Longer Lives, Longer Independent Living, More American Jobs
Greater American Prosperity and Lower Health Costs
The Necessary Revolution in Health Solutions
As the Key to Lower Health Costs

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For nearly 50 years the United States has sought to lower health costs through more and more bureaucratic controls and micro management. The effort has made doctors miserable while leading to more expensive and more complicated regulatory systems which shift cost from medicine to bureaucratic administration.

As the baby boomers age and health solutions become more sophisticated this approach will eventually bankrupt the country while killing jobs and producing worse health results with greater suffering and less independence for many Americans with health challenges.

There is a dramatically different, more desirable, and more effective strategy available to lengthen lives, extend independent living, create more American jobs, grow the American economy and lower the cost of healthcare. This is a strategy of creating health solutions to eliminate entire classes of health costs while dramatically improving health outcomes.

America should pursue a program of the most rapid scientific discoveries, with the most rapid regulatory approval, with a constant focus on implementing and funding innovations designed to lengthen lives, increase independent living, and create more American jobs and more American prosperity.

Our model should be Salk and Sabin replacing the iron lung with the Polio vaccine.

No one today worries about an explosion of healthcare costs in American polio patients (and thanks to Rotary International the same may soon be true in even the poorest countries in the world).

The speed of implementation for polio vaccine was remarkable.

- 1952: Salk and team, with the support of the National Foundation for Infantile Paralysis, began its first tests on humans of their killed-virus polio vaccine. There were nearly 60,000 new cases of polio in 1952.
- 5/16/1953: Salk gave the vaccine to his family.
- 4/25/1954: Massive polio vaccine trial began in the US. In all, over 1.3 million children participated in the trial.
- By 1961, there were virtually no new polio cases in the United States. And earlier estimates of $100 billion in polio healthcare costs dropped almost to zero.

Take HIV/AIDS, where former NIH Director Elias Zerhouni estimates that $10 billion in research saved $1.4 trillion in healthcare costs – 140 to 1 leverage. (“Extracting

Knowledge from Science: A Conversation with Elias Zerhouni, Health Affairs 25 (2006), w94-w103, page 8 of 14).

We should use the discovery and rapid dissemination of polio vaccine and the consequent disappearance of the iron lung as people stayed healthy and contributed to the American economy as the model for American health and healthcare in the 21st century.

This science-discovery-innovation-growth strategy is especially important and timely because the human race is on the edge of the greatest explosion in scientific knowledge in history. There are more scientists alive today than in all previous history. They get better computers and better laboratory equipment every year. They are connected online, through email, data-sharing and by cell phone so new discoveries spread rapidly. They are increasingly connected by venture capital, licensing and royalties so knowledge can migrate from the laboratory to the market place.

There will be four to seven times as much new knowledge discovered in the next quarter century as in the last. That means we are as close to 2036 as we are to 1880 in the knowledge available to solve problems.

Biologicals promise a generation of breakthroughs. My daughter Kathy Lubbers has rheumatoid arthritis. Her life has been dramatically improved by breakthroughs in biologicals combined with a serious training regimen. She works today on the National Arthritis Foundation Board to expand research to save lives and improve the quality of life for millions of Americans with arthritis. She knows personally how important these new medicines are.

In regenerative medicine we stand at the edge of a dramatic new potential to use our own cells to grow solutions totally compatible with our bodies. In kidney dialysis alone the federal government now spends $27 billion a year. Kidney dialysis will soon be a larger cost than the entire National Institutes of Health. Yet regenerative medicine stands at the edge of making it an obsolete therapy.

Regenerative medicine is creating the potential for revolutionary breakthroughs for spinal cord injuries, cancer patients, heart disease and every aspect of our physical body.

Brain science stands on the edge of an even greater revolution in knowledge and capabilities than regenerative medicine. Because of breakthroughs in instrumentation and computation, brain science will almost certainly be the most exciting and explosive area of new knowledge in our lifetime.

Brain science opens up potential solutions for Alzheimer's, Parkinson's, Autism, Schizophrenia, Bipolar disease, and even in how fast and thoroughly we learn.

Helping with Alzheimer's alone could be a revolutionary reduction in costs. We currently spend $183 billion every year to treat Alzheimer's, and the disease is currently projected to cost the federal government $20 trillion – a number equal to one and a half

federal debts -- between now and 2050. Slowing Alzheimer's onset down by 5 years would save half of that projected cost—$10 trillion. Even today's limited breakthroughs in Alzheimer's medicine have had a big impact. Only 1% of the patients who use Alzheimer's medications are in nursing homes two years after severe onset as compared with 16% of those who do not use medication.

When Washington politicians risk a government shutdown to save a few billion dollars in spending it is amazing that they can't even begin to think about saving ten trillion dollars (250 times the size of the recent continuing resolution agreement).

The new knowledge will be developed and implemented. The only question is whether it will be developed first in the United States and lead to massive job and wealth creation while solving our health problems or whether it will be developed first in China, India, Singapore, Japan and Europe—forcing Americans to purchase the newest health breakthroughs from foreign companies and countries.

According to a 2004 economic report to the president, of the ten most profound medical innovations in the early 1970s, including MRI and CT scans, ACE inhibitors, statins, anti-depressant drugs, and coronary bypass surgery, only one was exclusively developed outside the United States. This is because the U.S. has a private system, centered on markets and individuals, which rewards achievement and innovation.

Given today's American tax and regulatory systems it is increasingly likely that the full implementation of the new knowledge will first occur outside the United States and be imported by us. This will be tragic for Americans in lost health opportunities, lost jobs and prosperity, and unnecessarily higher healthcare costs.

In recent conversations with scientists working on regenerative medicine, they have told me their American laboratory breakthroughs will almost certainly be developed commercially outside the United States because the Food and Drug Administration is so risk-averse, so bureaucratic and adds so much unnecessary expense to drug development. In one example the first seven bladders were grown and implanted for $7,000 each under the FDA academic protocol and the next 16 cost $100 million under the FDA commercial protocol. That kind of bureaucratic expense kills innovation and kills American jobs.

Many large pharmaceutical companies now expect to expand far more in China, India and Singapore than in the United States.

Many entrepreneurs who would like to be involved in biological breakthroughs in health, agricultural and other fields now believe the combination of tax policy, litigation policy, and regulatory policy make it too expensive and too risky to invest in the United States.

At a time of potentially revolutionary change the 1,968 grants of power to Washington bureaucrats outlined in the Center for Health Transformation wall chart number three (see healthtransformation.net) make experimentation in new better systems more difficult more time consuming and more expensive.

We have the potential to live longer, have healthier and more independent lives, save a great deal on the cost of healthcare and create far more American jobs and American income if we are prepared to fundamentally reshape the system toward a pro-entrepreneur, pro-scientist, pro-change model. The addendum to this outline shows the dramatic impact that investing in curing and preventing disease can have versus simply treating its symptoms.

Here in outline form are the key steps to a dramatic improvement in health and health costs, in American jobs and American prosperity.

1. Create a 21st century Food and Drug Administration which emphasizes collaboration and speed to market. This new FDA should collaborate from the laboratory to your medicine cabinet. It should have a strong sense of the alternative cost of people suffering without the new breakthroughs. It should have a continuous learning system to keep up with the new breakthroughs in science. It should be organized to work flexibly across bureaucratic lines to match the regulatory system with the new breakthroughs in scientific knowledge. For example, a number of the breakthroughs in regenerative medicine will involve both biology and devices. Today these are two different divisions of FDA with very limited collaborative abilities. A new system of adaptive clinical trials and conditional approval needs to be invented to enable true breakthroughs to reach people. When combined with electronic information systems to allow daily real time monitoring of side effects and unexpected developments a 21st century FDA can afford much more risk taking because it can monitor and modify with much greater speed than in a paper based system. Some conditional approvals might be made only for doctors and patients using electronic health records with real time monitoring. This would also accelerate the use of electronic health records which is vital to a 21st century health system.

2. The National Science Foundation budget should be substantially increased. When I was Speaker we doubled the budget of the National Institutes of Health while balancing the federal budget through entitlement reforms (welfare and Medicare), controlling discretionary spending and cutting taxes to accelerate economic growth. The biggest budget mistake we made was not tripling the NSF budget (from a much smaller base) while doubling NIH. Much of the basic breakthroughs in mathematics, physics, chemistry, and computation come from NIH and are the base of science at much of NIH.

3. The National Institutes of Health budget should be increased but NIH leadership should be challenged to fundamentally rethink the small grant peer review incremental approach. In the last decade the NIH has had a 50% increase from $20 billion to $30 billion a year. In that decade the NIH has had $275 billion in total spending. In a time of dramatic change it is totally appropriate for the American people to expect the NIH leadership to critically rethink research strategies and funding models. The examples of the Manhattan Project, the Apollo Project, the Human Genome Project, and some elements of the National Cancer Institute suggest

that a more outcomes-oriented, more translational, and more systematically resourced system might yield better results more rapidly. We need a much better and more equitable way for NIH to support academic institutional infrastructure than the current "indirect cost formula." The American people deserve better health for their research dollars.

4. A very bold approach to brain science is needed to both take advantage of the potential for enormous breakthroughs and the sheer financial threat of brain disease (of which Alzheimer's is merely the most expensive). We should quantify the current value of saving half the projected $20 trillion in Alzheimer"s expenditure and scale the research solutions to the size of our cost problem. The amount would certainly be many times the amount currently spent. We should create a Brain Science project funded off budget with Alzheimer's bonds. Rep. Michael Burgess, MD introduced the MIND Act to do just that. The commitment would be to take the first wave of savings from Alzheimer's research and use them to pay off the bonds. The Brain Science community should be challenged to develop a strategic plan for the maximum investment in brain science to maximize the rate of new discoveries and new solutions. The breakthroughs in Alzheimer's, Parkinson's, Autism, mental illness, traumatic brain injuries, etc. would more than pay for the investment. The breakthroughs in new models for effective learning could revolutionize our ability to learn more about these disorders and discover new treatments for them. Accepting a system which guarantees millions of lives ruined and trillions of dollars spent is a path toward national bankruptcy. Breaking out by accelerating and focusing scientific development is a path to better lives, lower costs and more American jobs.

5. Translating breakthroughs in biology into usable products requires a rebirth of small venture capital firms. New startups historically have been much more agile and much more effective at translating research into products. We should repeal Sarbanes-Oxley which had zero usefulness in providing information during the 2008 financial meltdown but which is a major burden crippling the venture capital and new startup system. We should adopt the Chinese capital gains tax rate which is zero. At a zero capital gains tax the amount of new capital available to invest in new startups in health would be extraordinary. We should adopt 100% expensing so companies could write off new equipment in one year to keep up with the continuous development of new laboratories, new computers and new production facilities. The 21st century FDA should consciously work and be held accountable by Congress for making the regulatory pathway more efficient and transparent and thereby making it less expensive and faster for small companies to bring their breakthroughs to the needs of desperately ill patients. There were 394 biotech companies in the United States in 2007 and there are only 294 today, a decline of nearly 25% in 4 years. If we are serious about creating American jobs and American health solutions we need a much healthier venture capital and new startup environment.

6. The Congressional Budget Office and Office of Management and Budget should be challenged to develop new models that study the history of scientific breakthroughs and their impact on spending patterns. Neither CBO nor OMB today is capable of

taking into account the coming scientific revolution and therefore their projections consistently favor bureaucratic static solutions over entrepreneurial dynamic solutions. Since they often set the terms of budget and spending debates they are profoundly reactionary inhibitors of bold thinking and new solutions.

7. The Center for Medicaid and Medicare Services and the private insurance industry should develop models for pilot projects and experimental payments for potential breakthroughs. A major inhibitor of some of the boldest regenerative breakthroughs (for example growing healthy kidney cells to eliminate the need for kidney dialysis) find it very difficult to get funding because there is no indication either CMS or the insurance companies would pay for the new approach. Given annual budgeting models it is difficult to quantify the value of a larger one year cost which saved vastly more money over time. Current budget analyses overvalue government costs and undervalue personal lives and personal costs. Thus the replacement of kidney dialysis with a system which allowed people to avoid going to a dialysis center three times a week and allowed people to stay gainfully employed and continue paying taxes would be overstated in government costs (and tax receipts from work would not count) while the advantages to the individual and the society of remaining productive and having a higher quality of life would not be scored.

This approach to a fundamental rethinking of our approach to research, to product development, and to solving health costs by solving health challenges represents a decisive break with the health policies and health structures of the last half century.

It offers enormous rewards but it will take very bold leadership and a willingness to produce solutions as big as the problems.

Addendum

Center for Health Transformation
Better health, lower cost

The Value of Curing and Preventing Disease

Smallpox:

"A $300 million effort succeeded in completely eradicating smallpox in less than ten years. The campaign was effective because variola virus produced acute illness, had no carrier stage or non-human reservoirs, and had an effective vaccine that was used in combination with international surveillance and public education" (Ann Marie Nelson, The Cost of Disease Eradication: Smallpox and Bovine Tuberculosis, http://onlinelibrary.wiley.com/doi/10.1111/j.1749-6632.1999.tb08048.x/full).

"The cost of the entire 10-year global eradication was $83 million for foreign assistance, and about $160 million spent by the individual countries. This is small compared to an estimated $2 billion yearly spent to control smallpox." (DA Henderson, The Eradication of Smallpox, http://www.ncbi.nlm.nih.gov/pubmed/788150).

"With the global eradication of smallpox, vaccination stopped and quarantine measures were no longer needed. Annual savings are estimated to be more than $1 billion, above and beyond the alleviation of a terrible burden of death and disability. The total cost for the programme over the period 1967 to 1980 has been estimated to be about $300 million of which two thirds was borne by the endemic countries themselves" (WHO: http://www.who.int/mediacentre/news/notes/2010/smallpox_20100517/en/).

Cholera:

"Only direct costs were assessed. Fixed treatment costs were estimated to be $75,000 for pre-emptive treatment, and variable treatment costs to be $14 per case. Vaccine cost was estimated at $0.50 per dose, and a pre-emptive vaccination programme was estimated to cost $13,000" (WHO: http://www.searo.who.int/en/Section23/Section1108/info-kit/who-cholera_vaccine.pdf).

From 1996 through 2006, only 40 confirmed cases of cholera in the United States were acquired abroad. (CDC: http://wwwnc.cdc.gov/travel/yellowbook/2010/chapter-5/cholera.aspx)

The UN appealed for $164 Million last year to combat the Cholera outbreak in Haiti. (France 24: http://www.france24.com/en/20101112-haiti-anger-mounts-with-cholera-death-toll-rise-disease-port-au-prince)

The cholera outbreak in Peru in 1991 cost the country $770 million due to food trade embargoes and adverse effects on tourism (WHO: http://www.who.int/topics/cholera/impact/en/index.html)

Yellow Fever:

Vaccine cost: $62.00 (John's Hopkins: http://hopkins-abxguide.org/vaccines/vaccines/yellow_fever_vaccine.html?contentInstanceId=265839).

The projected quantity of yellow fever vaccines as of February 2010 in doses was 44,500,000. (UNICEF: http://www.unicef.org/supply/files/2010_Vaccine_Projection.pdf)

During 1970–2002, a total of nine cases of yellow fever were reported in unvaccinated travelers from the United States and Europe who traveled to West Africa (five cases) or South America (four cases). Eight of these nine travelers died. Only one documented case of yellow fever has occurred, which was in a vaccinated traveler from Spain, who visited several West African countries during 1988. (CDC: http://wwwnc.cdc.gov/travel/yellowbook/2010/chapter-2/yellow-fever.aspx)

TB:

"While current drug regimens for MDR TB average approximately US $4,000 per patient, the cost of XDR TB treatment has been estimated to be more than twice this amount, depending on the extent of drug resistance and the need for hospitalization" (National Institute of Allergy and Infectious Diseases: http://www.niaid.nih.gov/topics/tuberculosis/Research/Documents/mdrxdrresearchagenda.pdf).

"Every dollar spent on TB prevention saves a country $3-4… An untreated person with active TB will infect between 10 and 15 people per year." (National Foundation for Infectious Diseases: http://www.nfid.org/factsheets/tb.shtml).

"TB control programs, if poorly funded and organized, often do more harm than good. Inadequate TB control is a major cause of Multi-Drug Resistant TB (MDR-TB). . . One case of MDR-TB may cost up to $250,000 to treat and in some cases is incurable" (National Foundation for Infectious Diseases: http://www.nfid.org/factsheets/tb.shtml).

"The estimated costs to poor households is $12 billion per year" (The International Union Against Tuberculosis and Lung Disease: http://www.theunion.org/download/factsheets/tb/facts_cost.pdf).

"In order to reach the DOTS Expansion targets of diagnosing 70% new cases and treating 85 % of them by the year 2005, the world's governments need to spend $1.8 billion per year" (The International Union Against Tuberculosis and Lung Disease: http://www.theunion.org/download/factsheets/tb/facts_cost.pdf).

Polio:

"In mid-1990s, vaccines to provide "basic" coverage for tuberculosis, polio, diphtheria, tetanus, pertussis, and measles cost about $1 per child" (WHO).

"More than $230 million will be saved annually in the United States alone when polio eradication is achieved and polio vaccination is stopped. Globally, more than $1.5 billion will be saved annually" (HHS: http://www.hhs.gov/asl/testify/t980923a.html).

"Since 1988, several million children worldwide who would have been paralyzed were not because of the dramatic reductions in polio virus transmission. More than 100,000 children who would have died from polio, were saved" (HHS: http://www.hhs.gov/asl/testify/t980923a.html).

Kidney Dialysis:

"Medicare incurs a first year cost of more than $100,000 and will pay for a re-transplant in the case of organ failure or a return to dialysis. Medicare spends $71,000 per year on a dialysis patient, which Medicare covers indefinitely (National Kidney Foundation: http://www.kidney.org/news/pubpol/pdf/QnA_ImmunosuppressiveDrugs.pdf).

Medicare spends an average of $17,000 on a kidney transplant recipient per year after the first year of the transplant. Medicare pays 80% of the cost of the immunosuppressive medications under Medicare Part B if an individual's transplant was eligible for Medicare. This is not impacted by the Medicare Part D prescription drug benefit (National Kidney Foundation: http://www.kidney.org/news/pubpol/pdf/QnA_ImmunosuppressiveDrugs.pdf).

Kidney disease is increasing at an alarming rate such that the number of kidney failure patients is expected to more than double to 650,000 by 2010 at a projected cost of $28 billion. (CDC: http://www.cdc.gov/healthmarketing/entertainment_education/tips/kdnydis.htm).

In 2007, Medicare spent $8.6 billion on the treatment and medications of dialysis patients, from babies to the elderly, according to the Medicare Payment Advisory Commission's March report to Congress. (USA Today: http://www.usatoday.com/news/health/2009-08-23-dialysis_N.htm).

"Need for" Iron Lung:

"In the 1930s, an iron lung cost about $1,500—the average price of a home" (Smithsonian Institute: http://americanhistory.si.edu/polio/howpolio/ironlung.htm).

"Dianne's yearly medical expenses [lived in an iron lung for over 60 years] range from $60,000 to $80,000" (CBS: http://www.kidney.org/news/pubpol/pdf/QnA_ImmunosuppressiveDrugs.pdf).

Measles:

"Global measles eradication would result in significant economic benefits for the United States. CDC estimates that more than $50 million annually in measles vaccine costs alone would be saved in the United States following a successful measles elimination initiative and termination of measles immunization. Additional savings would accrue from the prevention of hospitalizations and

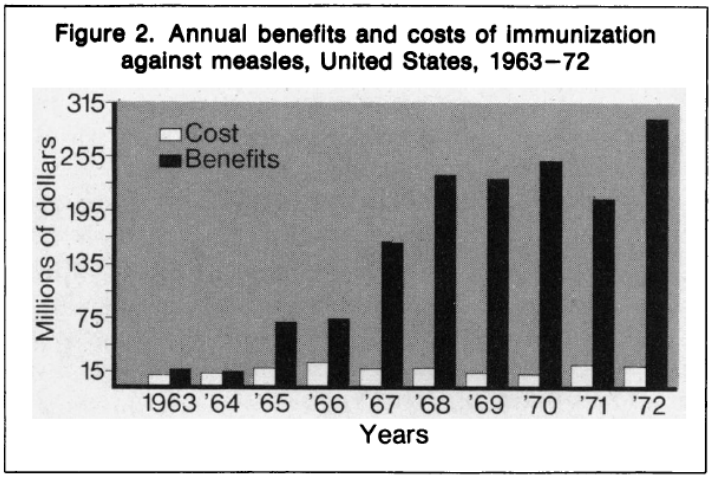
medical costs if future measles epidemics in the United States were eliminated. For example, hospitalization and other medical costs exceeded $100 million during the measles resurgence in the United States during the period 1989-1991" (HHS: http://www.hhs.gov/asl/testify/t980923a.html)

It costs less than one US dollar to immunize a child against measles. (WHO)

The estimated average cost per measles case is $276, $307 and $254 for the Netherlands, the UK and Canada, respectively. The estimated average cost of adverse events following immunization per vaccine is $1.43, $1.93 and $1.51 for the Netherlands, UK and Canada, respectively. (National Center for Biotechnology Information: http://www.ncbi.nlm.nih.gov/pubmed/12241559).

Economic savings from measles vaccination over 10 years:

Cases averted	23,707,000
Lives saved	2,400
Additional years of normal and productive life by preventing premature death and retardation	709,000
Physician visits avoided	12,182,000
Hospital days avoided	1,352,000



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