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Medical Technology, Innovation, and the Nature of Medical Progress

by

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I start with a fact that is now hitting us over the head: health care costs are once again rising, a trend that began in 1999 and continues to this day - and with no end in sight. American health care spending rose 8.7% in 2001, to \$14 trillion. Employer costs rose 15% in 2002 and the same is expected this year; more generally, the costs of various health plans are rising at a rate of 10-25% a year.

I was raised to marvel at the miracle of compound interest when saving money. Hardly anyone mentioned the horror of compound interest when it takes its annual toll on health care costs.

Why is that happening? There are many reasons, but for me the most prominent is the common estimate the somewhere between 40-50% of the rise is traceable to the introduction of new technologies and the intensified use of older ones. That phenomenon is made worse by an aging population and increased public demand. The pain of the increased costs is intensified because the technologies do much good and satisfy many needs, especially for the elderly. That makes it uncommonly difficult to deal with them in any economically or socially satisfying way. What I will call the technological factor is buried deeply in the American psyche, both popular and medical. We like technology, always want it to be better, and can hardly imagine living without it, much less being sick without it.

What, then, is to be done about that technological factor when it bears a heavy responsibility for rising health care costs and all the pathologies that it brings - rapid increases in the number of uninsured, cutbacks in the Medicare program, reductions in employer-based health benefits, and more out-of-pocket payments? There are of course many proposed ideas and schemes, many of them encompassing open or covert rationing, making people more aware of the actual cost of the medical care they want, and any number of possible financing plans for health care in the private and public sector. Most of them assume that some kind of organizational, distributional, or bureaucratic fix can be found. Along with our faith in medical progress is a no less strong faith in greater efficiency and clever financing strategies to get us out of tight corners.

Maybe so in this case, but I doubt it. I believe we have reached a point in our health care history - as have all other health care systems in the developed world - where a basic clash of values is occurring, one that we had until recently been able to avoid. That is a clash between the value of equitable access to affordable health care for all citizens, on the one hand, and that of constant medical progress and technological innovation, on the other.

I believe it is imperative to admit that there is now such a clash, and one that will not easily give way to more clever organizational and financing schemes. Rapidly rising health care costs have the capacity to trash all of them, in the process making the goal of equitable access more and more difficult and perhaps putting it forever out of reach. Keep in mind that even as most of us pine for a system of universal health care the Western European countries are hanging on to theirs by their fingernails.

What is to be done about this clash? My simple answer is that we will have to change our values about medical progress and the idea of infinite improvement in our health and technology. We have been working with a model of progress and health care that does not readily admit of limits. It is open-ended with no visible or projected end point; just more and more. That model is exactly what will have to change.

In the meantime, however, I want to suggest that there are four things we need to think about: the aggregate costs of technological innovation, the potential impact of evidence-based

medicine, the various meanings of medical progress, and the need for what might be termed an economic “precautionary principle” for the diffusion of technology.

The Aggregate Costs of Technological Innovation

Too often - and seemingly most of the time - whenever an alarm is sounded about a new and expensive technology, or the increased use of an old one, there are two common retorts. One of them is that, even if the increased costs will run into the hundreds of millions, that would be an insignificant drop in the bucket for a health care system that now spends \$1.2 trillion on health care. The other retort is that it would be wrong and a shame to withhold from needy patients the new technology, expensive or not. Let’s get it out there and then figure out how to pay for it.

We might do well to think about those responses using heart disease and the new technologies coming on line to deal with it. Five examples are pertinent here:

- 1. Johnson & Johnson’s New Drug-Eluting stent.** This new stent, called Cypher, will cost about \$3200, versus \$900-1200 for current stents. Within a year it is expected to double stent expenditures to \$4.6 billion.
- 2. Ventricular Assist Device (VAD).** This device, at a cost of \$160,000—about the same as a heart transplant—can be used for patients who are not candidates for transplantation. The estimated added cost of using it with clinically eligible patients will be about \$16 billion a year.
- 3. Implantable Cardioverter Defibrillator (ICD).** In 2000 there were 35,000 ICD procedures. The newly expanded indications for its use for 400,000 patients would cost \$24 billion (and \$120 billion for 2 million patients). There is an estimated backlog of 2-4 million patients who could benefit from the ICD.
- 4. The Artificial Heart.** If all eligible patients with chronic heart failure received an artificial heart—expected to be available shortly—the cost would be \$11.3 billion a year.
- 5. Aspirin plus Clopidogere Therapy.** This modality, useful for secondary prevention of heart disease, would add an incremental cost of \$130,000 per quality-adjusted year of life, compared with a cost of \$11,000 for aspirin alone.

If we omit that last treatment - where no total figures are available - we arrive at a total of a possible \$53 Billion in new costs. That aggregate figure is not a trivial one, nor as easily dismissed, as might be a focus on any one of them alone. Now of course I have provided no cost-benefit calculations. One would want to know what other costs would be saved or averted by the use of these technologies. And some economists would no doubt want to determine the value of the lives saved. Some of the technologies promise to save lives, others to extend lives for a time, and still others to avoid alternative forms of treatment. Even so, \$53 billion would be

a large bill, and even if half that amount could result in offset savings it would still be a big bill.

And this is just heart disease alone. A similar exercise with the technologies used to treat other medical conditions would surely turn up some striking figures as well. And if all of the new and forthcoming technologies were aggregated in their potential for the increase of health care costs, I suspect it would be a staggering figure. Moreover, there is every expectation that the drugs that will come out of genetics research and genetic technologies will be even more expensive than those coming out of the present pharmaceutical research.

Now there is an answer to worries of this kind, clearly expressed by Dr. Alastair J.J. Wood of the Vanderbilt University School of Medicine. Responding in the *New England Journal of Medicine* to a worry that the aspirin and clopidogrel therapy would add too much to the cost of treatment, he wrote, “the cost of additional therapeutic benefits of clopidogrel is certainly high... [but] to abandon the search for improved therapies by describing them as unattractive on the basis of cost would represent an enormous disservice to our patients.... Surely the search for better drug therapy is at least as important as the search for improved audio [system] performance.” At the end of his book on heart disease technologies, *Machines in our Heart*, Kirk Jeffrey notes that these devices are expensive but, as his final statement, he says, “they really Work.” In sum, between the view that of course new technologies increase costs but patients deserve them, and the view that they do work, the economic issues are neatly put to one side - overruled by patient benefit with the help of evidence-based medicine.

Evidence-Based Medicine

Let me take a closer and perhaps idiosyncratic look at evidence-based medicine. Along with just about everyone else I have welcomed the advent of a serious commitment to evidence-based medicine. As a patient I want treatments that will actually do me good. As a citizen I want my tax dollars to support federal programs that take care to support only procedures that have been proven beneficial. As an employer I want to pay for employee health benefits that are worth the money and good for my workers.

Putting to one side, however, the high cost of getting good evidence on dozens and dozens of old, improved, and new technologies, there is one important limitation of evidence-based medicine. It provides us with probabilistic knowledge only. It does not, as clinicians often enough lament, provide guidance about what to do about an individual patient; and the probabilities may in many cases be of small, but not insignificant, benefits. We are then often left with a problem for physicians trying to decide what to do with the evidence, and a problem in determining whether small benefits are morally and economically worth it. Evidence-based medicine may, that is, solve a technical problem at the cost of creating an ethical one of determining appropriate coverage.

If that is an important limitation, there is also an ironic, sometimes possibly perverse, message on the other side of the evidence-based coin. Obviously ineffective diagnostic and therapeutic procedures ought to be dropped, and as fast as possible. But from a cost and policy perspective it is those that are efficacious for patients that give us the real problems in the long run. Because it then typically happens that, costly or not, they then become enthroned as medically necessary treatment, which must then be paid for by employers or the government. Kidney dialysis is the great case in point. Once the evidence supported it, there was nothing to

do but to pay for it, which the government has done; and that particular bill has steadily grown over the years. And recall that every one of the heart disease technologies I listed seems to have passed the evidence test—which makes it all but impossible to evade paying for them.

In light of the desire that technologies prove themselves to be efficacious we might, a bit ruefully, recall the old adage: be careful of what you wish for - you may just get it.

The Various Meanings of Medical Progress

We would not be having a cost crisis or feel compelled to make a strong use of evidence based medicine were it not for medical progress. That progress and the technology it has spawned have kept people alive longer than ever, nicely setting them up for the expensive and chronic diseases of old age - and then keeping them alive, often expensively so, often for many years with those diseases. For those of us who are patients, or would-be patients, that is a great boon. But it is not such a great thing for the financing of health care, particularly when that progress means we will find more and better ways to keep us all going. Isn't that what it's supposed to be all about?

In fact progress as an idea and an ideal may be more complicated than meets the eye. There are three possible senses of progress: a scientific development, a clinical development, and a population development.

By a scientific development I mean a better understanding of human biology and the causes of human disease and illness. The germ theory of disease was one of the earlier forms of such progress while the mapping of the human genome is perhaps the latest, supposedly with its own great prospects for a translation into beneficial treatments and technologies.

By a clinical development I mean the devising of a therapy or treatment modality of great benefit to the health of individuals. The discovery of good vaccines or kidney dialysis would be examples of that; and so would the heart disease technologies cited earlier.

By a population development I mean a therapy or preventive strategy that markedly improves the overall health of a population and not just that of individuals. Vaccines are a splendid example of this, as is screening for hypertension. But not one of the new or improved heart technologies clearly offers that kind of population benefit or least offers it only marginally. No one is cured of heart disease by its use. They will remain in some important ways sick people, but perhaps living longer than they might have and able to function better than if they did not have the benefit of the technology.

For the long-time good of the health of the American people, it is the first and the third kind of progress that is most needed - that of progress in knowledge and progress in population health. Too much of the progress of technological innovation, however, ends in the second category, good for individuals but with a negligible impact on population health. As a patient I will happily settle for the second form of progress. I am the one who will be sick and I am the one wanting to be healed - to hell with a population benefit if it does not directly help me or my loved ones.

But as someone who worries about health policy, that is not quite good enough, not by a long shot. For this audience, interested in technology diffusion, I would suggest that the third category should be the most important. Is the diffusion of a technology that is very expensive, but increases life expectancy by less than a year, a technology we should want and hope to

diffuse rapidly? The ventricular assist device has been estimated to increase a patient's life expectancy to 408 days in comparison with 150 days for patients receiving conventional drugs. That desperate patients will understandably want it, and that state legislatures will be easily persuaded to mandate it if there is any foot-dragging on reimbursement, is something to take seriously when we try to determine if it is worth it. But for those of us interested in the best use of technology should we be happy with that kind of likely outcome - one that uses pressure of one kind or other to bypass a full evaluation.

I will leave that question hanging in the air. If you are well, you may be inclined to say we should not be happy with such a result. If you are sick with heart disease, you will more than likely scream and shout with every other victim that it would be an outrage for you to be denied such a benefit by the government, your insurer, or your employer's health plan. It is just that different reaction, which should underscore how difficult the problem of progress can become - that is, has already become.

Devising an Economic Precautionary Principle

It was the environmental movement that first developed the concept of a precautionary principle. Its aim was to have a set of principles to help make decisions on potential risks to the environment. There have been various formulations of such a principle and its use has been a bit contentious in trying to reach agreement on the wording of a principle that would find a good balance between economic development and protection of the environment. I want to suggest that health care might profitably develop what could be called an "economic precautionary principle." By that I mean a principle that would try to find a satisfactory way of weighing and balancing the need for equity and the need, or at least desire, for continued medical progress.

In fashioning such a principle, two extremes would have to be avoided, not because they are necessarily irrational but because they could probably not command much medical or political support. One of the extremes would be that implicit in the kind of argument used by Dr. Wood: technological innovation should go forward in utter independence of economic considerations. As long as it would benefit patients, at whatever the cost, it should be fostered and supported. The other extreme would be to hold that no technological innovation would henceforth be allowed into the health care system unless it could be proved decisively, and in advance, that it would not add so much as a dollar to present health care costs.

The obvious problem with the first extreme is that it would be foolish any longer to say, in effect, additional health care costs are irrelevant. We know with perfect clarity that excessive cost increases do excessive harm to equitable distribution of care; and that is too high a price to pay. The obvious objection to the second extreme is that it would be nearly impossible to know in advance exactly what the cost impact of a new technology will actually be in the long run. Not only may new, better, and less costly technologies for various conditions come along someday but it is exceedingly difficult to accurately forecast what the actual diffusion of the technology will be. Every one of the cost figures I cited above is a speculative forecast at best. That is no reason to simply ignore them but good reason not to base policy wholly on such speculations.

Three considerations would have to be encompassed in an economic precautionary principle. One of them is that good and appropriate technologies, of clear patient benefit, should

be diffused as quickly as possible. The second is that it would make no economic sense to diffuse a technology that had not passed, with flying colors, a solid evidence-based analysis. The third is that, in addition to its clinical validity, a technology should pass some kind of cost-benefit analysis test. I will not here deal with the first two considerations. They are the stuff of this conference and I doubt that I can add anything else of value.

The stickler in any case is the third consideration. How might that be dealt with? And it must be dealt with in the future if we are to avoid having those technologies, splendid though they might be, do their unhappy part in increasing our costs and at the same time increasing our present inequities. To that I might add: helping to guarantee we will never have universal health insurance coverage, already a fading ideal.

I want to suggest some possible alternative strategies, looking at their pros and cons. The most extreme, at one end of the continuum, would be to require that no new technology be accepted (that is, reimbursable by the government or private insurers) unless it could be shown, with hard figures, that it would not significantly raise costs over present technologies. Patient benefit would be put to one side altogether, out of recognition that the greatest long-term problem will be with expensive technologies that pass all of the effectiveness tests. Who might be required to work through such cost-benefit calculations? The tough answer to that question would be those who are selling them and would profit from their diffusion. There should be no reason why the government or some other agency should have to pay for such a calculation.

No doubt there would be distrust of private sector data, developed by the companies themselves. A national commission could be put in place, perhaps at government expense, much like the FDA, whose job it would be to evaluate the cost-benefit data and determine if it was solid. Then it could be approved. Even if this approval formally applied only to federal health care programs, its prestige should be significant enough to sway the private sector, at least morally empowering the private sector to follow the federal lead. Most important of course would be that such a process would have enough clout and prestige to deal with the howl of frustrated technology entrepreneurs and companies that had sunk research capital into the technologies. Furthermore, the howls of patients who, upon hearing of their denial for treatment using technologies up for review that might help them, would feel betrayed. Moreover, the Dr. Woods of the world would in turn be outraged that cost considerations were standing in the way of useful, perhaps life-saving, technologies.

I must confess that this is my utopian solution for dealing with the clash between medical progress and equitable health care. Would it slow the development of new, and often valuable, technologies? Yes, it surely would. Would it slow the diffusion of those new technologies? Possibly, since time would be needed to develop good economic data, though probably nowhere near the time needed to develop good clinical efficacy data. But here I show my true colors, as someone who would prefer to see a less advanced technological medicine that everyone could have, and that did not harm the overall provision of equitable care, than one that was up-to-date, incorporating every technological advance but indifferent to equity.

If we could go back to the technologies available a decade ago, but using none developed since then, we could afford universal health care. To me, that would be a good trade-off, but I suspect that not everyone is so enthused by the idea of equity. Furthermore, the counter-attack would say that we should not halt real progress; that what may be inequitable at first may not always be so; that we can't really know what the economic fall-out of an initially expensive technology will be; and that, because an expensive new technology may not be available to all,

we should not withhold it from everyone. Good points, I would respond, but then say that with technology and health care costs I am not someone who believes everything will just turn out fine if we let progress, with the help of the market, have its way.

Since my admittedly draconian solution might just, here and there, run into some opposition, I offer a more moderate way to go. That would be to set, as at least an economic ideal—as a high social and business value to be accorded respect and action—a request that developers of technology voluntarily develop useful economic data, with the help of independent experts. They would then make available, together with the efficacy data, what they have found. If it turns out that the cost-benefit balance was not favorable for their technology, they would be free to make any kind of defense they liked: the uncertainty of the data, the right of those who pay to have the benefit of the technology, proposals for ways of having the technology paid for. I am sure they would think up something.

They might want to turn to Dr. Wood and physicians of a like mind for favorable testimony in favor of patient needs trumping crass, cold economic considerations. Whatever their defense, the main requirement would be candor about the data. No fudging with that. Then they could make whatever case they liked in defense of their technology. There would be no government coercion, no big brother breathing down their neck. They could even refuse to carry out such calculations in such a voluntary system. But then they would have to publicly explain why they did not want to, and it is difficult to imagine how they would word public statements to the effect that they were taking advantage of an economic Fifth Amendment right to avoid incriminating themselves. I happen also to be a great believer in social stigmatization, and taking the Fifth in the context would surely bring that down on their heads.

The third approach would combine a number of strategies. One of them would be to hold that the situation is not nearly so bad as it appears. Why should we worry that health care spending has reached 14% of the Gross Domestic Product, the highest on record? After all, who is to say what the “right” figure should be, and what would be so terrible if we went to 16% or 18%? Moreover, by virtue of its size and expenditures, the health care system is an important source of jobs, income, and exportable technologies. It is a central engine of American economic vitality. And as some economists have pointed out, the true economic gains from research and technological innovation run into the trillions of dollars, outrunning any other economic benefit.

Another strategy is to argue that research will eventually find cures for many if not most of the diseases and pathologies that are so costly to treat. Whether as a result of the Human Genome Project or stem cell research the way is potentially open for fantastic gains to human health and longevity. Even the general worry about the eventual impact of the baby boomers on the Medicare program may be overblown. There is increasingly good data to show that they will enter old age in remarkably good health and with disability rates much lower than earlier generations. Even now it is new and better technologies coming out of research that account for the great improvement in the health of those over 80, now the greatest in the world. In a word, more money for research may be the best cure of our present cost problems.

The final strategy would be a greater reliance on market principles and tactics to control health care costs. Market proponents have long held that our present system of third-party payers shields the medical consumer (a.k.a. patients) from the real costs of the care received. Allowing the consumer great choice of health plans (and requiring an exercise of that choice), increasing co-payments and deductibles, promoting medical savings accounts, and similar kinds of tactics would force consumers to decide just how much and what kind of health care they

should want. It goes without saying of course that a greater use of financial incentives and disincentives with physicians, hospitals, and other health care providers would help bring the bracing tonic of the market to systems that have grown soft over the year because of assorted public and private subsidies.

I will leave it up to others to decide which of these strategies ought to be pursued. I have made my own bias clear enough. I will only say of the second and third strategies that they seem to me prime examples of what my wife, a psychologist, has called “pathologies of hope.” The second strategy focuses entirely on individual patient needs and simply sweeps the problem of costs under the rug. It is a reprise of a belief that has been around for decades, and a hangover from the days when medical care was inexpensive, that it is the physician’s duty to think only of the welfare of individual patients, uncontaminated by economic considerations. The hope is that, somehow or other, the costs will be taken care of. Not to worry!

The third and multi-pronged strategy has a pleasantly soothing quality: it does not really matter how much we spend on health care, a fine economic investment. And if you are worried, relax. Research will sooner or later get us out of these unpleasant problems. The fact that the NIH and the pharmaceutical industry has contended, for at least three decades, that research will lower costs - but has in reality help drive them up - is not enough to stifle that pathology of hope.

Now I will have to concede, as my final comment, that my own preferred strategy, that of greater assessment and control of new technologies, displays its own pathology of hope. Do I really believe that researchers and technological innovators, and the massive industries that support them, would tolerate that kind of outside interference? After all, this is the United States, not one of those socialist European countries! Or that they would not muster a squadron of health policy experts to show how such an approach would surely fail? Or that the country is so worried about rising health care costs that it is ready to run some risks in the introduction of new technologies?

Well, when the pain of any illness, medical or economic, gets strong enough people will consider many remedies they would have scorned when in good health. We are approaching that point now. When everyone begins to cry “uncle” - taxpayers, Congress, those who manage the Medicare and Medicaid programs, employers, and the uninsured - the stage is set for a change. That pathologies of hope are running down, the need for something serious to happen is increasing. We will see.

Here is my proposed economic precautionary principle for the acceptance and diffusion of new technologies and improved old technologies:

Technological innovation is an important ideal of contemporary health care and an historically important contributor to improved health. Yet that innovation, resulting in either new technologies or improved older technologies, is an acknowledged source of health care cost increases, threatening the ideal of equitable access to care. The diffusion of technology should be judged by three standards. The first is that technological innovation needs to be encouraged and supported. The second is that medical technologies should be subject to careful examination using the best available methods of evidence-based medicine. The third is that there should be a parallel economic examination. Its aim should be to develop realistic projections on the likely economic impact of the technology. The combination of the scientific and

economic assessment should be the basis of judgments about rapid or slow diffusion. Those that fail either the scientific or economic test should either be abandoned or given enough support to be tested in an experimental way. When there is uncertainty of a serious kind about the outcome of either form of assessment, the benefit of doubt should be given to the technology, but accompanied by ongoing evaluation to allow experience to resolve the uncertainty.

Those who are unhappy with my precautionary principle are encouraged to develop their own version. I would simply ask that it take serious account of the potentially harmful economic fall-out of even the most beneficial technologies and propose a way of dealing with them - curbing any temptations to pathologies of hope.

Daniel Callahan is the author of six books:

- *False Hopes: Why America's Quest for Perfect Health is a Recipe for Failure*
- *The Troubled Dream of Life: In Search of a Peaceful Death*
- *Setting Limits: Medical Goals in an Aging Society*
- *The Tyranny of Survival: And Other Pathologies of Civilized Life*
- *Abortion: Law, Choice and Morality.*