equipment and Other Personal Care</td>
<td>$3</td>
<td>$51</td>
<td>$7</td>
<td>$61</td>
</tr>
<tr>
<td>Subtotal Personal Health Care</td>
<td>$767</td>
<td>$298</td>
<td>$87</td>
<td>$1,152</td>
</tr>
<tr>
<td>Administration and Net Cost of Private Insurance</td>
<td>$112</td>
<td>$0</td>
<td>$2</td>
<td>$113</td>
</tr>
<tr>
<td>Public Health Activity</td>
<td>$0</td>
<td>$0</td>
<td>$0</td>
<td>$0</td>
</tr>
<tr>
<td>Research Equipment and Structures</td>
<td>$0</td>
<td>$0</td>
<td>$104</td>
<td>$104</td>
</tr>
<tr>
<td>Subtotal, Other</td>
<td>$112</td>
<td>$0</td>
<td>$105</td>
<td>$217</td>
</tr>
<tr>
<td>Total</td>
<td>$879</td>
<td>$298</td>
<td>$193</td>
<td>$1,369</td>
</tr>
<tr>
<td>Percentage</td>
<td>34</td>
<td>12</td>
<td>8</td>
<td>54</td>
</tr>
</tbody>
</table>
As we have presented elsewhere the growth in the Government supported payments is anticipated to be explosive for several reasons. Specifically:

1. The population is aging and thus Medicare coverage will expand in a natural manner.

2. Medicaid will expand as universal service expands. This is also including full child coverage via the SCHIP programs.

3. Universal service and a Government sponsored plan will also drive up Government coverage as well.

It is important to note that the Government coverage frequently had greater hospitalization due to the requirements for payment. Namely hospital reimbursement is higher than in office reimbursement and thus hospitalization rates are often higher. In addition there is also the natural tendency to hospital older patients and perform fewer outpatient procedures. Ironically this tactic results in increased co-morbidity due to nosocomial infections and the like.

9.2  Key Factors

Before proceeding we will discuss several key factors which will become part of any Health Care proposal.

9.2.1  Patient Characteristics

The following details several key principles regarding the patient's issues in a Health Care plan. There may be many options here.

9.2.1.1  Universal

There is a growing emphasis on the need for universal coverage. As auto insurance is required for the driving of a car, so too it is argued is health care insurance. The problem associated with not having universal coverage is several fold. First is the arbitrage effect of covering only those who may be coverable and then putting the others who may be at risk or not in a pool of the uncovered. Second is that the costs of covering those not covered can be exceedingly high since they typically enter the system when the costs of providing service may be excessively high. They may have avoided preventative care and may have overly exposed themselves to risks. Third, by including all in any plan then the risks carried by any plan underwriter may be leveled out. There is a reduction in the picking and choosing.

The second major issue of a universal plan will be who pays for those who cannot pay. The third issue is who is covered. Clearly the only existing method of covering those who
cannot be a via some tax of Federal subsidy. As one receives other Government social benefits then so too would health care payments be assured. This may mean a separate Government insurer of last resort or Government payments to existing providers akin to food stamps. The last issue of who is eligible is a challenging question. If I were to go to Russia I need a visa and part of the Visa is proof I have health insurance which will cover me if I get ill in Russia. Thus any citizen or legal resident must have coverage and pay for coverage. Should illegal aliens have coverage and if they cannot pay should the Government, namely the taxpayers, subsidize them? That is a political hot potato. Perhaps service can be provided and the bill sent back to their country of origin.

9.2.1.2 Catastrophic Coverage

Catastrophic coverage is essential and without limits. It is akin to a reinsurance plan. There should be some means to deal with the ALS, MS, stroke, Alzheimer's, Parkinson's and other catastrophic diseases. This should include not only physician care, medication, and hospice/hospital care. The question would be can there be differing levels of such care? Can one subscribe to various levels and pay a premium. Can one pay out of pocket above and beyond the norm and seek improved service from a different provider? Or is the care to be made uniform? Clearly if one has the means then one should be able to enhance the level of care. At the other extreme the minimal level of catastrophic care should be above a reasonable norm.

9.2.1.3 No Pre Existing Conditions Limitations: Equality in Payment and Benefits

If the service is universal, then a second issue is that of a pre-existing condition and if that should be an element in increasing rates. That means that a patient must pay more if they have say Type 1 Diabetes or have had surgery for some form of cancer. Once that door is opened it also opens the door for all sorts of other issues such as genetic profiling and risk stratification. Thus there is a compelling argument that the fee is the fee no matter what the pre-existing condition. This then seems to be the only way to eliminate risk arbitrage amongst the providers of the insurance.

9.2.1.4 Preventive Care and Screening

Preventative care and screening are essential elements of any plan. The question is what level of preventive care and screening and then the responsibility of the patient to adhere to this. For example if mammographies are required on an annual basis for all women over 45 then if a woman opts out should she then have her insurance increased to adjust for the increased risk. Should a smoker have an increased payment? Should anyone with a BMI in excess of 25 have some form of increasing premium payment to adjust for increasing risk. It would seem reasonable if there are substantial reasons for certain preventive care procedures and certain screening procedures that it benefits both the patient and the pool of payers. If a patient opts out, and they should have the right to do so, then there is a cost.
9.2.1.5 **Contributory and Taxable**

Any plan must be individually contributory. This is at two levels. First at the basic level of individual payments per person per year and at the level of payments for opting out and opting in, namely obtaining a level of care in excess of a norm. This would strike against such plans which are common amongst unions where the employer pays the total. To motivate people there must be some out of pocket even for company sponsored plans. Also for equity purposes taxing any company contributions would balance costs amongst self employed and employed. Every individual should see the same cost curves.

9.2.1.6 **Equity in Pricing**

One of the greatest problems is inequity in pricing. Insurers charge dramatically different prices to large corporations and small companies and individuals. In a manner the small entity underwrites the large entity. This should be eliminated. Perhaps one may retain overage benefits to large entities who guarantee a large group of insurers. But at the base level pricing should be public and essentially the same for any subscriber to any plan of an insurer. There may be different plans and each insurer is allowed to bundle, package, promote and price.

9.2.1.7 **Choice**

Choice is a sine qua non principle. That means choice in insurer, provider, location, level of service. The basic plan should provide a bundle of core services from catastrophic, acute, screening and the like. However if I determine that I should be treated at Memorial Sloan Kettering and not at Cape May Hospital then I should have that right. The issue will be do I have to pay a premium or is this an allowable choice? Clearly it will depend on the disease. If one has a limited basal cell carcinoma then local treatment is fine. If one has a bilateral Stage II ovarian cancer then Sloan Kettering is necessary. The patient should be able to make the choice and the physician should be able to make the recommendation and the service should be covered.

9.2.1.8 **Acute Care**

Acute care is for accidents, MI, seizures, strokes, extremely high fevers, and the most significant things which bring a patient to an emergency room. If a patient comes to an emergency room for what should have been a normal office visit, then there should be some fee for excess service. There are a small fraction of the population who over utilize the emergency room, and with universal service that should be quite a small fraction.

9.2.1.9 **Chronic Care**
Chronic care means nursing home care as well as pharmaceutical care, including physician visits. Chronic care is associate with such disease as congestive heart failure, emphysema, hypertension, Type 2 Diabetes, renal failure and the like. It may require some limited hospitalizations but in general is costly regarding medications and out-patient treatments. Chronic care is not immediately life threatening and it may occur in both young and old. Any plan must have a core level of chronic care treatment including generally accepted procedures and medications.

9.2.2 Provider Characteristics

The problem that we assume we face is that there is too great a demand and that the cost per unit Health Care provided is too high. The plans proposed by various people have all attempted to ignore demand modulation and focus on cost containment. The underlying assumption is twofold; (i) the delivery is inefficient and (ii) the costs of what is delivered are too high. The inefficient delivery is assumed to be a result of the many who are uninsured and thus require care extra the normal channels and the costs issue is based upon the fact, remember Fleck, that the deliverers of healthcare charge too much and do too many procedures thus driving up total costs.

9.2.2.1 Quality Control

Quality control of providers is essential. There should be metrics based upon procedures, as well as patient perceptions of the providers. This information should be readily available to the provider and the patient and the provider should have the right to contest and claims of quality deficiencies which may have been made. The quality measures should generally be based upon established metrics of efficacy. In addition procedures as well as providers should have their efficacy made available per provider as well.

For example such quality measurements as the mortality and morbidity of heart valve transplants, bypass surgery, femoral head replacement surgery and the like should be collected and made public. Providers should not be penalized for being in a lower range as long as they meet the levels set for professional competence. However the patients should make informed choices of who they want service to be provided by.

9.2.2.2 Procedure Control

The process of controlling procedures aligns itself with the CCE. The providers should have no limits on procedures to be provided but should be part of the CCE program. This means that having an EMR and reporting to a CCE program will assist in managing the over abuse of procedures. For example, the excess use of MRIs and other imaging should be managed. In the case of back pain of undetermined origin, if the physician determines that it is best handled by rest and medication and the patient demands a MRI, then there must be a balance between the patient demands, cost control, and the
physician's judgment. Perhaps a payment by the patient may be useful to manage abuse but if a problem is determined that the payment is returned or credited to the patient. This however may create conflict between patient and provider.

9.2.2.3 Referral Control

What controls should the primary provider have on referrals? What rights does the patient have to seek referrals? Does a primary care physician have to deal with dermatological problems without referring to a dermatologist? If a patient has a diagnosed dysplastic nevus syndrome then may the primary physician refer the patient to a qualified dermatologist? If a patient has a family history of colon cancer can the primary physician refer the patient to a gastroenterologist who does endoscopies? Can the patient select their own specialists? Can a patient having Type 2 Diabetes select an endocrinologist for care? Or should the patient be kept under the care of the primary physician. The same issue relate to patients with cardiology related problems. At what point must a patient get referred to a cardioligist?

Referral control is one of the proposed steps in cost control. The intent is to keep the patient in the primary care setting for as much as possible. On the other hand the patient should have some wide degree of choice. For example, take a patient who is well educated and knows that he has a family history of Hemochromatosis. Should the patient have the right to select a competent GI specialist and be tested for iron overload in his liver say with an MRI? We believe that such educated patient self referrals are not only required but can be highly productive and cost effective.

9.2.3 Payment

The various methods of payment being discussed are a combination of old and new. They range from bundling methods, fee for service, capitation and the like. Each payment scheme has some underlying logic and some underlying objective. As we have seen in the 1990s with the explosion of HMO plans and the use of capitation, the patients and physicians disliked those schemes and the result was a move back to the more classic FFS. Medicare pays on a FFS basis but it caps its fees significantly. Physicians can opt out of Medicare but this typically results in a boutique practice. There are a few of these practices in highly upscale markets.

There have been simple proposals and extremely complex ones as the one proposed by Luft. The Luft model creates a set of payment distribution centers including an automated clearing house, ACH, center, akin to that used by banks for clearing of checks. There is a single payer model as promulgated by Hillary Clinton in the early 1990s. The list of options may very well be endless.

The following are Payment issues which must become part of any plan:

9.2.3.1 Unit of Payment
The initial issue is what is being paid for. Classically the payment is for a service. The classic fee for services approach meant a fee for every contact and the contacts were categorized by certain procedures. Thus by defining procedure and allocating a standard fee to each the process was somewhat logical. Thus patient coding for billing was an almost full time task. One diagnosed the problem and related a set of procedures (ICD9) and then using a standard set of charging mechanisms established a charge.

Some have proposed different models. Some at one extreme, the bundlers, have suggested that the procedure be a mega procedure and that there be an owner of the mega procedure such as the hospital and that the hospital worry about how to split the pie.

Thus the unit of payment issue is what is paid for and who determines the price. Is this a market driven process or is it a price controlled process. If it is market driven then it is incumbent for the seller to post prices so that the buyer can choose. However a patient is oftentimes the least competent consumer in making such a choice. In fact unlike the view of many free market types, consumer chooses their physicians in one of a few ways, almost none of which relate to prices. Referrals dominate the selection of physicians. Then the relationship built between patient and physician comes to play. A patient frequently goes to a physician referred by a friend or physician. If the "chemistry" works they stay and if not they seek an alternative. This is hardly a free market process.

9.2.3.2 Payer of Payments

Insurers and the Government have been the intermediaries as payers. The ultimate payer is the employee or the taxpayer. Just as a reminder the Government does not really have any money. They can print it but that ultimately costs the taxpayer in inflation as well. Thus ultimately the taxpayer is the ultimate payer of first and last resort.

Yet in any system, we look to the intermediaries and they are insurers and the Government.

9.2.3.3 Source of Payments

When a patient is provided a procedure by a provider then the provider electronically submits the claim to the payer and it is reimbursed promptly via an electronic means. There should be some form of separation of payment with validation. Validation is ex post facto with significant penalties for fraud. Yet the system should have some modicum of testing for invalid claims just to avoid unnecessary fraud claims.

9.2.3.4 Who Pays; Patient, Employer, Government
Ultimately the taxpayer pays. They pay now or latter. They may have already paid as in the case of the retired and Medicare. However it may be essential that each enrollee have some personal payment as part of the plan. One question is regarding the amount. Is the amount to be scaled to income? That may be too drastic. Is there a minimum income under which Government subsidies kick in, most likely? Do the Government subsidies go to the payer or the plan, most likely the plan? One can go through the many options here.

9.2.3.5 Cost Control, Rationing

Cost control has always been the bane of the provider. Medicare strictly controls costs and Medicaid even more so. One theory is that cost can be controlled by rationing. Economically we know that rationing just does the opposite. Rationed gasoline drives up price unless one also institutes price control and then that drives out supply. Then people just die. The Government went through price and rationing controls in World War II. It had some effect but it exploded before the War ended.

9.2.4 Process Management

Process Management is a broad term which includes all interparty information management, flow, and accountability. This includes such issues as actual payment processing and payment flow as well as patient medical records and inter-provider communications and quality management.

9.2.4.1 Electronic Medical Records

We have argued that the EMR is a vital part of an ongoing health care delivery system but at the same time it is a complex and evolving system. It cannot as the current Administration optimistically believes be implemented in a short period of time. It is complex and evolutionary. It is akin to implementing the Internet in a year or two. The Internet took three decades. And that was with the right people and the right organization. The EMR will be dominated by Government bureaucrats and hangars on. It will be a culture festival amongst groups who bring nothing of merit and everything of a burden to the process. Yet having an effective EMR system is essential. It must be patient based and it must be able to be searchable in a full multimedia format.

9.2.4.2 Quality Measurement and Management

Health care quality like some many other quality issues may be quite elusive. We measure quality generally in terms of outcomes and less in terms of the patient experience. The old aphorism of "If all else fails listen to the customer." may very well apply here. Quantitative outcomes are clearly one of many measures of quality. The morbidity and mortality rates for various procedures inter facilities are also an
important metric. Yet the patient's perceptions and how they are reflected are also important. Thus quality metrics must be a balance between actual results and performance as well as patient perceptions.

9.2.4.3 Payment Management and Flow

Payment to providers is notoriously complex and arcane. It requires significant documentation, tracking, delays, and denials and then the following up of various attempts to remediation. This applies to both Government and private payers. It is essential to develop improved payment systems that balance simplicity and timeliness with the safeguards against abuse and outright fraud. At one extreme one may just pay all Medicare claims at the close of business of the day the service is provided. The technology is there. Then one could imagine a penalty system which would make the cost of cheating the system so high that it would reduce the fraud to a manageable level while still allowing short term payment. Such a simple system could be self policing, assisted by post transaction audits, and would reduce the bureaucratic overhead costs dramatically. The same could apply to private insurers. The Luft ACH mechanism may have some merit here albeit a rather arcane approach.

9.2.4.4 Patient Information, Education and Monitoring

Patients are coming to the offices of physicians more educated than ever before. That may be for the better or the worse. On the other hand the physicians are generally ill equipped to educate and inform their patients. Take the simple issue of informing the patient about test results. HIPPA places a significant burden on the provider not to use the Internet unless there are strict written and agreed to guidelines. Few physicians are equipped to deal with this. Thus patients call and deal with office staff to gain information about their procedures and results and this leaves the patient hanging until they finally gain what they seek. Physicians must communicate with their patients and the time and effort doing so should be compensated. HIPPA must be amended to readily allow internet access to patient results and physician to patient communications. This also must apply to inter-provider sharing.

9.2.4.5 Comparative Clinical Effectiveness Data Collection and Analysis

CCE is a new buzz word in the current Administration. It looks at the many procedures and mediations that are used to treat problems and then in essence ranks them and suggest the most favorable. There are many problem with strict adherence to such an approach. First not every problem is the same. In addition patients may have multiple problems. Third the recommended procedure may be recommended based upon faulty data. Third the recommendation may be the result of a gross misinterpretation of the data available in the field. In this paper we present examples of faulty CCE data from two areas; screening for prostate and ovarian cancers. We argue that the data was correct, the conclusion was correct for the question asked, but it was the wrong
question and that a generalization to the right question cannot be attained using the data available. Thus in the prostate case the generalization of the result to the point of saying that screening for prostate cancer is ineffective is wrong. Screening at the level of PSA used was the wrong level; not that screening has any benefit. Thus any CCE recommendations based upon this paper would be wrong and harmful. Thus CCE can be a minefield of improper interpretation.

9.2.4.6 Screening

We add screening to this portion of the requirements. Screening is a critical element in the delivery of Health Care. All too often it is not done as part of patient care. Many if not most patients are screened for correctable or even preventable diseases. Mammograms are one of the few which are promoted on a national basis. Prostate screening, glaucoma, diabetes, skin cancer, ovarian cancer, colon cancer, and the list would go on can see some improvement by screening. The question is what is discretionary and what is mandatory. If a person is obtain Health Care then is it limited to acute and severe chronic care or is it mandatory that it also include screening. There are debates as to the effectiveness of screening. We argue later that many of the concerns related to screening are more experimental design issue than true screening deficiencies. Physicians do not mandate screening because they may neither see a benefit nor may they obtain compensation or both. Patients are in many cases ignorant of the screening issues.

Thus should screening be mandatory, at what level, and what price? Should a patient have the right to opt out of screening? What if a woman does not want a mammography? Does she have a right? She has a right to reject end of life treatments, does she have a right to reject screening if she demands extreme end of life treatment? Is there some quid pro quo at play?

9.3 Obama Plan

We first look at the proposed Obama Health Care Plan as has been presented. (See Healthcare policy in an Obama administration: Delivering on the promise of universal coverage, PricewaterhouseCoopers’ Health Research Institute). The following Table outlines the issues:

<table>
<thead>
<tr>
<th>Obama’s proposal</th>
<th>Parallel Massachusetts reform</th>
</tr>
</thead>
<tbody>
<tr>
<td>Increase eligibility for Medicaid and SCHIP to 300% of poverty level.</td>
<td>Eligibility for MassHealth, the state Medicaid program, increased up to 300% for certain populations.</td>
</tr>
<tr>
<td>Obama’s proposal</td>
<td>Parallel Massachusetts reform</td>
</tr>
<tr>
<td>--------------------------------------------------------------------------------</td>
<td>-----------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>“Pay or play” system in which large employers must provide health insurance for their workers or pay a penalty.</td>
<td>Same pay or play system. Large employers must have 25% of their workers enrolled or pay 33% of the premium. Employers that do not make the “fair and reasonable” contribution to employee healthcare premiums are required to pay a $295 annual “fair share contribution” for each full-time employee. This amount is pro-rated for part-time employees.</td>
</tr>
<tr>
<td>Provide subsidies for low-income consumers to purchase health insurance.</td>
<td>Subsidized premiums for individuals with income below 300% of poverty.</td>
</tr>
<tr>
<td>Parents must enroll their children in public or private health insurance.</td>
<td>Adults must enroll in either public or private coverage if it’s affordable for them; those who don’t enroll pay higher taxes through the loss of exemption. Children are not required to have coverage but low income children would be covered under SCHIP or Medicaid.</td>
</tr>
<tr>
<td>Provide subsidies for small businesses and individuals who can’t afford coverage.</td>
<td>Small employers are not required to provide coverage.</td>
</tr>
<tr>
<td>Create a National Health Insurance Exchange that would allow consumers to purchase health insurance from a range of private and public insurance options.</td>
<td>Massachusetts Connector establishes creditable coverage and links individuals, families, young adults, employees, and employers, with plans that are rated gold, silver and bronze. Small group and individual markets are combined into one group allowing both increased purchasing power and lower plan rates.</td>
</tr>
<tr>
<td>Required level of coverage: nothing specified, but there likely will be a minimum level of coverage set. In addition, his health insurance exchange will likely have certain minimum standards included.</td>
<td>Minimum creditable coverage (MCC) determines the baseline benefits an individual must obtain to avoid tax penalties, including: 1. Comprehensive coverage including preventive, primary, emergency, ambulatory patient, and mental health services along with prescription drug coverage; and 2. Maximum deductible, annual and life benefits, coinsurance, and out-of-pocket spending.</td>
</tr>
<tr>
<td>Create a national insurance plan for consumers to purchase individual coverage.</td>
<td>Nothing similar.</td>
</tr>
<tr>
<td>Reinsurance subsidy for employers’ catastrophic healthcare costs.</td>
<td>Nothing similar.</td>
</tr>
</tbody>
</table>

Note that this creates an exchange but the issues of bundling and the other elements such as EMR and the like have been placed elsewhere. This is a near universal coverage approach. PWC summarizes the Obama Plan as follows:

- President-elect Obama’s promised reforms are aimed at providing tax subsidies for the healthcare disenfranchised: the 15% of Americans who are uninsured and those
small businesses that cannot afford to offer health coverage to their workers. However, he has proposed new rules for insurers, which could impact the overall industry.

- Many of Obama’s proposed reforms are being tested at the state level in Massachusetts, where they have resulted in the nation’s lowest uninsured rate in what has been the most costly healthcare state.

- Based on the results in Massachusetts, PricewaterhouseCoopers estimates Obama’s plan would provide coverage for two-thirds of the nation’s uninsured at a cost to the government of $75 billion a year.

- Of the 30 million Americans who would be newly insured under Obama’s proposals, nearly 40% would obtain coverage through their employers. That would mean a reversal in the current decline of employer based coverage. Most of the gains in coverage are likely to come from small employers.

- Not all of those who will receive subsidized coverage under the new plan would have been previously uninsured. PricewaterhouseCoopers estimates that about 4.5 million people would trade their current private coverage for insurance with higher government subsidies.

- Obama’s reform plan does not include a requirement that individuals purchase coverage, an aspect that Massachusetts health leaders say has been important to reducing their uninsured numbers.

- Over one-third of the cost of Obama’s plan could come from existing funding for the uninsured; much of that funding now goes to hospitals. The rest will have to be raised through repealing tax cuts, raising taxes, or limitations on other spending.

- Expanding coverage to more Americans will exacerbate current deficiencies in the health system, such as shortages of primary care clinicians.

- Unless successful cost containment strategies were put into place, growing healthcare costs will increase the costs of Obama’s plan dramatically over time and reduce the effectiveness of mandates. This could make the federal costs unsustainably high.

- Obama’s proposal is likely to lower margins for providers, pharmaceutical companies, and health plans that increasingly depend on government payment.

- Regardless of whether Obama’s proposals are implemented, the health industry can improve care and lower costs through public-private efforts on five ideas:
  
  - Keep people well
  - Reorder treatment around collaboration
• Simplify the system
• Make interoperable electronic medical records a reality
• Use genes to pick the lock on disease

9.4 Baucus Plan

The Baucus Plan is outlined as follows. We include this Plan as one of the two because Baucus seems to be the lead since Kennedy has fallen ill. The plan demands universal coverage, a buying pool and introduces bundled payments46. It continues employee coverage. It modifies some provisions of malpractice and it also covers an expanded group via SCHIP and tax rebates.

The Baucus Plan is detailed in various documents presented by his office.

| Change Insurance Coverage |  |
|----------------------------|-------------------------------------------------
| **Individual Mandate**    | The responsibility for all Americans to obtain health insurance coverage would be enforced possibly through the U.S. tax system (or some other point of contact between individuals and the federal government). Each individual would receive a certificate of coverage from their insurer to verify that they are meeting their responsibility. |
| **Employer Mandate**      | The vast majority of large employers would probably continue to provide coverage as a competitive benefit to recruit employees. If these employers choose not to provide coverage, under the Baucus plan they would have to contribute to a fund that would help to cover those who remained uninsured. The contribution would likely be based on a percentage of payroll that took into account the size and annual revenues of each firm. Mid-sized and small employers would also have the option of providing adequate coverage or paying into the general coverage fund, but the required contribution would be less for them than that for larger firms. |
| **Purchasing Pools**      | The Baucus plan would establish the Health Insurance Exchange through which individuals and small businesses in the market for insurance could obtain affordable health care coverage. The Exchange would be an independent entity, the primary purpose of which would be to organize affordable health insurance options, create understandable, comparable information about those options, and develop a standard application for enrollment in a chosen plan. Participating employers must enroll all employees through the Exchange—not only the most costly to insure. Insurance plans participating in the Exchange could operate nationally, regionally, statewide, or locally. Participating insurers would have to charge the same price for the same products inside and outside the Exchange. Plans participating in the Exchange would be subject to regulatory oversight by states. |

---

46 See http://www.randcompare.org/proposals/federal.php?start=0&max=15&ty
### Refundable Tax Credit

In order to make health coverage affordable for all Americans, refundable tax credits would be available to individuals and families with incomes at or below four times the Federal poverty level. These tax subsidies would be available to individuals and families who purchased coverage through the Health Insurance Exchange.

### Medicaid/SCHIP Eligibility

The Baucus plan aims to extend Medicaid eligibility to every American living in poverty. Establishing a national eligibility minimum of 100 percent of the Federal poverty level would help to streamline Medicaid. Additional efforts to streamline Medicaid eligibility and enrollment are also part of the plan. Uniform and simplified verification and renewal rules should be established to help minimize the “churning” that typically occurs within Medicaid. Simplifying eligibility would expedite and lower the costs associated with states’ eligibility determination processes. The Baucus plan also would require states to use SCHIP to cover all children at or below 250 percent of the poverty level and who is not Medicaid eligible. States that currently cover children above 250 percent of the poverty level would continue to do so. Existing matching and other policies not inconsistent with a responsibility to have health coverage would remain in place for states with income eligibility that exceeds 250 percent of the poverty level.

### Open Enrollment in FEHBP

### Change Benefit Design

### High Deductible Health Plans

### Change Payment Rules

#### Hospital P4P

Congress and CMS have enacted and implemented policies to increase the focus on quality in the Medicare payment systems, particularly in the areas of inpatient hospital care and physician services. The Baucus plan will build on these efforts by establishing a pay-for-performance program for hospitals in Medicare and further strengthening physician programs that are focused on quality improvement.

#### Physician P4P

Congress and CMS have enacted and implemented policies to increase the focus on quality in the Medicare payment systems, particularly in the areas of inpatient hospital care and physician services. The Baucus plan will build on these efforts by establishing a pay-for-performance program for hospitals in Medicare and further strengthening physician programs that are focused on quality improvement.
| Change Health Services Delivery | Consistent with recommendations made by MedPAC and others, the Baucus plan proposes three strategies to encourage the adoption and use of health IT: (1) financial incentives, (2) assistance to providers in navigating the health IT market and implementing systems, and (3) promotion of information sharing among providers. |
| Change Legal Environment | The Fair and Reliable Medical Justice Act introduced in the 109th Congress and again in the current Congress, includes ideas for ensuring safe and effective medical care, while working to limit malpractice insurance premiums. This legislation would provide grants to states to create alternatives to current tort litigation in an effort to increase access to recovery for patients with low-dollar value claims and improve satisfaction with claims resolution for patients and providers. States would have flexibility in developing alternatives to civil litigation, with three specific models outlined in the bill: (1) the early disclosure and compensation model, (2) the administrative determination of compensation model, and (3) the health court model. Like the legislation, the Baucus plan would call on states to take the opportunity to develop alternatives for resolving conflicts and compensating patients who are the victims of medical errors. In addition to receiving Federal assistance to establish an alternative model, states would also receive assistance to collect data about medical errors, which would help keep patients better informed and create an opportunity for providers to learn from each other. |
| Disease Management | Congressional proposals have called for a more coordinated national strategy to prevent chronic disease and reduce obesity. Congress should authorize a study to identify the various federal programs that can help prevent the development of chronic disease and suggest options to more effectively coordinate efforts going forward. |
| Bundled Payment | Using its administrative authority, CMS has taken steps toward bundled payments by establishing the Medicare Acute Care Episode (ACE) demonstration. Currently under development at CMS, this demonstration project would allow hospitals and physicians to receive a global payment for services provided to patients who receive certain cardiac and orthopedic procedures. A similar project, the Medicare Participating Heart Bypass Center demonstration, was tested in the early 1990s. More recently, bundled payment initiatives have been tested in the private sector. Building on these efforts, the Baucus plan would develop and test other models for bundled payments. As part of this effort, the plan would allow the current CMS bundling demonstration to expand to other sites and to focus on other clinical conditions if certain criteria are met. In addition, this plan would encourage CMS to include services that are provided post-hospitalization as part of the bundling payment model. |
9.5  Other Plans

There are hundreds of other plans. Rand, CBO, Brookings, Cato, Commonwealth Fund and many others have provided summaries and critiques of plans.

We summarize the plans from the work done by Rand\textsuperscript{47}:

9.5.1  Public Plans

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Change Insurance Coverage</td>
<td>Individual Mandate</td>
<td>Employer Mandate</td>
<td>Purchasing Pools</td>
<td>Refundable Tax Credit</td>
<td>Medicaid/SCHIP Eligibility</td>
<td>Open Enrollment in FEHBP</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Change Benefit Design</td>
<td>High Deductible Health Plans</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Change Payment Rules</td>
<td>Hospital P4P</td>
<td>Physician P4P</td>
<td>Bundled Payment</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Change Health Services Delivery</td>
<td>Health IT</td>
<td>Disease Management</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Change Legal Environment</td>
<td>Medical Malpractice</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

\textsuperscript{47} See http://www.randcompare.org/proposals/federal.php?start=29&max=15&type=current
9.5.2 Private Plans
<table>
<thead>
<tr>
<th>States A-B</th>
<th>Advanced Medical Technology Association</th>
<th>AFL-CIO</th>
<th>America's Health Insurance Plans</th>
<th>American College of Physicians</th>
<th>American Medical Association</th>
<th>American Nurses Association</th>
<th>Better Health Care Together</th>
<th>Brooking Institution</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Change Insurance Coverage</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Individual Mandate</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Employer Mandate</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Purchasing Pools</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Refundable Tax Credit</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medicaid/SCHIP Eligibility</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Open Enrollment in FEHBP</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Change Benefit Design</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>High Deductible Health Plans</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Change Payment Rules</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hospital PAP</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physician PAP</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bundled Payment</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Change Health Services Delivery</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Health IT</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Disease Management</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Change Legal Environment</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medical Malpractice</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Change Insurance Coverage</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Individual Mandate</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Employer Mandate</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Purchasing Pools</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Refundable Tax Credit</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medicaid/SCHIP Eligibility</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Open Enrollment in FEHBP</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Change Benefit Design</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>High Deductible Health Plans</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Change Payment Rules</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hospital PAP</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physician PAP</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bundled Payment</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Change Health Services Delivery</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Health IT</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Disease Management</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Change Legal Environment</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medical Malpractice</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
9.6 Problems with Bundling

In this section we consider one of the Baucus proposals, bundling, and demonstrate its serious defects. In the next section we will look at a second proposal of Baucus, the CCE effort, and delineate many of its shortfalls as well.

There has been a flurry of proposals for paying and reimbursing under Medicare as well as in the development of a national Health Care Plan. One of the strangest proposals is the Bundling approach which seems to have originated out of a Medicare advisor group. We look at that proposal briefly. The Baucus Plan promotes the development and deployment of such a plan.

We begin by looking at MedPAC and evaluate its proposals and work in this area. MedPAC is a Government policy panel formed under law to do the following:

"The Medicare Payment Advisory Commission (MedPAC) is an independent Congressional agency established by the Balanced Budget Act of 1997 (P.L. 105-33) to advise the U.S. Congress on issues affecting the Medicare program. The Commission's statutory mandate is quite broad: In addition to advising the Congress on payments to private health plans participating in Medicare and providers in Medicare's traditional fee-for-service program, MedPAC is also tasked with analyzing access to care, quality of care, and other issues affecting Medicare."
In a 2008 paper in the New England Journal by Hackbarth and others, all part of MedPAC, the authors propose a "Bundled" payment system. This bundled system simply stated is that

"Under a bundled payment approach, Medicare would pay a single provider entity (comprising a hospital and its affiliated physicians) a fixed amount intended to cover the costs of providing the full range of Medicare-covered services delivered during the episode, which might be defined as the hospital stay plus 30 days after discharge. Bundling payments in this way should provide incentives to increase efficiency, coordinate in-hospital and post-hospital care, and, if combined with pay-for-performance initiatives, improve the quality of care."

MedPAC published a detailed report in 2008 on bundled care. This report is in many ways the blueprint for Bundled payments.

This bundled approach of MedPAC assumes that if one needs medical care in a hospital that the patient in some manner stops dealing with their physician and then enters into some yet to be defined agreement with a hospital which in turn provides the full "team" and a bundled price. Thus if you require an aortic heart valve replacement, or breast cancer surgery, or prostate cancer surgery, you first get the hospital to tell you what bundle you get.

They choose all physicians and surgeons and they tell you the procedures and they set the price, somehow in accord with Medicare. You just show up and pray that the person or persons who treat you have some idea what they are doing. You choice, your responsibility, your freedom as a patient are destroyed for the better good, in this case the hospital, which in turn reports to the Government!

A detailed paper by Fisher et al called Fostering Accountable Health Care states that:

"We then present a specific payment reform proposal for Medicare designed to foster the development of accountable care organizations (ACOs) and provide empirical evidence of the potential impact of this approach..."

They continue:

"We propose a voluntary and incremental program that would foster the development of ACOs. Our proposal builds on the current Physician Group Practice (PGP) Demonstration, a program in which large group practices are rewarded with a share of the savings they achieve in caring for their Medicare patients if they also achieve documented quality improvement. During the first two years of the program, the participating groups achieved major gains in quality and savings for the Medicare program overall."
They conclude:

"But other approaches to reducing the growth of health care spending and fostering integration face serious constraints and even stronger resistance. The political opposition to requiring all beneficiaries to join capitated health plans would likely be fierce.

Bundled payments reinforce the principle of shared accountability and encourage collaboration and coordination among providers but are unlikely to have much impact on the overall costs of care. Bundled payments will not discourage the provision of unnecessary services outside the context of the episode; nor do they necessarily reduce the provision of unnecessary or questionable episodes of care. And cuts in payment rates will be vigorously opposed as threats to providers’ ability to provide care to Medicare beneficiaries. The tensions that have to be managed include the difficult physician-hospital relationships pervading some markets, the increasing need to slow spending growth, and the widely held perception that cost containment requires income loss for some providers.

A promising middle ground. In this difficult environment, we believe that a voluntary payment reform designed around ACOs and shared savings offers an incremental and promising middle ground that could meet the interests of providers, beneficiaries, and taxpayers better than the competing alternatives. And interest in the approach is growing....."

In effect their proposal is in contradistinction to the bundled plan. The above highlights their view that the bundled plan would not achieve its goals.

There is also a paper called the Long Term Care Quality Alliance which presents a comparison of the following approaches:

1. Accountable Care Organization (Shared Savings or ACO)
2. Primary Care Medical Home
3. Bundled Payments
4. Partial Capitation
5. Full Capitation

This paper views many negative aspects of the bundled care approach. The paper promotes the ACO model which it defines as:

"The Accountable Care Organization (ACO) model establishes a spending benchmark based on expected spending. If an ACO can improve quality while slowing spending growth, it receives shared savings from the payers. This model is well-aligned with many existing reforms, such as the medical-home model and bundled payments, and also offers additional support (and accountability) to the provider organization to enable
them to deliver more efficient, coordinated care. This approach has been implemented in programs like Medicare’s Physician Group Practice (PGP) Demonstration, which has shown significant improvements in quality and savings for large group practices.

This paper concludes on a positive note regarding the ACO approach:

"The ACO model is receiving significant attention among policymakers and leaders in the health care community, not only because of the unsustainable path on which the country now finds itself, but also because it directly focuses on what must be a key goal of the health care system: higher value. The model offers a promising approach for achieving this goal without requiring radical change in either the payment system or current referral patterns. Rather, fee-for-service remains in place, and most physicians already practice within natural referral networks around one or a few hospitals. By promoting more strategic and effective integration and care coordination, the ACO model holds substantial promise as a reform that offers a potential win-win for providers, payers, and patients alike."

The unintended consequences of a Bundled approach are many:

1. The Patient and Provider lose a Nexus: The relationship becomes one with the hospital and not the physician. It breaks the fundamental bond that is the cornerstone of health care.

   The patient and the physician are an important nexus. The only physicians who have little to no contact with a patient are the pathologist, radiologist, and anesthesiologist. The surgeon has contact as does the other specialists. It goes to the heart of practicing medicine. The hospital has the least.

   In my experience, hospitals are run by managers who care less about patients and more about their bottom line. They are not professionals as are physicians. The only fear a hospital administrator faces is possible loss of accreditation, which only comes after gross negligence if even then. The hospital is run for the benefit of the management and not the patient.

   Teaching hospitals may be different in that they are run to produce new physicians. Thus the teaching hospital may be further out on the risk profile.

   By placing the hospital at the focus as is done in a bundled approach one creates a barrier between patient and physician and further places the worst possible party in a position of control, the hospital administrator.

Hackbarth et al state:
"Bundling the payments for multiple providers would create incentives for providers not only to contain their own costs but also to work together to improve their collective efficiency. Providers accepting bundled payments would have the flexibility to develop entirely new approaches to organizing care and allocating payments among themselves in ways that could help them achieve efficient, high-quality care. They could then share in any savings gained by improving coordination, quality, and efficiency."

There is no basis for this statement. They continue and state that perhaps some adjustments may be made. In fact by placing the hospital in the nexus one creates the most inefficient form as we have shown in our analyses.

2. It institutionalizes and memorializes the hospital at a time when the role of the hospital may be at a massive turning point with genetic medicine.

The Bundled approach places the hospital at the center of the model. We have argued that this entity is the most vulnerable to downsizing and change and is also at the heart of the explosion in costs. This is especially true for Medicare patients. Thus we see that placing such an entity at the core creates a tension for continuation of bad practices.

3. It creates massive problems with the issue of transfer pricing of services and creates the incentive for further padding by hospitals.

Anyone who has ever been in business, in a large multifunction company, has come to grips with the transfer pricing problem. Many business school doctoral theses have been written on the topic and many a corporate war has been fought over the issue. The price one unit charges another for a good or service is difficult to ascertain. This is difficult even when there is a market for the product. For the buying unit may easily say the internal price is too high and that they will go elsewhere. The hospital could do the same. They may say your physician is too costly so you must accept theirs or no surgery, just go home and die!

4. It drives good physicians out of the delivery of Medicare services further disenfranchising those on Medicare.

Physicians are opting out of Medicare in droves, as was reported by the New York Times. As the paper states:

"Many people, just as they become eligible for Medicare, discover that the insurance rug has been pulled out from under them. Some doctors — often internists but also gastroenterologists, gynecologists,... and other specialists — are no longer accepting Medicare, either because they have opted out of the insurance system or they are not accepting new patients with Medicare coverage. The doctors’ reasons: reimbursement rates are too low and paperwork too much of a hassle."
This means that with the system as it is already, it is becoming harder for Medicare patients to find physicians which will take them. If one adds the burden of bundling then it becomes worse.

In our opinion, as we have stated many times in the past, the rearrangement of deck chairs, namely the many plans on how to cut costs via payment and control mechanisms miss the point. First, demand can be modulated, second, costs can be reduced by multiple means, third, genetic medicine will change the paradigm fundamentally and having the agent which will be changed the most in the middle will just delay this change, and finally, and only as the last step is the payment issue.

Let me pose a different issue, however. The plans discussed by Fisher, albeit well posed and meaningful, work for the majority of chronic and acute care problems, such as acute MI, heart valve replacements, and even hysterectomies. However, consider the following. A woman has a BRCA positive breast nodule which upon fine needle aspiration is determined to be a malignancy. She lives somewhere in New Jersey and she has the option, assuming that it still exists, to seek service through one of the Fisher like plans in the local hospital or she goes to Memorial Sloan Kettering in New York. Well, off to New York she would go! She may often have a greater chance of dying from nosocomial infection at some local hospital; I am not saying it would be the one in the town in New Jersey, before the cancer gets to her. The plans proposed by Fisher for Medicare would prevent her from going to a tertiary care facility, even if it could save her life.

My concern is that the on the average approach works on the average. Yet there must always be room for exceptions, yet the exceptions are always what Government seems so unwilling to deal with, it is inherent in any bureaucracy. I strongly believe that as patients become more aware and as medicine has centers of excellence, that patient choice, albeit at a price, must be maintained. The abuse that Fisher in his many writings presents can and must be eliminated but not at the price of patient choice.
9.7 The Problem with Comparative Clinical Effectiveness

Comparative Clinical Effectiveness ("CCE") has been lauded as a key foundation element of the Obama Health Care Plan and is also a key element of the Baucus Plan. Simply stated the CCE concept states that by means of some Government managed entity and process, results from various clinical trials will be assembles and the result will be a ranking of procedures and perhaps a list of permissible procedures and those for which reimbursement will be provided. As a corollary there also will be a de facto list of non-reimbursable procedures.

As we have discussed earlier with Fleck, the assumption made by the CCE process is that there exist facts, namely results from clinical trials and that these facts are irrefutable because they have been developed via the scientific method. We will show with two recent examples that the facts are brought into question.

There are provisions in the new Stimulus Bill to create a Government Oversight Board for ensuring that there is nationwide compliance with comparative clinical effectiveness, namely rating and ranking procedures, medications and the like for the treatment of various medical ailments.

9.7.1 Colonoscopies

Let us consider the colonoscopy. There already exists a "Centers for Medicare and Medicaid services" the "CMS" which has been performing that task for Medicare and Medicaid for years. Their most recent prognostication was that CT virtual colonoscopy had not met the level for acceptance so that it would not receive payment as an accepted procedure. This may very well be a valid conclusion. The reasons themselves may be varied and the procedure may still be performed unless the new Board as passed under this new Bill agrees with the CMS and then eliminates it.

But let us take another further look. A group of Canadian physicians performed a study that reached the conclusion as follows:

"Conclusion: In usual practice, colonoscopy is associated with fewer deaths from CRC. This association is primarily limited to deaths from cancer developing in the left side of the colon."

Namely they contend that based upon their study there is no benefit to screening for ascending colon lesions. The devil is in the details, however. First the Canadian system admits patients to colonoscopies at very late stages, it is truly a rationed system and in preventative medicine rationing means getting there too late.
Second, these are Canadian physicians in Canadian medicine which means that they permit less than fully qualified practioner to perform these tests which require true skill and care. Their results included the following Table demonstrate that almost anyone can perform this procedure which demands great experience. The procedures were performed by a mix of physicians, most, if not all, not certified as endoscopist.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Gast/enterologist</th>
<th>General Surgeon</th>
<th>General Internist</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total colonoscopies, n</td>
<td>1,806</td>
<td>2,303</td>
<td>944</td>
<td>696</td>
</tr>
<tr>
<td>Complete colonoscopies, %</td>
<td>83%</td>
<td>79%</td>
<td>80%</td>
<td>66%</td>
</tr>
<tr>
<td>All colonoscopies, %</td>
<td>31%</td>
<td>40%</td>
<td>16%</td>
<td>12%</td>
</tr>
<tr>
<td>Case patients, %</td>
<td>50%</td>
<td>42%</td>
<td>17%</td>
<td>11%</td>
</tr>
<tr>
<td>Controls, %</td>
<td>32%</td>
<td>40%</td>
<td>16%</td>
<td>12%</td>
</tr>
</tbody>
</table>

As is well known, colonoscopies can nearly eliminate colon cancer if performed by a skilled endoscopist. Sessile lesions in the folds of the colon are generally the greatest threat. They get missed and they are the killer lesions. Thus the endoscopist must be skilled, must take care and time, and must be thorough. The result is that a procedure costing some $1,200-1,800 can save not only a life but hundreds of thousands in subsequent medical costs.

So how does the new Stimulus Bill, the existing CMS and the Canadian study all blend together? Simply, first we have a functioning Comparative Effectiveness system in place; it functions and already controls over 50% of healthcare. Thus Medicare and Medicaid will see no change, unless, and that is the big question, unless it is done for other purposes than patient care. However it is now possible that all other patients will see an impact, NO! Will most likely become a common refrain.

Secondly, studies like the less than useful Canadian Study may become the hook to hang reduction of procedures on, especially as we see the new Board has a mix of Physicians and non-Physicians.

There has been a flap over the inclusion in the **HR 1 Senate** version of a **Section 802** mandating the development of methods of Comparative Clinical Effectiveness (CCE). The Section of the Bill is devoid of definition but one need look no further than a **CBO** report in December 2007 by Orszag which details these efforts. The Section states:

**"SEC. 802. FEDERAL COORDINATING COUNCIL FOR COMPARATIVE CLINICAL EFFECTIVENESS RESEARCH. (a) ESTABLISHMENT.—There is hereby established a Federal Coordinating Council for Comparative Clinical Effectiveness Research (in this section referred to as the “Council”).**

**(b) PURPOSE; DUTIES.—The Council shall— (1) assist the offices and agencies of the Federal Government, including the Departments of Health and Human Services, Veterans Affairs, and Defense, and other Federal departments or agencies, to coordinate the conduct or support of comparative clinical effectiveness and related health services research; and (2) advise the President and Congress on— (A) strategies with respect to the infrastructure needs of comparative clinical effectiveness**
research within the Federal Government; (B) appropriate organizational expenditures for comparative clinical effectiveness research by relevant Federal departments and agencies; and (C) opportunities to assure optimum coordination of comparative clinical effectiveness and related health services research conducted or supported by relevant Federal departments and agencies, with the goal of reducing duplicative efforts and encouraging coordinated and complementary use of resources."

It is not something new and frankly it is akin to the work done in the area of Evidenced Based Medicine (EBM). EBM espouses the practice of medical procedures based upon established clinical trials and using those trials one would incorporate a set of best practices. The CCE as defined by the CBO states:

"A variety of evidence suggests that opportunities exist to constrain health care costs both in the public programs and in the rest of the health system without adverse health consequences. Perhaps the most compelling evidence of those opportunities involves the substantial geographic differences in spending on health care—both among countries and within the United States—which do not translate into higher life expectancy or measured improvements in other health statistics in the higher spending regions. For example, Medicare’s costs per beneficiary vary significantly among different regions of the country, but much of the variation cannot be explained by differences in the population, and the higher-spending regions perform no better on available measures of average health outcomes than the lower-spending regions do.

Furthermore, hard evidence is often unavailable about which treatments work best for which patients and whether the added benefits of more-effective but more expensive services are sufficient to warrant their added costs—yet the current health system tends to adopt more expensive treatments even in the absence of rigorous assessments of their impact. Indeed, the extent of the variation in treatments may be greatest when evidence about their relative effectiveness is lacking. Together, those findings suggest that better information about the costs, risks, and benefits of different treatment options..."

Regrettably Senator Specter was questioned on this Section 802 as if it were a rationing provision. If done properly it is a quality improving position. As we have argued we must reduce costs and we must reduce demand. However, on the other hand, if one desires to pay personally for services which exceed those clinically proven to be effective, say rhinoplasty for a stuffy nose, then one should have the right to seek that out and pay accordingly. However Medicare or Medicaid, or even a private plan should have no obligation to pay.

The shaky ground occurs when dealing with catastrophic diseases and new protocols! Take the simple case of imatinib and CML. When it first came out, it was and frankly still is quite expensive. Does it prolong life, slightly, does it improve the quality of life, greatly. Thus the problem will be one of determining quality effects and their values and
thus seeking the CCE solution. This will be especially the problem in Medicare, and with an aging population what treatments are proper, and which exceed the bounds. Marrow transplants for CML in patients over 80 is most likely not reasonable.

Then what of prostatectomies in men over 75, must they have only the watchful waiting option. For many men that is acceptable, but frankly we do not know enough of the genetic elements of PC to determine for what patients the protocol is best.

Thus the major problem of CCE is that it makes measurements which may fail to reflect the underlying differentiator, namely the genetic class of the patient. A woman with a BRCA gene defect will most likely best be served with aggressive treatment. A man with an indolent PC can watch and wait. In contrast a man with an aggressive PC, one which we cannot yet determine since we do not have the proven CCE approved test, will suffer bone mets and in agony! The balance is a challenge to the Hippocratic Oath and to the bean counters in DC. Perhaps Peter Orszag would think differently if he ever had to assist and dying patient with bone mets who had poorly treated PC!

9.7.2 Ovarian Cancer Screening

First we present a chart on the increase in survival based on frequency of testing for ovarian cancer. This report is entitled "Genomic Tests for Ovarian Cancer Detection and Management" and was prepared for the Agency for Healthcare Research and Quality of HHS. It shows that an 80% reduction in mortality can be achieved if one screens every three months for ovarian cancer. Thus it is known what could be done. We will work through this approach again later.

Let us look at another view of this same problem. Let us start with a recent article in the journal Obstetrics & Gynecology: April 2009 - Volume 113 - Issue 4 - pp 775-782. The
article is entitled, "Results from four rounds of ovarian cancer screening in a randomized trial". The abstract states:

"OBJECTIVE: To test whether annual screening with transvaginal ultrasonography and CA 125 reduces ovarian cancer mortality.

METHODS: Data from the first four annual screens denoted T0-T3, are reported. A CA 125 values at or above 35 units/mL or an abnormality on transvaginal ultrasonography was considered a positive screen. Diagnostic follow-up of positive screens was performed at the discretion of participants' physicians. Diagnostic procedures and cancers were tracked and verified through medical records.

RESULTS: Among 34,261 screening arm women without prior oophorectomy, compliance with screening ranged from 83.1% (T0) to 77.6% (T3). Screen positivity rates declined slightly with transvaginal ultrasonography, from 4.6 at T0 to 2.9-3.4 at T1-T3; CA 125 positivity rates (range 1.4-1.8%) showed no time trend. Eighty-nine invasive ovarian or peritoneal cancers were diagnosed; 60 were screen detected. The positive predictive value (PPV) and cancer yield per 10,000 women screened on the combination of tests were similar across screening rounds (range 1.0-1.3% for PPV and 4.7-6.2 for yield); however, the biopsy (surgery) rate among screen positives decreased from 34% at T0 to 15-20% at T1-T3. The overall ratio of surgeries to screen-detected cancers was 19.5:1. Seventy-two percent of screen-detected cases were late stage (III/IV).

CONCLUSION: Through four screening rounds, the ratio of surgeries to screen-detected cancers was high, and most cases were late stage. However, the effect of screening on mortality is as yet unknown."

This is a bit obtuse for the non-professional but it displays the standard approach to the study of many disease and the efficacy of procedures used to screen for their presence and the results of actions taken thereto. The question that the researchers went out to answer was the one which says did yearly screening for ovarian cancer have any benefit. We believe in a Fleckian manner that this question and the answer could be generalized by politicians and their ilk into one which is screening for ovarian cancer effective. They are two different questions. We have already shown above that they are effective.

Now let us look at the data from a different perspective. Namely, in contrast to the above study let us look at the underlying "physics" of the process and look at the facts and data as say an engineer would do. Here we go with the logic:

1. We know that the incidence of ovarian cancer is 14.4% in women 45-54, 21.4% in women 55-64, 25.3% in women 65-74, and 16.3% in women 75-84. (See Berek, Gynecology, 2008). Thus there are many women who will come down with this disease, a deadly disease if caught late.
2. The five year survival for ovarian cancer is 86% at State I, 70% at stage II, 34% at stage III and 19% at stage IV. (Schorge et al Gynecology 2008 p732). Thus if one can detect the cancer at State I it is possible under current means to have 86% or better survival. Stage I means growth limited to one or both ovaries with possible growth on the surface.

3. The ovary limitation means a tumor size of 2 to 4 cm diameter at most. That is the size of an ovary and it is also the size at which one can detect the lesion on ultrasound with some specificity. Using the CA125 at a level below 35 one may get better detection but higher false alarm rates. The problem with higher false alarm rates is that it requires surgery, and although it may be performed laparoscopically at first, it may or may not require full laparotomy. The latter is the case if a malignancy is detected at surgery.

4. Cancer is a disease that starts with one aberrant cell. The cell multiplies and attempts to double, each division, although that is not the case in reality for a variety of known and yet to be known reasons. However, 20 doublings can occur in less than one day that is a total of 106 cells, not detectable. In 50 days we get to 40 doublings, or 1012 cells. By 125 days we get to 70 doublings, a bulky mass. (Weinberg, Cancer, p 365, 2008). However for many reasons due to the individual's immune system the doubling may take longer because there may be multiple genetic steps involved.

5. Cancer masses can be detected at 108 cells by imaging and at 109 cells by palpation. At 1012 cells the patient is on the road to death from the disease. (Weinberg, Cancer, p 363, 2008).

6. Thus if one performed the tests as described in the article every 120 days, then one may have a substantially improved chance of detecting the cancer at Stage I and achieving an 86% cure rate.

7. The current death rate from ovarian cancer is 8.6 per thousand females. This is a total of 280,000 women per year based upon CDC data.

8. If screening at 120 day intervals can reduce this to 42,000 deaths or equivalently save 238,000 women, at a cost of say $250 per screening or $1,000 per woman per year, over 45 years of age. The census states we have then we have a cost of 64.5 million women over 45. Thus it will cost $64.5 billion. Or, the cost per woman saved would be $271,000 per life saved per year.

   First note that our simple analysis yields the same result as the HHS study we started with.

The question is it this worth it? What is a woman's life worth? Do we stop at say 65 or 75, do we continue to 85.
The other issue is that the authors of the article assumed annual testing. Based upon the logic above we see it means at least quarterly testing due to the tumor growth rate. By the way this applies to all tumors. Perhaps a study should address the question; "How frequently should testing be performed to obtain a material reduction in mortality from that disease". Clearly annual testing will at best get say one sixth of the cases; say 18% if everyone is tested.

This analysis has raised two issues:

1. When considering revising health care, what screening should be done and at what cost. Can, for example, a patient, person, pay for their own screening costs, at a price pari passu to the lowest cost paid, if they feel that they want more testing. Or will the Government as do the insurance companies today, have the lowest price forcing individual payers to subsidize the group payers, and in this case the Government. If the Government agrees to do annual testing and to be reliable it demands at least quarterly testing, then can a patient have the right to play on a level playing field or will the individual be taxed to seek better care on top of the costs?

2. When medical research is performed, there is a strong Fleck influence of a "thought collective" approach. The Fleck view of facts plays a significant role as well. The questions that should be posed are, "What level of screening result in what level of reduction in mortality?" Instead the way these are done is to take say an annual screening and determine if it is useful. The problem with this Fleckian "thought collective" approach is that it will then become part of the comparative clinical effectiveness schema as proposed by the Administration. Namely, the clinical result says that the screening is not useful. Wrong! The experiment shows that that specific type of screening is not useful.

Thus there are the above two issues of a much broader scope which can be drawn from this article, obscure as it may initially seem.

9.7.3 Prostate Cancer

The New England Journal of Medicine published two studies today on prostate cancer screening. Before presenting their results for analysis let me first show what the NY Times said. Their headline was: "Prostate Test Found to Save Few Lives"

First the NY Times author, one Gina Kolata, states:

"The PSA test, which measures a protein released by prostate cells, does what it is supposed to do — indicate a cancer might be present, leading to biopsies to determine if there is a tumor. But it has been difficult to know whether finding prostate cancer early saves lives. Most of the cancers tend to grow very slowly and are never a threat and, with the faster-growing ones, even early diagnosis might be too late."
The PSA test is not just one test. It is not a black and white thing. It is a process that has evolved over time. There is not a good and bad PSA per se. admittedly if you are 65 and have a PSA of 60 you are in some trouble. But as we now know a PSA of 2.1 when you are 50 is of concern. But more critically the rate of change in PSA is almost diagnostic. Thus a 25% rate of increase per year should be followed up.

In July 2003 Punglia et al in the New England Journal of Medicine published a study which demonstrated that the then current set point for PSA missed many cancers. They stated:

"Adjusting for verification bias significantly increased the area under the ROC curve (i.e., the overall diagnostic performance) of the PSA test, as compared with an unadjusted analysis (0.86 vs. 0.69, P<0.001, for men less than 60 years of age; 0.72 vs. 0.62, P=0.008, for men 60 years of age or older). If the threshold PSA value for undergoing biopsy were set at 4.1 ng per milliliter, 82 percent of cancers in younger men and 65 percent of cancers in older men would be missed. A digital rectal examination that is abnormal but not suspicious for cancer does not affect the overall performance characteristics of the test....A lower threshold level of PSA for recommending prostate biopsy, particularly in younger men, may improve the clinical value of the PSA test."

They presented the following Figure:
The PSA test has been refined over the period of these studies, the PLCO Study, "Prostate, Lung, Colon, and Ovary".

Now to issue two, Let us assume that a biopsy is performed. If a Gleason score of 7 is noted then you best have some attention paid, even a 6 is a problem. You have cancer! It will grow. It may very well kill you! That is if you do not die of something else. The problem is twofold; first, the doubling time of the cancer cells may be short, and second, the metastatic potential could be great. For Prostate cancer has the habit of metting to the bones, especially the spine. Does one want to take that risk?

The European study states the following protocol:

"We identified 182,000 men between the ages of 50 and 74 years through registries in seven European countries for inclusion in our study. The men were randomly assigned to a group that was offered PSA screening at an average of once every 4 years or to a control group that did not receive such screening. The predefined core age group for this study included 162,243 men between the ages of 55 and 69 years. The primary outcome was the rate of death from prostate cancer. Mortality follow-up was identical for the two study groups and ended on December 31, 2006..."

The European trial is akin to a Fire House which uses an answering machine which it checks every three days to see if there is a fire. They then study the town with this Fire House and a town without a Fire House and discover that there is no difference in destroyed houses. Well one would perhaps think that having someone there to answer the phone when it rings and then immediately dispatching a fire engine would improve things.

Let me explain. PSA screening once every year, this is based upon a tumor doubling time of 3 months, a DRE and PSA are performed. If the PSA is measured as per Punglia statistic then we would use 2.6 for men under 60. Punglia states:

"These findings, as well as recent data from a randomized trial showing that prostate-cancer treatment improves disease-free survival, 28 indicate that reduction of the threshold PSA level at which biopsy is recommended to 2.6 ng per milliliter, at least in men under 60 years of age, may be reasonable."

Subsequent studies indicate that the added measurement of velocity or rate of change per year is also critical. Thus a 25% per year rate of change should be used as a way to seek an examination.

The American Group provides the following results:
"From 1993 through 2001, we randomly assigned 76,693 men at 10 U.S. study centers to receive either annual screening (38,343 subjects) or usual care as the control (38,350 subjects). Men in the screening group were offered annual PSA testing for 6 years and digital rectal examination for 4 years. The subjects and health care providers received the results and decided on the type of follow-up evaluation. Usual care sometimes included screening, as some organizations have recommended. The numbers of all cancers and deaths and causes of death were ascertained….In the screening group, rates of compliance were 85% for PSA testing and 86% for digital rectal examination. Rates of screening in the control group increased from 40% in the first year to 52% in the sixth year for PSA testing and ranged from 41 to 46% for digital rectal examination. After 7 years of follow-up, the incidence of prostate cancer per 10,000 person-years was 116 (2820 cancers) in the screening group and 95 (2322 cancers) in the control group (rate ratio, 1.22; 95% confidence interval [CI], 1.16 to 1.29). The incidence of death per 10,000 person-years was 2.0 (50 deaths) in the screening group and 1.7 (44 deaths) in the control group (rate ratio, 1.13; 95% CI, 0.75 to 1.70)."

This American group was one with PSA at 4.0 and a second where PSA may or may not have been used as was a DRE. This is NOT a comparison of two distinct samples. The control group is a mix of anything and everything. Thus there are in my opinion two major faults;

First, the PSA numbers were set too high since we now know they should be set lower.

Second, the Control group was not the untested group as may be inferred, it was unlike the European study which alleges no treatment, and it was tested but just haphazardly.

Thus we have four groups:

Group 1 (American): PSA at 4.0 and DRE annually

Group 2: (American) PSA at 4.0 and DRE haphazardly

Group 3: (European) PSA at 4.0 but only once every 4 years

Group 4: (European) No screening

What is missing is what we now know to be the case. A PSA at 2.0 and an age dependent PSA with velocity measurements.

Thus our conclusion is that the Bayesian analysis, namely determining the probability of death given PSA measurements is or is not independent of the PSA measurement. We believe that the Bayesian approach of using screening at 2.0 under 60 and then testing and addressing a malignancy will reduce the a posteriori mortality. The data assessing that hypothesis appears to bear that out.
The NY Times headline is confusing, and frankly in error. The study proved at best that the specific screening protocol did not result in longer lives. That has been known now for six years! The question is what protocol will prolong life. It is not that PSA does not work; it just does not work as it was being used ten years ago. This study only shows that.

The Times further states:

"In the European study, 48 men were told they had prostate cancer and needlessly treated for it for every man whose death was prevented within a decade after having had a PSA test. Dr. Peter B. Bach, a physician and epidemiologist at Memorial Sloan-Kettering Cancer Center, says one way to think of the data is to suppose he has a PSA test today. It leads to a biopsy that reveals he has prostate cancer, and he is treated for it. There is a one in 50 chance that, in 2019 or later, he will be spared death from a cancer that would otherwise have killed him. And there is a 49 in 50 chance that he will have been treated unnecessarily for a cancer that was never a threat to his life. Prostate cancer treatment can result in impotence and incontinence when surgery is used to destroy the prostate, and, at times, painful defecation or chronic diarrhea when the treatment is radiation."

Again that is not what the data says. The data shows that men were treated and did not die in either case. The two US cases are so overlapping that a bright line is not there and the European cases due to the longer time between screenings also merge to being identical. The statement about impotence and the like are scare statements since we know that if you have cancer and if we do not know the true level of malignancy then we just remove it, we don't want to be sued.

This leads to the final issue, genetic evaluation. Namely as we have discussed elsewhere we believe that genetic testing for predisposition, presence, staging, and prevention is slowly making progress. It is this effort which will eventually bear fruit.

In a 2005 paper in Science by Tomlins et al they state:

"A central aim in cancer research is to identify altered genes that play a causal role in cancer development. Many such genes have been identified through the analysis of recurrent chromosomal rearrangements that are characteristic of leukemias, lymphomas, and sarcomas (1). These rearrangements are of two general types. In the first, the promoter and/or enhancer elements of one gene are aberrantly juxtaposed to a proto-oncogene, thus causing altered expression of an oncogenic protein. This type of rearrangement is exemplified by the apposition of immunoglobulin (IG) and T cell receptor (TCR) genes to MYC, leading to activation of this oncogene in B and T cell malignancies, respectively (2). In the second, the rearrangement fuses two genes, resulting in the production of a fusion protein that may have a new or altered activity..."
Their conclusion is:

"The existence of recurring gene fusions of TMPRSS2 to the oncogenic ETS family members ERG and ETV1 may have important implications for understanding prostate cancer tumorigenesis and developing novel diagnostics and targeted therapeutics. Several lines of evidence suggest that these rearrangements occur in the majority of prostate cancer samples and drive ETS family member expression."

Thus gene expression will be essential as a diagnostic tool. In a recent 2008 NEJM article by Zheng et al they state:

"Multiple SNPs in each of the five regions were associated with prostate cancer in single SNP analysis. When the most significant SNP from each of the five regions was selected and included in a multivariate analysis, each SNP remained significant after adjustment for other SNPs and family history. Together, the five SNPs and family history were estimated to account for 46% of the cases of prostate cancer in the Swedish men we studied. The five SNPs plus family history had a cumulative association with prostate cancer... In men who had any five or more of these factors associated with prostate cancer, the odds ratio for prostate cancer was 9.46..., as compared with men without any of the factors. The cumulative effect of these variants and family history was independent of serum levels of prostate-specific antigen at diagnosis...SNPs in five chromosomal regions plus a family history of prostate cancer has a cumulative and significant association with prostate cancer."

This further indicates that significant gene progress is being made.

The key fact to take from this exercise is that the results proved something which has some merit. It did not address the true question of what PSA testing if any can reduce mortality. It proved that there was no difference between two sets of PSA testing protocols. However as we have argued one would not have expected a difference. Furthermore the work done since this trial has begun has fine tuned this testing. The true question will ultimately be a genetic question.

The New York Times today has an editorial on the prostate papers in NEJM which we commented upon yesterday. The Times says:

"The studies — one done in the United States, one in Europe — both show that screening had little or no effect in reducing prostate cancer deaths."

That is NOT what the papers said. They said that the protocols used to screen had little or no effect. NOT that "screening had little or no effect". Really, words count. The question the researchers should have asked was:
"What level of PSA yields a positive result regarding the reduction of mortality?"

Or even better:

"What level of PSA and what level of PSA velocity yields a positive result regarding the reduction of mortality?"

They did not ask that question. They asked the question:

"Does a PSA test of 4.0 threshold reduce mortality as compared to two sample groups?"

Well, as we also said the American sample groups were both "tested" albeit not as frequently, and the European sample groups were for all purposes untested. Thus frankly the level was wrong, which was known since 2003 as in NEJM, in the paper by Punglia et al, which showed that a PSA of 2.3 was required to get reasonable levels! The 4.0 level was outdated for six years. No wonder there was any positive result, in addition to the samples used.

Why worry about stupid reporters and editorial staff writers, well because it may become health policy! And that policy can kill. Consider if we did a test that said for women we screen for palpable breast lesions only larger than 4 cm in diameter. Then we would likely conclude that breast screening is ineffective since those screened and those not screened died at the same rate! Dumb, yes.

This demonstrates two issues:

First, the newspapers do not have the basic competence to read and report the facts. Words mean something and in this case lives hang in the balance.

Second, you may get answers to a question but it may very well be the wrong question. Ten years ago this may have been the right question, but we learned something. So does that mean we just continue a flawed study? I truly hope not.

9.7.4 Impact on CCE

The above two examples show that CCE results can be dramatically misinterpreted. Screening for both ovarian and prostate cancer can and do work, the issue is how the question is posed and how the research is done. In the case of ovarian cancer there is a Government report showing the efficacy. In the case of prostate cancer the New York Times chimed in the process totally misinterpreting the results. Thus we let women live and men die? Is there an arbiter of the questions asked? If that arbiter is the Government then our health is controlled by Government bureaucrats.
9.8 Conclusions

Unlike almost all of the current policy makers who seem to be worrying about how the pay for it, we believe that one should first understand what the "it" is and where it may be proceeding. Then, and yes possibly simultaneously, we can determine how to pay for "it". We believe it is an iterative process since we clearly see that many things are changing, all at the same time.

It is critical not to fall into the fatal trap of assuming that we are changing an old health care system, for the target is a moving target, and the motion of that target can be influenced for better or worse by your actions.

We have just published a set of Chapters on the health care issue. The intent of the Chapters was two-fold: first, develop a simple analytical model to understand how it works and what the consequences of current thinking are. Second, to consider the alternatives of reducing demand and reducing costs as well as seeing what changes may fundamentally change health care as we know it. Our conclusions are as follows in four simple steps:

STEP One: DEMAND REDUCTION IN HEALTH CARE IS ACHIEVABLE AND IS REQUIRED TO ACHIEVE ANY GOAL. BY ADDRESSING PREVENTABLE AND REMEDiable DISEASES IT IS POSSIBLE TO REDUCE LONG TERM HEALTH CARE COSTS BY 25% OR MORE. DEMAND REDUCTION IS AN ESSENTIAL STRATEGY TO BE DEPLOYED IN ANY HEALTH CARE ENVIRONMENT AND IT IS ONE STEP THAT IS MOST SUCCESSFULLY PERFORMED WITH THE SUPPORT OF GOVERNMENT.

All the policy makers assume that demand is inelastic, namely the demand by people for health care is independent of price. A simple counter example is cigarette smoking. Taxes on cigarettes have driven male deaths from lung cancers down 35%-40% from their peak.

The counter to that is the epidemic in Type 2 diabetes driven almost solely by obesity. If we were to continue the trend, we will go from the current 8% of health care being spent on Type 2 Diabetes and its consequences, heart, kidney, neurological, eye, and other problems to almost 20% by 2030! Type 2 diabetes is a simple disease to cure, just lose weight, exercise and drop the carbohydrate intake.

Taxing carbs, as Governor Patterson of New York suggested, is a great first step. Banning carbs, high fructose corn syrup, and frankly many carbs, will do more for reducing health care costs than reducing everyone's LDL! This is a superb example of how Government can cut costs by using taxation as a negative modulator. Cigarette smoking and over
eating if controlled can prevent the two major threats to cost explosion in health care. They are preventable disease and preventable by demonstrated Government action.

The second area of disease management if remediable diseases, namely those which if screening is used then the impact will be significant reductions in long term costs. In this case I have analyzed the list of top screenable cancers. I have analyzed this and determining that it is possible by universal screening, the cost can be reduced by 5%.

STEP TWO: THE COSTS OF THE SUPPLY SIDE OF HEALTH CARE CAN BE REDUCED BY A MULTIPLE OF MEANS, AND A TOTAL REDUCTION APPROACHING 15% TO 20% IS ACHIEVABLE. THIS WILL REQUIRE A COMBINE TECHNOLOGICAL, MEDICAL MINDSET, REGULATORY AND GOVERNMENTAL SET OF CHANGES.

Health care costs are assumed to be managed and controlled by external controls such as insurance companies and the Government. We argue that this is not the case. In fact there are facts to demonstrate that Government regulation is one of the significant drivers in the explosive overhead costs of health care.

Thus there are several things which will reduce the costs of health care delivery.

First, electronic medical records are critical but their development and introduction must be organic and evolutionary. Like the Internet, which was organically and evolutionarily developed via the Internet Engineering Task Force, the IETF, the EMR should see a similar development, facilitated but not controlled by the Government. It is well known that Government is not good at picking market winners and at managing ill defined programs. Thus the Government should facilitate and not manage.

Second, medical billing and collections should be fully integrated and automated. There is a plethora of such systems and medical practices are all too often placed in the position of financing insurance companies and Medicare via accounts receivable and bad debts. Third, a set of best practices oversight to reduce nosocomial infections, faulty diagnoses and misapplications of drugs is essential. The three of these and many more can reduce health care costs by 12-15%.

Third, there are many "housecleaning" issues that can dramatically reduce costs. These include control of nosocomial infections, misdiagnoses and treatments, and drug errors in hospitals. These issues have been around for years and account for well over 200,000 deaths per year in aggregate, not to mention well over a million cases of increased and costly morbidity.

We believe that the following specific actions are then required:

1. Billing Coordination
a. Implement single entry billing process
b. Implement short time payment

2. Electronic Medical Records
   a. Develop profession supported EMR system
   b. Utilize an IETF framework for implementation
   c. Evolve it in time, not all at once

3. Nosocomial Infections, Mis-Diagnoses, Drug Errors
   a. Implement best practices to reduce nosocomial infections
   b. Utilize integrated EMR/Billing systems to reduce drug errors
   c. Use the EMR as a means to track compliance with these areas requiring compliance

STEP THREE: THERE WILL BE A MASSIVE CHANGE IN HEALTH CARE RESULTING FROM THE APPLICATION OF GENETIC TECHNIQUES IN THE AREAS OF SCREENING, STAGING, TREATMENT AND PREVENTION. THESE CHANGES WILL RESULT IN AN UPHEAVAL IN THE VERY ARCHITECTURE OF HEALTH CARE DELIVERY IN THE UNITED STATES. IF THE US MAINTAINS A LEAD IN THIS AREA IT WILL ALSO PROVIDE A CRITICAL PART OF THE UPSIDE GROWTH POTENTIAL FOR THE US ECONOMY IN THE CENTURY TO COME.

Genetic testing can be used for screening, staging, treatment and prevention. These applications of genetic methods will be explosively expanded in the next ten years. After that will be genetic applications to treatment and prevention. Thus in a twenty year span we expect to see a dramatic change in the delivery of health care whereby disease we see causing the greatest burden can be dramatically and economically managed in a totally outpatient basis. Thus we argue that any health care policy must not only consider this effect in its development but must stress these efforts in its implementation.

1. Screening: The screening for the BRCA gene in breast cancer and of many other genes in cancers can provide the physician with better insight to how best to treat the disease. Companies like Correlagen in Cambridge screen for genes for which remediation can be achieved, not just telling the patient that they may have a problem. Screening can dramatically reduce certain disease mortality and morbidity and also create an environment for more focused management and monitoring.
2. Staging: Looking for the presence of a Philadelphia chromosome in CML and other genetic tests can assist in the staging of the disease once it is detected. In prostate cancer, for example the staging can be done with the following genes: (i) TMPRSS2 Promoter and TES Transcription, (ii) Androgen receptor pathways, and (iii) PTEN and HER2.

3. Treatment: New treatment methods using targeted genes are in thousands of clinical trials. Again in prostate cancer we have: (i) Immune based gene therapy, (ii) Cytotoxic gene therapy, suicide genes, and (iii) Conditionally replicating oncolytic adenoviruses.

4. Prevention: The use of the vaccine in cervical cancer to treat the influence of papilloma virus is a prime example.

We know that looking solely at the past as prologue to the future to be patently false. Consider two past examples; infectious diseases and psychiatry.

In the early part of the 20th century health care was dominated by the management of infectious diseases. New York City had its own Tuberculosis hospital, Sea View Hospital, which was filled with TB cases which the City cared for. With the introduction of an aggressive public health care system in New York and the ultimate development of drugs such as Rifampin and isoniazid, cures or at least strong containment of TB could be achieved. Thus it is no longer the case that one needs massive numbers of beds for TB patients.

The psychiatric centers such as Willow Brook Hospital on Staten Island in New York City were filled with psychiatric patients until the early 1970s. With the advent of drugs such as haloperidol and the like they closed in just a few years. The Commonwealth of Massachusetts had in 1965 a total of 45,000 hospital beds occupied every day. 25,000 of those were for psychiatric patients. By 1975, the psychiatric beds were reduced to 6,000 and today they are less than 1,000.

Thus, if we planned health care in 1965 for twenty years into the future using the past and not recognizing the impact of the new "technologies" then we would have been grossly in error! This is a clear warning as the Government approaches this task.

Also it is critical to understand that if the U.S. continues to dominate the genetic medical field that it is also establishing a base for a truly expansive economy throughout the current century. This is an area where the Government, through its funding and clinical support, can be of significant assistance. I see this also missing from the discussion of a plan by the current Administration.

STEP FOUR: RESTRUCTURING THE OVERALL HEALTH CARE APPARATUS IN THE U.S. CAN BE ACHIEVED IN AN INCREMENTAL MANNER. HOWEVER CERTAIN PRINCIPLES ARE REQUIRED.
Finally, I address the issue of a plan and the principles of a plan. I strongly believe that the above prior three issues must be discussed before or at least contemporaneously with the health plan structural issues. Otherwise the "what" one plans for is not a true reality or reflection of the future. In fact, planning for the wrong "what" can cause a great deal more harm to the optimal path discussed above.

The following I believe are essential for any evolving health care plan:

• **Catastrophic Coverage:** There should be coverage of catastrophic incidents such as cancers, stroke, and long term disabling diseases such as MS, ALS, Parkinson’s and Alzheimer’s. The costs of these catastrophic diseases are on average low but to those who are affected they are disastrous. They are not preventable and in the most part currently not curable. Any one or family in one of these cases should be financially protected and should be available with the best of care, medical and palliative.

• **Universal:** Like the Massachusetts Plan, it must require all to participate. Unless the requirement for coverage is universal it cannot work. Arbitrage will occur and the system will not work as an insurance system but almost akin to a hedge fund, with the taxpayers paying for those who lose their bet. Coverage should not be denied and pre-existing conditions should not be factored into rates. Having Type 1 diabetes is a matter of fate not a matter of choice. Yet as we have stated earlier certain choice results such as Type 2 Diabetes and lung disorders related to smoking may have excess premiums applied.

• **Choice:** The Plan(s) must allow choice so that a patient may choose their health care provider and hospital. The physician must also have broad flexibility, since any stringent application of evidence base medicine or comparative clinical effectiveness applied too broadly is destined to disaster. Choice should also be allowed to selection of plans. Plans should at a minimum cover catastrophic coverage and other drastic forms of coverage. However any broadly based coverage and out of pocket expenses should be discretionary.

• **Motivate Removal of “Bad Habits”**: Use economic rewards and taxes to remove such things as obesity and improve screening.

• **Reward Good Health:** There must be a system which incentivizes good health practices and dis-incentivizes bad ones.

• **Establish Public Health Facilities:** Utilize Public Health Clinics in place of the ER as a means of dealing with those in need of non-urgent care. Facilitate this by staffing with Medical School Graduates with tuition repayment.
• Evolve Enabling Technology: Mandating technology solutions means the Government is choosing winners and losers and this always leads to increased costs and reduced quality of care. Thus allow the health care community to evolve their own solutions within the community and not have a Federal mandate. Federal "czars" breed politically correct solutions to non-problems and these solutions line the pockets of favorites at the expense of the taxpayers.

Finally it is essential that any health care plan look forward and not backward. Addressing the payment mechanism without addressing the other three more critical elements is a major failure. It will just keep the past frozen in the future. The current assumption is that the provisioning of health care will be a natural extension of the current practice. This is an approach of accountants and economists. They are the archeologists of our economy. We need future looking insight not recriminatory looks at the past.

The concerns reflect those of one who has successfully run business as well as having been professionally and academically involved in medicine. The problem that I see with many of the others proposing a health care policy is that their proposals all too often are just too academic. Books like those of Luft, Porter, Cutler and others, with their academically contrived plans, reflect views from the ivory tower of academe and grossly fail to do what any good business person would do. Namely they fail to look ahead as well as look at reducing costs. They all focus on the issue of how to pay for "it". That approach appears to be vacuous.

The changes that we face in the provision of health care are sea changes that exceed those in health care in the past. It is essential I believe that we develop and implement a new health care policy in an orderly and business-like manner and just not rearrange the deck chairs which is a costly and non-productive exercise.
10 REFERENCES


4. ADA, Prevention or Delay of Type 2 Diabetes, Diabetes Care, Vol 26 Jan 2003.

5. ADA, Screening for Type 2 Diabetes, Diabetes Care, Vol 26 January 2003.


29. Cannistra, S., M.D., Cancer of the Ovary, n engl j med 351;24 www.nejm.org December 9 2004


35. CDC Diabetes Cost-effectiveness Group, Cost Effectiveness of Intensive Glycemic Control...for Type 2 Diabetes, JAMA, Vol 287 No 16, May 2002.


46. DeFronzo, R., Pharmacologic Therapy for Type 2 Diabetes Mellitus, Annals of Internal Medicine ∙ Volume 131 ∙ Number 4, August 1999.


56. Fein, R., Medical Care, Medical Costs, Harvard University Press(Cambridge), 1989.


58. Ferrone, E et al, Clinicopathological Features of and Risk Factors for Multiple Primary Melanomas, JAMA, October 5, 2005—Vol 294, No. 13 pp. 1647


64. Freytag, S, et al, Prostate Cancer Gene Therapy Clinical Trials, Molecular Therapy, vol. 15 no. 6, 1042–1052 June 2007.


The Telmarc Group

HEALTH CARE POLICY: POLITICS VS REALITY

93. J Foong, M Maier, C A Clark, G J Barker, D H Miller, M A Ron, Neuropathological abnormalities of the corpus callosum in schizophrenia: a diffusion tensor imaging study, J Neurol Neurosurg Psychiatry 2000;68:242-244 ( February )
98. Julie Ma, M.D. Mania Resulting From Brain Tumor, UCLA School Medicine, Clinical Vignette, http://www.med.ucla.edu/modules/wfsection/article.php?articleid=120 v


133. Moore, R. G., How Do You Distinguish a Malignant Pelvic Mass From a Benign Pelvic Mass? Imaging, Biomarkers, or None of the Above, JOURNAL OF CLINICAL ONCOLOGY. VOLUME 25 _ NUMBER 27 _ SEPTEMBER 20 2007


153. Royal College of Obstricians and Gynocologists, OVARIAN CYSTS IN POSTMENOPAUSAL WOMEN, Guideline No. 34 October 2003.


158. Sassi, F., Calculating QALYs, London School of Hygiene and Tropical Medicine, Oxford Univ Press 2008.


172. Steineck, G., Quality of Life after Radical Prostatectomy or Watchful Waiting, NEJM Vol 347 Sep 2002.


185. The North Dakota Experience: Achieving High-Performance Health Care Through Rural


200. Williams, R., Medical and economic case for Prevention of Type 2 Diabetes and Cardiovascular Disease, European Soc of Cardiology, Vol 7 2005.


