Dear Taryn,

It was an interesting session at the focus group and I look forward to reconvening on the 15th.

In all good faith to the underlying principle of addressing the crisis in healthcare in the United States and as it relates to Medicare, I have to object to our task to arbitrarily assign a cover or do-not-cover status to various conditions. I am not trying to waylay the effort of the focus group but to the contrary, I hope you will find the comments contained herein cogent and relevant to your research goals. I hope you might clarify those goals for us.

I am compelled, however, to challenge the underlying premise of the assignment since I believe it derails us from a more rigorous discussion of the underlying problems in healthcare access and means to address those problems. Addressing healthcare inequities is my focus and I hope to some degree, this dovetails with the objectives of your research. The ramifications could not be more critical: a perfect example arose the other night with General Motors' announcement of a layoff of 25,000 workers, citing rising healthcare costs as a significant basis for their fiscal trouble.

First, the entire session on "cost effectiveness" underscores that there are at least two broad elements to calculating a quality-adjusted life year (QALY) (my reservations with regard to such calculations notwithstanding). First is cost. The second is efficacy.

In terms of the assignment, the first element of the equation is entirely lacking: there are no data on costs. So how in good faith can we fulfill such an assignment, irrespective of the assignment's validity, when we lack critical data? The costs of drugs, devices, diagnostics and procedures is a dynamic, evolving arena. With regard to the Medicare drug-coverage legislation, as we noted, the Congress abrogated the right (indeed, I'd argue the DUTY) to negotiate drug prices, a huge giveaway of public funds to a profit-bloated industry. By contrast, the Veteran's Administration has a more robust approach to negotiating pricing. This bears, of course, directly and immediately on how tools like QALYs may be distorted. And renders the current exercise absurd, given the lack of cost data.

There are other factors besides cost and efficacy. How do various risk factors combine to produce different disease states? For example, further reductions in smoking have impacts on a range of diseases. Ditto, obesity.

Further, "Health policies to improve population health need information on the level of diseases and the relative contribution of underlying causes" (see http://www.ub.rug.nl/eldoc/dis/rw/l.w.niessen/c1.pdf). Beside being an argument for prevention, this statement reflects that incidence and prevalence data are relevant to the various conditions under discussion, as those data bear on overall cost.

Thus, simply to look at a condition and a comment about its efficacy is hardly an adequate basis to make what ultimately are pointless choices. Indeed, others have noted that "Medical outcomes for the same diagnoses and procedures vary from hospital to hospital" (see http://www.healthcare-consulting.com/2004ElectionVotersGuide.html).

On a deeper level, I believe the premise driving the exercise is misleading and inappropriate. The choice of whether a procedure is appropriate or inappropriate should rest primarily with a physician and her or his patient as a mutual decision. That first portal to access should have patient need as its primary focus. Not an accountant's arbitrary and capricious abuse of QALY data.

Our task seems to imply that there is a Congressional effort to "HMO-ize" Medicare, leaving such deeply personal decisions to the arbitrary hands of bureaucrats I'm not willing to trust. Clearly, the HMO model

has failed abjectly in many respects in that regard and now, is it accurate to presume that this is what they intend for Medicare? That's offensive as it is fiscally irresponsible and ethically bankrupt. Although it is not as boneheaded and simplistic as Bush's "health savings plans" nonsense that has happily dropped off the radar into the steaming pile of the administration's failures, such failures counted in corpses and exacerbated misery as much as dollars.

On the public policy end of the spectrum, at the level of developing a national healthcare program, it is reasonable and prudent to address costs. To that extent, it is reasonable to discuss how to more narrowly apply certain interventions (e.g., via standards of care *guidelines*) so as not to over-utilize them or waste precious resources.

But one of the central challenges faced by any system of medical care is the inequities in its distribution. In some areas of deeper poverty, many technologies, procedures, drugs and diagnostics are less available. For 45 million of us without insurance, NONE of it is available--short of highly cost-ineffective visits to emergency rooms, a tactic most uninsured people are compelled to use. Seems to me that THIS is a more critical aspect of the healthcare crisis in the United States that we could better be addressing?

In short, healthcare resource distribution is a more pragmatic concern. There are compelling data to underscore that in the United States, access to care is intensely **racist** first (see, e.g., http://www.asbh.org/resources/taskforce/pdf/accesstf.pdf and http://www.annals.org/cgi/content/full/141/3/226). Higher income African Americans with salaries equivalent to their caucasian counterparts have reduced access to care. Socioeconomic status is probably a tight second as an explanation for disparities in healthcare access.

By contrast, some geographic regions are swamped with large numbers of procedures and prescriptions that may be of questionable utility. THAT is the area where a deeper understanding of the underlying forces that drive over-utilization merits attention. As was mentioned at the meeting, one motivation may be test-for-everything psychology of the malpractice-suit shy practitioner. It may simply reflect greed on the part of physicians or institutions.

A clear case in point is the need for further physician training in the prescribing of antibiotics. Purulent discharge even accompanied by fever, let alone a request for a prescription because of an ad the patient may have seen, are not adequate bases for prescribing antibiotics. (The June, 2005 edition of *Emerging Infectious Diseases* is almost entirely devoted to this topic.) A serious consequence to overprescribing is evidenced by the increasing number of pathogens that have developed resistance to one up to all available agents in the arsenal used to combat them. Thus, there is both a reduction in efficacy and concomitant cost increases associated with overprescribing of antibiotic therapy. As well as the costs associated with need for often costlier second or third line drugs, not to mention other costs associated with management of increased morbidity.

However, solving these issues must be undertaken by a more careful assessment of how and where such excesses occur. Other excesses may reflect criminal fraud. Indeed, Medicaid fraud is committed not nearly so much by end-users as by physicians and/or hospitals applying for payments for services never rendered. (Do similar rates of abuse apply to the non-means-tested Medicare program? Some data suggest the answer may be "yes" - see, e.g., http://www.hhs.gov/asl/testify/t981005a.html)

By contrast, arbitrarily casting tests or procedures to a litmus paper test rooted in simplistic notions of "fair innings", "personal responsibility" or "prevention or cure" merely perpetuates cheap polemics rooted in facile and frequently deeply subjective assessments. These are elements of evaluating a cost, not determining whether a procedure should be covered in a national health system per se.

As an example, prevention will not and should not be sacrificed at the altar of "cure" any more than vice versa. A case in point? The AIDS pandemic. HIV prevention strategies in developing nations clearly have been linked in their improved outcomes to greater access to care and treatment. (A caution here in that "cure" is inappropriately used for SO many treatments; antiretrovirals are NOT a cure for AIDS but represent a damned good advance in reducing morbidity and mortality.) Thus "prevention *or* treatment" may be more apt--and "prevention **AND** treatment" preferable).

I raise these issues as they are critical to our understanding that the issue of health and how to sustain it goes way beyond a list of what should be covered and what not. Our assigned task isn't problem solving, in my view, but quite likely may represent a distorted view of peoples' opinions, when they have been shaped and corralled down a pre-determined route (selection bias?) and thus potentially merely result in an exacerbation of the extant crises. Let us take the examples provided as illustrative of my objections.

As a prelude to that, let me ask--***how do we know what we know?***

Treatment of Erectile Dysfunction
It would be my guess that this is an easy one to throw in the "deny" pot. In some cases, such denials would probably be of little great consequence to public health--but to make a blanket denial based on perceptions of who uses sildenafil or other phosphodiesterase inhibitors to manage this disorder places numerous highly subjective qualifications upon managing the disorder that are inappropriate in a medical care setting. God knows, it was horrific enough when some physicians and nurses in the 80s refused to even touch patients with AIDS due to hysteria and ignorance--the notion that such subjective considerations might be *codified* into decision making is deeply troubling.

However, costs may be managed if we were to have PRICE CONTROLS in the United States (thus limiting the burden to the public health system). Another cost management strategy might be to have the disorder managed by a general practitioner rather than the extra costs incurred by visits to a urologist, although of course, this may not always be desirable (see *Cleve Clin J Med*. 2005 Apr;72(4):293-4, 296-7, 301-5 passim).

An accurate diagnosis may lead to better and less costly treatments. For example, a variety of agents may be the underlying etiologic agents inducing erectile dysfunction (e.g., antiandrogenic, anticholinergic, antidepressants, antihypertensive, major tranquilizers, anxiolytics, and certain medicines/metabolites; *Arch Androl*. 2005 Jan-Feb;51(1):15-31). Perhaps better management of medications would obviate the need for such interventions? But where a need for drug needed for medical management induces erectile dysfunction, for example, should sildenafil therapy be denied? Aren't these decisions best left to physicians?

Again--a problem that opens up a great number of more interesting facets than a glib "cover it, don't cover it" assessment.

Physician Counseling of Smokers
Clearly, this falls in the category of prevention. My brother died of lung cancer at age 46. Had he had access to a universal, single-payer health care system and such counselling, would he have stopped smoking? Would he have received earlier diagnosis and treatment and might he not be alive today? The long term impact in reducing lung cancer and smoking-related cardiovascular diseases IS of critical importance but is rarely considered by myopic policy wonks. But clearly, here is an intervention with a major public health impact for a relatively minimal investment (see www.evidence-based-medicine.co.uk, 2003 May1(6):5).

It is rather bitterly ironic to note that the Bush administration has sought to cut to 10% the fine big

tobacco faces for its years of concerted lies to the American people and their insidious and persistent efforts to addict more individuals. A New York Times article quoted
"Why, in the middle of a lawsuit, would you give up, which is exactly what this administration has done?" said Senator Richard J. Durbin, Democrat of Illinois. "Was it because of the power of the tobacco lobby? Was it their close connection with people within the administration? Was it the fact that they'd never had the stomach to tackle this special interest group in Washington?" He added, "I think it's all of the above." (http://www.nytimes.com/2005/06/09/politics/09tobacco.html).

Healtcare reform will undoubtedly have to wait for a new administration. This one is characterized by the range and depths of its lies, deceptions, hypocrisy, broken promises and abject disingenuousness to the point they are will to fleer at the Geneva conventions, torture and murder prisoners, deny due process of law, destroy the environment, take a surplus and turn it into enormous domestic and foreign deficits, broaden the divide between the hyper-wealthy and the rest of us, perpetuate extremist factions of christianity, start wars based on lies, destroy social security.....

Total Hip Replacement for Arthritis
Though the QALY for this is moderately high, again the incidence and prevalence will have a bearing on the societal cost. I doubt anyone would put this in the no pile, in any event. And again--this means of establishing what should be covered comes across as capricious and arbitrary.

Outreach/Flu and Pneumonia Vaccines
Here is one that could possibly be placed in the "forget it" column! Why? Well, again, it depends on the individual but in general, elderly individuals have reduced immune responsiveness and actually do not necessarily obtain immunological protection from flu vaccinations. They must rely instead on herd immunity and adequate vaccination of children and healthy adults to limit their exposure. See, e.g., *Immunol Res*. 2004;29(1-3):113-24. This may also be applicable in the case of pneumococcal polysaccharide vaccines (*Vaccine*. 2004 Aug 13;22(23-24):3214-24).

Indeed, this raises a point regarding the nature of research and how the use of patent law has been vigorously distorted in ways that, while they appear to have a dramatic impact on short-term profit have waylaid a great deal of research. Where is the research in new vaccines that may overcome impaired immunity among the elderly? Let alone vaccines or new drugs for infectious diseases ranging from *Staph aureus* to TB to viral infections like dengue or yellow fever? These don't represent lucrative markets--there is little new drug discovery here.

Thus, yet another important facet that influences costs is not the disease or condition to be covered, but rather serious and significant distortions in the systems and institutions commissioned to address these issues. And the concomitant impact on reduced discovery and the subsequent long-term impact on societal costs, health and well-being.

Finally, a review that points to other issues and factors to weigh in:

De Graeve D, Beutels P. Economic aspects of pneumococcal pneumonia: a review of the literature. *Pharmacoeconomics*. 2004;22(11):719-40
Faculty of Applied Economics, University of Antwerp, Prinsstraat 13, 2000 Antwerp, Belgium. Diana.degraeve@ua.ac.be
In this review, the economic aspects of pneumococcal pneumonia are analysed, including the costs, cost effectiveness and cost benefit of treatment and prevention. We identified eight cost-of-illness studies, 15 analyses comparing the costs of different treatment options and 15 economic evaluations of prevention that met our search criteria. The studies were conducted largely in Europe and the US. Most pertained to community-acquired pneumonia (CAP) in general, without specific analysis of pneumococcus-related

illness. Many of the studies were considered to be of poor quality for the following reasons: comparison without randomisation or control variables, disregard of health outcomes, small sample size, restriction of costs to drug costs and vague or disputable sources of cost information. In the US, hospitalisation costs resulting from CAP can be estimated to be between US 7,000 dollars and US 8,000 dollars per admission or US 4 million dollars per 100,000 population. Hospitalisation costs are significant (representing about 90% of total costs), but are much lower in Europe than in the US (one-third to one-ninth of the US estimates in the UK and Spain, respectively). In general, economic studies of treatment for pneumococcal pneumonia are in line with clinical evidence. A drug with proven clinical effectiveness would also appear to be supported from an economic stand point. Furthermore, economic data support an early switch from an intravenous to an oral antibacterial, the use of quinolones for inpatients with CAP, and also the use of guidelines built on clinical evidence. Of all the possible preventive strategies for pneumococcal pneumonia, only vaccination has been subjected to economic evaluation. Pneumococcal polysaccharide vaccine seems relatively cost effective (and potentially cost saving) for those between 65 and 75 years of age, for military recruits and for HIV positive patients with a sufficiently high CD4 cell count. Evaluations of the pneumococcal conjugate vaccine (PCV) indicate the price of the vaccine to be the main determinant of cost effectiveness. As the current price is high (in the order of US 50 dollars per dose), the economic attractiveness of the universal PCV vaccination strategies hinges on the potential for price reductions and the willingness of decision makers to adopt a societal perspective.

Treatment of Major Depression
The sad and desperate fact is that there is very little that is efficacious in managing Major Depression (while numerous interventions may alleviate mild-to-moderate depression). A 0.40 improvement (from 5.0 to 5.4 say) appears somewhat dismal. But better than nothing for the person and their family and friends! Yes?

Indeed, this is an area that is RIPE for evaluation of a wide array of nonconventional interventions as well as in the understanding of the etiology and pathogenesis of this condition (really, probably, "these conditions").

Also, in the paragraph provided, you note that psychotherapy+medication is twice as effective....than what? Based on what data?

But again--not a condition that could be blithely removed from consideration when a standard of care exists, such as it is. Costs, again, could be further reduced were non-patentable agents and interventions evaluated and, where efficacy is or has been determined, broadly utilized. And an are that underscores a pressing need for basic science in etiology and pathogenesis of severe depression!

Gastric Bypass
I would rather pay for 137,000 gastric bypasses than a botched, $400 billion war based on deceptions and lies...and I suspect that there would have been money left over for quite a number of other procedures...oh, dear. I know. Firewalls and relevance and all that. Of course the fact that a lot of people will come back brutalized, maimed and psychotic from the experience has no relevance to our healthcare system....nor does it matter that disproportionate numbers of homeless are vets--cause we have the VA to care for them!

Anyway, again, this is a procedure that has shown great promise. And at least we have prevalence data for last year (2004, I presume). What we don't know is if we're talking about open or laparoscopic approaches. The former may be somewhat safer and more efficacious (slightly?) but requires a 7-day hospital stay. Others feel LS is as effective and less costly (*Obes Surg*. 2005 Jan;15(1):24-34). In a single payer system, ongoing care is needed to assure that long-term complications such as nutritional deficiencies (*Diabetes Care*. 2005 Feb;28(2):481-4) or bone loss (*Am J Med Sci.* 2005 Feb;329(2):57-61)

do not develop.

Let's talk about managing costs, not discarding a potential intervention. But it is breathtakingly idiotic to think that one can look at this procedure in isolation and not see that there is a need for a robust and vigorous national program from school-age onward (lunch programs for example) of promoting improved nutrition and eating habits, increased exercise and so forth. This touches, if distally, on agricultural issues (such as soil nutrient and mineral depletion). Yet another good way to spend some of our resources.

Yet another basis for arguing the potential long-term positive impact on GDP yielded from a single-payer healthcare system.

Osteoporosis Treatment
Here I am not entirely convinced about the use of bisphosphonates in the management of a moderately deteriorated T-score (osteopenia vs. osteoporosis). Use of agents such as calcium, vitamin D3, strontium, boron and so forth may have some impact, especially in the context of exercise. Other agents are commonly used or under investigation and surgery is sometimes indicated (see, e.g., *Am J Manag Care*. 2004 Jul;10(7 Pt 1):445-55). Others note that a variety of modalities should be considered: "Nonmedical treatment of osteoporosis complements the appropriate pharmacologic treatment, and these treatments should be used together to maximize outcomes for patients with osteoporosis" (*Clin Orthop Relat Res*. 2004 Aug;(425):126-34). Which drug to use, when to initiate therapy, how long to maintain therapy, side effects and costs are all considerations (see http://www.jco.org/cgi/content/full/20/17/3719 or *Journal of Clinical Oncology*, 2002 Sep;20(17):3719-3736).

Understanding the etiology of disease also is critical. Corticosteroids, excessive alcohol intake, smoking may all contribute to bone loss. Diseases such as cystic fibrosis, breast cancer and HIV (possibly an antiretroviral side effect) may affect bone density.

Others note that in the United States, "bisphosphonates are expensive (up to $US775 per month, 2002 value)" (*Drugs & Aging*, 2003;20(9):631-642(12)). By contrast, in Canada, a YEARLY dose of alendronate is $800 (http://www.womenshealthmatters.ca/centres/osteo/treatment/bpshow.html).

Again--the issue is the need for PRICE CONTROLS on an industry that has gotten SO out of control they are willing to fight access to generic HIV medications by African nations. Thus, antiviral agents that collectively cost up to $20,000 or more per patient per year could cost from $130 to $800 but the Pharmaceutical Manufacturers' Association, along with the US Trade Representative and some truly vindictive, positively genocidal trade agreements, has worked assiduously to thwart these nations' sovereign right to access generics. The result? Millions of men, women and children dead because they believe intellectual property rights trump human life.

One of the reasons we MUST have price controls in the United States as exist in most industrialized nations.

Screening for Colon Cancer
This is most likely an issue relevant to where and how services are accessed. In regions where excessive testing is done, some evaluation might be undertaken to streamline this. One possible outcome might be a more thoughtful development of standards of care that would delineate levels of risk, etc. There may be other means to evaluate numbers of procedures per site or practitioner that may help to rein in costs if excessive testing is occurring--but gauging what is "excessive" must be carefully undertaken. What is NOT an option is elimination of a clearly important procedure (at least until alternatives are developed).

Another example you could have chosen would have been liver biopsy; newer blood tests may obviate the

need for these in the near future. Here again, choices should be guided by research and evidence-based medicine, not accountants.

Is this an example of a procedure impelled by malpractice fear in some regions or hospitals/practices? Again, malpractice suits are a relevant issue, though not nearly as pertinent as the Bush administration attempted to bamboozle people into believing in terms of its overall contribution to healthcare costs. But then that's expected from an administration that creates crises where none exist (social security, WMDs in Iraq) and pointedly ignores genuine crises (healthcare, global warming).

How do we appropriately balance the right of people to sue when negligence or incompetence harms people with the need of physicians to make diagnostic procedure and treatment decisions unfettered by unreasonable fear of retaliation? How do we deter abject avarice on the part of the insurance companies? How to alleviate the financial burden to doctors, reducing a climate of fear but not instilling one of laissez-faire? These issues seem to me of more critical relevance for a focus group discussion than the current exercise.

Implantable Cardioverter-Defibrillators

Perhaps stronger regulations and oversight of industry might be in order. A recent article notes that "Guidant acknowledged late Wednesday that it continued to sell older units of the device well after it produced an improved version that appeared to fix the flaw." See:
http://www.nytimes.com/2005/06/03/business/03guidant.html
While not ICDs (rather, defibrillators), the story underscores that the private sector is prone to corruption in an environment feverish with the urgency to ever and always show profits.

A couple of reviews wax eloquent over this new standard of care for those with severe cardiac failure (*Rev Cardiovasc Med*. 2005;6 Suppl 2:S32-42; *Rev Cardiovasc Med*. 2005;6 Suppl 2:S43-57). Must one worry that they authors have potential conflicts of interest, possibly holding stocks with device manufacturers or simply self-interest as practitioners? Is this an aspect to over-utilization we might better address? Yet without necessarily starting witch hunts.

Clearly, though, the impact of industry on university- and hospital-based research is growing and one might even say pernicious. The rights of patients enrolling in clinical trials are being trampled. Demands are made that negative data not be published. Academia and hospitals desperate for funding risk increasing corruption of ethics and scientific responsibility arising in part from agreements that favor industry's fiscal interests over that of patients.

And once again, that relationship has just been discussed in depth with regard to the heart problems caused by Merck's drug, Vioxx:
http://www.npr.org/templates/story/story.php?storyId=4696609 They noted:

> At Merck, Medical Director Sherwood wrote an e-mail to bring the marketing department up to speed. NPR has obtained that e-mail. It suggests that part of Merck's strategy to suppress criticism was intimidation. The e-mail, dated Nov. 7, 2000, reads:
>
> Fries and I discussed getting Singh to stop making the outrageous comments he has in the past few months... I will keep the pressure on and get others at Stanford to help."

Another devastating quote that shows outright threat when bribery fails on the part of a big pharma company that sees its profits threatened:

> The profile was dispatched to Sherwood and six other executives. Around the same time, Singh heard from a friend inside Merck: "I was told that Dr. Lou Sherwood, who was then vice president at Merck, had become 'very interested,' in quotes, in what I was doing, and that Dr. Sherwood is "very powerful, and he's going to crush you and he's going to fix you.'"

To the matter at hand, then we must NOT eliminate a procedure unless it is shown to be ineffective or unsafe. Here, it becomes more important if drug therapy fails in part due to lies of the industry.

Again, though, it may be possible to delineate risk profiles to develop more relevant standards of care. Addressing comorbidities such as the observed 87% rate of assorted psychiatric disturbances among recipients of ICDs (*Mayo Clin Proc*. 2005 Feb;80(2):232-7). These then serve merely as GUIDELINES for a physician--and the decision, based on benefits, risks and costs, may be made by the patient, their friends and family as relevant, and the physician. As well as strong conflicts of interest laws.

Lung Volume-Reduction, Emphysema
Insufficient information to make an evaluation of the utility of this palliative procedure but the benefit of the stated 15% improvement seems somewhat dismal and should be weighed against the risks of surgery. This is a physician-patient decision, not that of some policy wonk, in my view. Others, however, have a somewhat more optimistic assessment (see below) that again draws into question HOW DO WE KNOW WHAT WE KNOW.

If a QALY is based on inaccurate or incomplete assessments of the extant data, one has a potential GIGO situation: Garbage In, Garbage Out.

Wood DE. Quality of life after lung volume reduction surgery. *Thorac Surg Clin*. 2004 Aug;14(3):375-83.
Section of General Thoracic Surgery, Lung Cancer Research, University of Washington, Box 356310, 1959 NE Pacific, AA-115, Seattle, WA 98195-6310, USA. dewood@u.washington.edu
The common physiologic and functional variables that quantify limitation in emphysema patients have been the most common outcomes measured after LVRS. Spirometric values and exercise capacity are merely surrogates, however, for their impact on symptoms and QOL in patients with severe emphysema. Because LVRS has been developed as a surgery to palliate disabling symptoms of emphysema, many studies now have included HRQOL outcomes along with the commonly measured physiologic and functional outcomes. Some studies have centered on the QOL as the primary outcome instead of physiologic variables. Many symptom scales and disease-specific and general instruments of HRQOL have been used for evaluating emphysema patients before and after LVRS. Case-control studies and randomized studies have shown a consistent improvement in symptoms related to emphysema and general QOL. *These studies validate the use of LVRS as a palliative therapy for selected patients with emphysema. The NETT suggests that this benefit is applicable primarily to patients with an upper lobe-predominant pattern of emphysema or patients with low exercise capacity.* [emphasis added] Validation or refinement of these criteria depends on the continued contributions of the many investigators performing LVRS.

Here we see other possibilities for more narrow application of technologies--but recognizing a population where an intervention may have a better chance of success shouldn't preclude its application in less optimistic situations.

Again, of course, one might ask: does the author have any conflicts of interest? Yet another aspect of a rapidly deteriorating system in crisis.

"Tight" Control of Diabetes
Clearly, this is the ROLE of a good physician! But the blurb doesn't even say if we're talking about insulin-dependent diabetes or not. This is also a prevention approach that alleviates the burden of public costs of worsening disease.

Based on my understanding of botanical medicine and other forms of traditional healing, I believe this is another area ripe for investigation. Several botanical agents, such as bitter melon (*Momordica charantia*, Linn.) could be an excellent addition to a regimen that might reduce the need for agents such as metformin. Sadly, such interventions are off the radar. See, e.g., *Diabetes Care*. 2003 Apr;26(4):1277-94 and *J Altern Complement Med*. 2004 Apr;10(2):369-78. In the *Diabetes Care* article, the authors note "The available data suggest that several supplements may warrant further study. The best evidence for efficacy from adequately designed randomized controlled trials (RCTs) is available for Coccinia indica and American ginseng. Chromium has been the most widely studied supplement. Other supplements with positive preliminary results include Gymnema sylvestre, Aloe vera, vanadium, Momordica charantia, and nopal."

Elevated Cholesterol

I have read but have not seen a citation that a significant percentage of statin users stop after a year or two of therapy. Here is another issue where the story is "take statins, they're totally safe, stopping might kill you." Profits are enormous. Yet, there are ALWAYS some risks. Indeed: "According to the report, which looked at 500,000 Danish residents, one year of statin therapy raised the risk of nerve damage by about 15 percent. Taking statins for two years raised the risk to 26 percent." (see http://www.yourlawyer.com/practice/news.htm?story_id=2884&topic=Baycol). How much are we being lied to? How can we make good risk/benefit/cost evaluations if the industry is prone to lying and threatening physicians and institutions if their profits are threatened?

Yet another issue is that very often, blockbuster drugs are not studied for more than 6 months to a year. Promises of phase IV post-marketing studies to assess longer-term toxicities or risks based on approval on efficacy data are routinely reneged upon.

Atorvastatin is THE top selling drug on the planet, a multi-billion dollar a year business. (And in the US, the cost of atorvastatin is $76 for a month versus costs as low as $43 in Italy; see http://www.cbsnews.com/stories/2005/06/03/60minutes/main699606.shtml). The class of statins has serious toxicities, not the least of which is rhabdomyolysis. They also interact strongly with the cytochrome P450 system and thus extreme caution must be undertaken when mixing and matching other drugs.

So the point? We'll undoubtedly still need statins. They definitely have their uses (and pravachol, while not as potent in terms of LDL reduction, is at least water soluble and has much less in the way of drug-drug interaction problems). What we'd be BETTER off having is better data.

But the more important issues I see are
1) The need for PRICE CONTROLS
2) The need for research into other agents that have a reasonable basis for believing they may be of benefit in managing lipid dyscrasias (among which and perhaps in factorial or tree design evaluation include policosanols, niacin or inositol hexanicotinate, pantethine and an array of botanical agents). Policosanols, sugar cane wax-derived mixtures of aliphatic alcohols, cost as little as $12 a month.
3) Greater openness and transparency in clinical research, whether privately or publicly funded.

Resuscitation for Cardiac Arrest

Here again--gee--put it on the DO NOT COVER list. Right. Tell granny, sorry you just hit 80 and we're gonna let you die.

Actually, the point this issue raises has more to do with end of life care, the need for understanding living wills, do not resuscitate orders--and hell, as a gay man, I'd add the need for civil unions or marriage to give us the same rights as other married couples with regard to these kind of issues. Yet another good

topic for a focus group.

Left Ventricular Assist Devices
Well, gosh, forget paying for the heart transplants then you won't need to prolong the agony of the wait by using LVADS. Is that where this can head if LVADs wind up in the "no" pile? One review noted that "Although several of these devices have only just entered the clinical phase, internal cardioverter defibrillators, left ventricular assist devices and biventricular pacemakers can no longer be viewed as experimental tools" (*Acta Chir Belg*. 2004 Jun;104(3):290-6) and others have also pointed to LVADs as a viable alternative for people not eligible for transplant (*Curr Opin Cardiol.* 2004 Nov;19(6):613-8).

Of course, other approaches are perhaps more cost effective "Prevention of acute heart failure by avoiding factors known to precipitate decompensation remains the most cost-effective strategy" (*Am Heart Hosp J*. 2004 Fall;2(4 Suppl 1):10-4).

But should prevention strategies trump interventions for which data on safety and efficacy are strong? Public policy isn't the place for triage.

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Well, there you have it. I think that if you want a FOCUS group to discuss problems in healthcare, obviously we can't have simple, single solutions. But the notion that the method or means of managing the system is arbitrarily picking and choosing procedures is grim even as it is a bit silly. Clearly, some interventions will fall by the wayside as better approaches are developed. That kind of attrition is a more natural evolution. The excesses of the system though will not be solved by this HMO-style approach.

Recognizing the excesses of the system, while important, has the unfortunate tendency of utterly eclipsing the devastating and enormously costly deficiencies in the system.

By contrast, and in summary, I feel the following points are of greater interest to me as a middle-aged guy living without health insurance as I'm too rich for means-tested Medicaid, too well for SSI or SSD (though living with hepatitis C) and too young for Medicare:

1) A single payer health care system that could actually REDUCE GDP outlay while covering everyone--we do have a robust pool of nearly 300 million citizens!

2) Price controls on drugs, devices, diagnostics and procedures (could start by enforcing Cooperative Research and Development Agreements or CRADAs);

3) Patent reform of some kind to address inequities in the system that do not reward individual discoverers but rather merely enrich company executives and stockholders. The dense thicket of patents, some with exceedingly and intentionally loose definitions, actually stymies research and drug development as licensing fees all up and down the stream of development grow and grow....

4) Increased public sector involvement in clinical trials research;
[Another fertile area of discussion: the exaggerations of industry regarding the costs of R&D; I wonder how much it cost to bring penicillin to market??]

5) Stronger conflicts-of-interest rules and disclosure among and within NIH, universities and hospitals (increasingly compromised in their research) with greater transparency and better regulation; and

6) in reference to how do we know what we know, more complete publication of clinical trial results (i.e., negative results as well).

[It should simply be the law. If human beings put their health and lives on the line for ANY clinical study, it should be published. Positive, negative or non-results. And such results should be FREELY available to people.]

I'm absolutely certain that this is FAR more information than you needed or wanted. But it is my humble offering to your effort and hope that it helps shape your thinking and is of benefit to your research project.
George M. Carter

(PS: please bring a copy of my informed consent. Thanks!)

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For consideration and just to keep things lively from the UK's Office of Health Economics:
http://www.oheschools.org/ohech5pg4.html
Problems with QALYs

QALYs provide the best attempt so far to solve the problem of measuring health care outcomes but they still suffer from a number of serious problems. A key question is who is to make the subjective choices which determine the QALY? Is it health professionals, the general public or patients who have experience of the particular medical condition and treatment? Experiments have shown that the value of a QALY can change radically according to who is making the choices. Other problems include the fact that the responses given are to hypothetical situations and so may not accurately reflect people's real decisions, and the fact that valuations are influenced by the length of the illness and the way in which the questions are asked. Finally, QALYs are likely to undervalue health care because they do not capture the wider benefits (externalities) which may be gained, for example, by a patient's family and friends.

Developing QALYs and extending RCTs promises to provide the information we need to judge whether health care is being produced efficiently or not. A more fundamental question is whether health care is really that vital for health?