Health Care Delivery Options and Strategies

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1 INTRODUCTION

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 The old adage that fifty percent of what you learned in medical school is out of date the day you complete it has a certain ring of truth.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.

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.

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. Ralwsians 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 stead 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 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.

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 I 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.

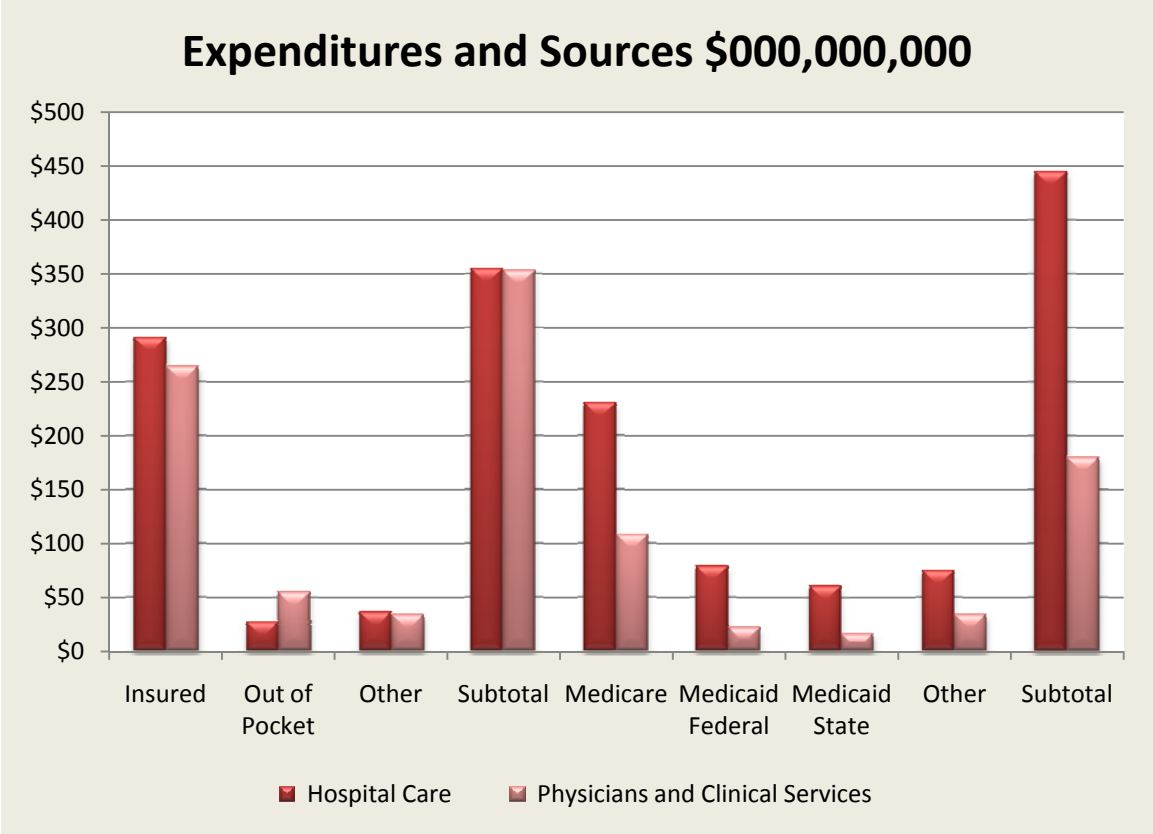
Chapter 4 is a discussion of Prozac and the cure of mental disorders. He states that this is a recent phenomenon, the last twenty years, since the early 1990s. In fact this has been growing since 1950 with the introduction of haloperidol and Thorazine. In the 1960s the mass number of psychiatric hospitals 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.

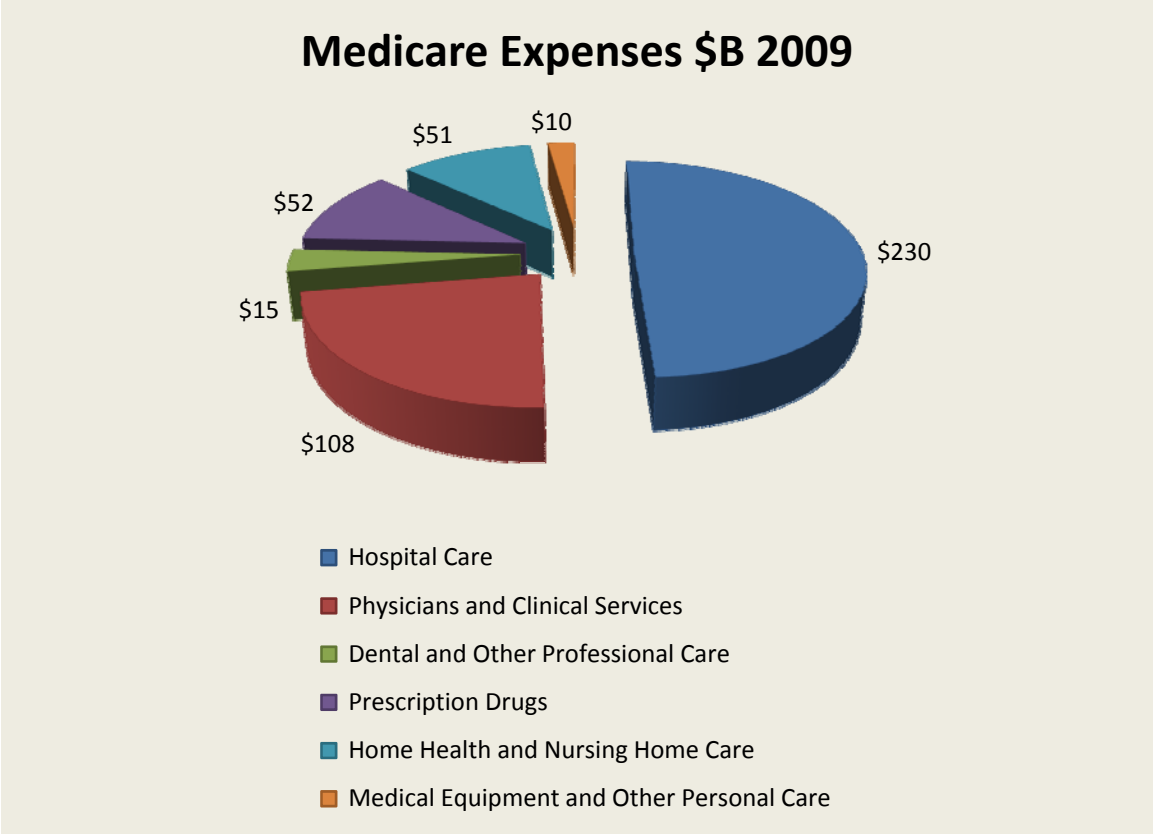
Cutler continues on in a variety of other areas discussing quality in a vague manner and then universal service in a similar fashion. He lacks any details to understand what his proposal truly is but one does get a view of the thought styles of the thought collective.

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.

		Private				*Government*					
	Insured	*Out of Pocket*	*Other*	*Subtotal*	*Medicare*	*Medicaid Federal*	*Medicaid State*	*Other*	*Subtotal*	*Total $*	*Percent*
Hospital Care	$291	$27	$36	$355	$230	$79	$61	$75	$445	$800	31
Physicians and Clinical Services	$264	$55	$34	$353	$108	$22	$16	$34	$180	$533	21
Dental and Other Professional Care	$79	$65	$3	$148	$15	$6	$4	$4	$29	$177	7
Prescription Drugs	$113	$56	$0	$170	$52	$14	$10	$19	$95	$264	10
Home Health and Nursing Home Care	$17	$43	$6	$67	$51	$48	$39	$6	$144	$210	8
Medical Equipment and Other Personal Care	$3	$51	$7	$61	$10	$34	$27	$14	$85	$146	6
Subtotal Personal Health Care	$767	$298	$87	$1,152	$467	$203	$156	$152	$978	$2,131	83
Administration and Net Cost of Private Insurance	$112	$0	$2	$113	$28	$16	$13	$14	$71	$184	7
Public Health Activity	$0	$0	$0	$0	$0	$0	$0	$72	$72	$72	3
Research Equipment and Structures	$0	$0	$104	$104	$0	$0	$0	$65	$65	$169	7
Subtotal, Other	$112	$0	$105	$217	$28	$16	$13	$151	$207	$424	17
Total	$879	$298	$193	$1,369	$495	$219	$169	$303	$1,186	$2,555	100
Percentage	34	12	8	54	19	9	7	12	46	100	

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.

2 KEY FACTORS

Before proceeding we will discuss several key factors which will become part of any Health Care proposal.

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.

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 is a via some tax of Federal subsidy. As one receives other Government social benefits then so too would health care payments are 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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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 cardiologist?

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.

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:

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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 mine field of improper interpretation.

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?

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:

Obama's proposal	*Parallel Massachusetts reform*
Increase eligibility for Medicaid and SCHIP to 300% of poverty level.	Eligibility for MassHealth, the state Medicaid program, increased up to 300% for certain populations.
"Pay or play" system in which large employers must provide health insurance for their workers or pay a penalty.	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.
Provide subsidies for low-income consumers to purchase health insurance.	Subsidized premiums for individuals with income below 300% of poverty.
Parents must enroll their children in public or private health insurance.	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.
Provide subsidies for small businesses and individuals who can't afford coverage.	Small employers are not required to provide coverage.
Create a National Health Insurance Exchange that would allow consumers to purchase health insurance from a range of private and public insurance options.	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.
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.	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.

Obama's proposal	*Parallel Massachusetts reform*
Create a national insurance plan for consumers to purchase individual coverage.	Nothing similar.
Reinsurance subsidy for employers' catastrophic healthcare costs.	Nothing similar.

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

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 payments[1]. 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.

[1] 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.

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.
Change Health Services Delivery	
Health IT	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.
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.
Change Legal Environment	

Medical Malpractice	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 provides. 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.

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[2]:

5.1 PUBLIC PLANS

111th Congress: Sponsors A-E	Rep. Altmire H.R. 1776	Rep. Baldwin H.R. 1117	Sen. Baucus Call to Action	Rep. Berry H.R. 684	Rep. Blackburn H.R. 1118	Sen. Brown S. 29	Sen. Brown S. 93	Rep. Burgess H.R. 1031	Rep. Burgess H.R. 1468	Rep. Conyers H.R. 676	Rep. Diaz-Balart H.R. 319	Rep. Dingell H.R. 15	Sen. Durbin S. 330	Sen. Ensign S. 45	Rep. Eshoo H.R. 1321
Change Insurance Coverage															
Individual Mandate			●												●
Employer Mandate			●												●
Purchasing Pools			●				●								
Refundable Tax Credit			●			●									
Medicaid/SCHIP Eligibility		●	●								●				
Open Enrollment in FEHBP															
Change Benefit Design															
High Deductible Health Plans					●										●
Change Payment Rules															
Hospital P4P	●		●												
Physician P4P			●												
Bundled Payment			●												
Change Health Services Delivery															
Health IT			●					●							●
Disease Management			●												●
Change Legal Environment															
Medical Malpractice			●						●			●		●	●
	Rep. Altmire H.R. 1776	Rep. Baldwin H.R. 1117	Sen. Baucus Call to Action	Rep. Berry H.R. 684	Rep. Blackburn H.R. 1118	Sen. Brown S. 29	Sen. Brown S. 93	Rep. Burgess H.R. 1031	Rep. Burgess H.R. 1468	Rep. Conyers H.R. 676	Rep. Diaz-Balart H.R. 319	Rep. Dingell H.R. 15	Sen. Durbin S. 330	Sen. Ensign S. 45	Rep. Eshoo H.R. 1321

[2] See http://www.randcompare.org/proposals/federal.php?start=29&max=15&type=current

111th Congress: Sponsors F-O	Rep. Fortenberry H.R. 109	Rep. Fortenberry H.R. 321	Rep. Gingrey H.R. 1086	Rep. Gingrey H.R. 1087	Rep. Granger H.R. 688	Rep. Granger H.R. 879	Rep. Green H.R. 465	Sen. Hatch S. 314	Rep. Johnson H.R. 1039	Rep. Kaptur H.R. 956	Sen. Kerry S. 79	Sen. Kerry S. 142	Sen. McConnell S. 326	Rep. Obey Stimulus Package H.R. 1
Change Insurance Coverage														
Individual Mandate														
Employer Mandate														
Purchasing Pools	●									●				
Refundable Tax Credit						●				●		●		
Medicaid/SCHIP Eligibility							●			●		●		
Open Enrollment in FEHBP														
Change Benefit Design														
High Deductible Health Plans														
Change Payment Rules														
Hospital P4P														
Physician P4P														
Bundled Payment														
Change Health Services Delivery														
Health IT				●				●	●					●
Disease Management								●			●			
Change Legal Environment														
Medical Malpractice			●											
	Rep. Fortenberry H.R. 109	Rep. Fortenberry H.R. 321	Rep. Gingrey H.R. 1086	Rep. Gingrey H.R. 1087	Rep. Granger H.R. 688	Rep. Granger H.R. 879	Rep. Green H.R. 465	Sen. Hatch S. 314	Rep. Johnson H.R. 1039	Rep. Kaptur H.R. 956	Sen. Kerry S. 79	Sen. Kerry S. 142	Sen. McConnell S. 326	Rep. Obey Stimulus Package H.R. 1

111th Congress: Sponsors P-W	Rep. Pallone SCHIP Reauthorization H.R. 2	Rep. Paul H.R. 1495	Rep. Price H.R. 464	Rep. Putnam H.R. 542	Rep. Scott H.R. 747	Rep. Sestak H.R. 694	Sen. Stabenow S. 179	Rep. Stark H.R. 193	Rep. Stark H.R. 194	Rep. Velazquez H.R. 850/859	Sen. Vitter S. 82	Sen. Whitehouse S. 438	Sen. Whitehouse S. 441	Sen. Whitehouse S. 444	Sen. Wyden S. 391
Change Insurance Coverage															
Individual Mandate															●
Employer Mandate															●
Purchasing Pools										●					
Refundable Tax Credit		●	●												
Medicaid/SCHIP Eligibility	●				●										
Open Enrollment in FEHBP															
Change Benefit Design															
High Deductible Health Plans		●													●
Change Payment Rules															
Hospital P4P															
Physician P4P															
Bundled Payment															
Change Health Services Delivery															
Health IT	●						●		●				●	●	●
Disease Management															●
Change Legal Environment															
Medical Malpractice															●
	Rep. Pallone SCHIP Reauthorization H.R. 2	Rep. Paul H.R. 1495	Rep. Price H.R. 464	Rep. Putnam H.R. 542	Rep. Scott H.R. 747	Rep. Sestak H.R. 694	Sen. Stabenow S. 179	Rep. Stark H.R. 193	Rep. Stark H.R. 194	Rep. Velazquez H.R. 850/859	Sen. Vitter S. 82	Sen. Whitehouse S. 438	Sen. Whitehouse S. 441	Sen. Whitehouse S. 444	Sen. Wyden S. 391

5.2 PRIVATE PLANS

States A-B	Advanced Medical Technology Association	AFL-CIO	America's Health Insurance Plans	American College of Physicians	American Medical Association	American Nurses Association	Better Health Care Together	Brookings Institution
Change Insurance Coverage								
Individual Mandate	●							
Employer Mandate		●						
Purchasing Pools		●			●		●	●
Refundable Tax Credit	●		●		●			●
Medicaid/SCHIP Eligibility	●	●	●					
Open Enrollment in FEHBP								
Change Benefit Design								
High Deductible Health Plans								
Change Payment Rules								
Hospital P4P	●		●					
Physician P4P	●		●	●				
Bundled Payment				●				●
Change Health Services Delivery								
Health IT	●	●		●		●	●	●
Disease Management	●		●			●	●	
Change Legal Environment								
Medical Malpractice			●		●			
	Advanced Medical Technology Association	AFL-CIO	America's Health Insurance Plans	American College of Physicians	American Medical Association	American Nurses Association	Better Health Care Together	Brookings Institution

States C-H	Catholic Health Association	Citizen's Health Care Working Group	Coalition to Advance Healthcare Reform	Council for Affordable Health Insurance	Economic Policy Institute	Federation of American Hospitals	Foundation for American Health Care Leadership	Health Coverage Coalition for the Uninsured
Change Insurance Coverage								
Individual Mandate		●	●		●	●		
Employer Mandate					●			
Purchasing Pools								
Refundable Tax Credit				●				●
Medicaid/SCHIP Eligibility						●	●	●
Open Enrollment in FEHBP							●	
Change Benefit Design								
High Deductible Health Plans				●				
Change Payment Rules								
Hospital P4P							●	
Physician P4P							●	
Bundled Payment								
Change Health Services Delivery								
Health IT	●	●	●				●	
Disease Management	●	●	●				●	
Change Legal Environment								
Medical Malpractice				●			●	
	Catholic Health Association	Citizen's Health Care Working Group	Coalition to Advance Healthcare Reform	Council for Affordable Health Insurance	Economic Policy Institute	Federation of American Hospitals	Foundation for American Health Care Leadership	Health Coverage Coalition for the Uninsured

States K-P	Kaiser Foundation Health Plan	Mayo Clinic Health Policy Center	National Business Group on Health	National Federation of Independent Business	National Small Business Association	Plan for a Healthy America	Progressive Policy Institute
Change Insurance Coverage							
Individual Mandate		●	●			●	●
Employer Mandate	●						
Purchasing Pools	●	●		●	●		●
Refundable Tax Credit	●	●			●	●	●
Medicaid/SCHIP Eligibility	●				●	●	●
Open Enrollment in FEHBP						●	
Change Benefit Design							
High Deductible Health Plans				●	●		
Change Payment Rules							
Hospital P4P			●		●		●
Physician P4P			●				
Bundled Payment		●					
Change Health Services Delivery							
Health IT		●	●		●	●	●
Disease Management							
Change Legal Environment							
Medical Malpractice			●	●	●		●
	Kaiser Foundation Health Plan	Mayo Clinic Health Policy Center	National Business Group on Health	National Federation of Independent Business	National Small Business Association	Plan for a Healthy America	Progressive Policy Institute

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:

"T*he 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.

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.

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 2. **Self-designated Specialty of Endoscopist**

Variable	Gastroenterologist	General Surgeon	General Internist	Other
Total colonoscopies, *n*	1,808	2,303	944	695
Complete colonoscopies, %	83%	79%	80%	66%
All colonoscopies, %	31%	40%	16%	12%
Case patients, %	30%	42%	17%	11%
Controls, %	32%	40%	16%	12%

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.

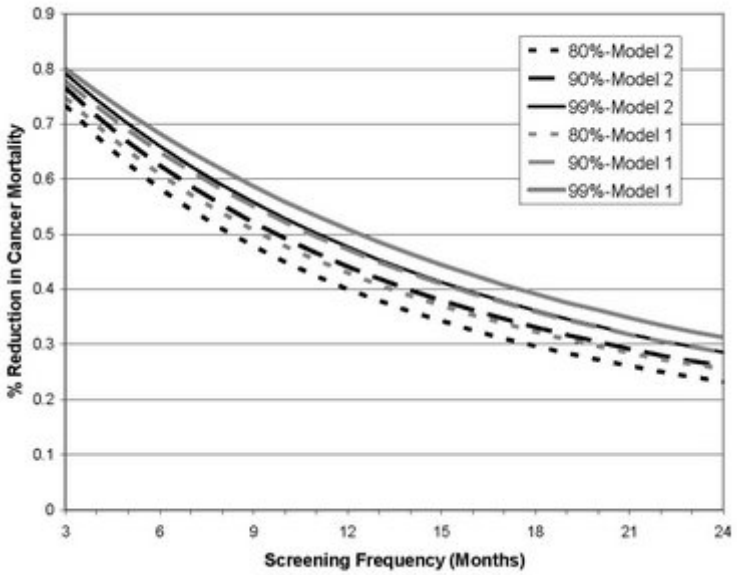
Then what of prostatectomies in men over 75, must they have only the watchful waiting option. For many men that is acceptable, but frankly we do not know enough of the genetic elements of PC to determine for what patients the protocol is best.

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!

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.

Figure 12. Effect of screening frequency on reduction in cancer mortality at different levels of test s



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 laporascopically at first, it may or may not require full laporotomy. The latter is the case if a malignancy is detected at surgery.

4. Cancer is a disease that starts with one aberrant cell. The call 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.

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:

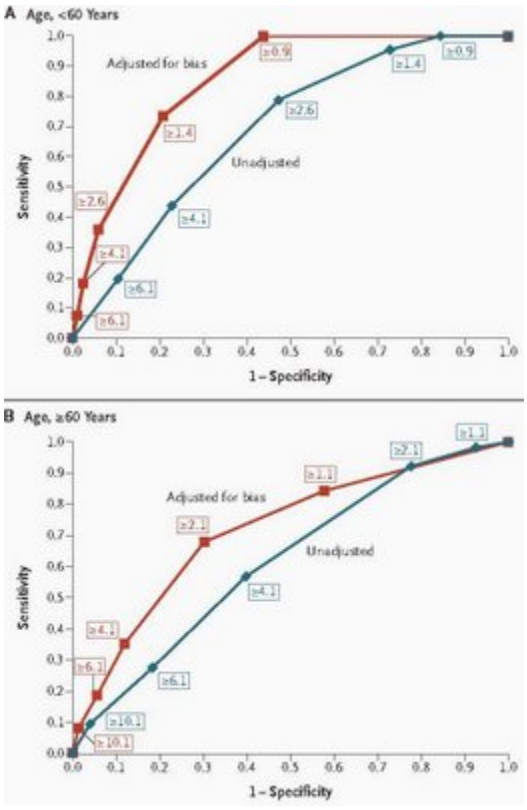
"The PSA test, which measures a protein released by prostate cells, does what it is supposed to do — indicate a cancer might be present, leading to biopsies to determine if there is a tumor. But it has been difficult to know whether finding prostate cancer early saves lives. Most of the cancers tend 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.

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.

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 White Papers on the health care issue. The intent of the White Papers 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.

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