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TRANSFORMING IRAQ'S ECONOMY

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before the

JOINT ECONOMIC COMMITTEE
CONGRESS OF THE UNITED STATES

ONE HUNDRED EIGHTH CONGRESS

FIRST SESSION

June 11, 2003

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Transforming Iraq's Economy

Wednesday, June 11, 2003

CONGRESS OF THE UNITED STATES,
JOINT ECONOMIC COMMITTEE,
WASHINGTON, D.C.

The Committee met, pursuant to notice, at 9:30 p.m., in Room 628, Dirksen Senate Office Building, the Honorable Robert F. Bennett, Chairman of the Committee, presiding.

Present: Senators Bennett, Sununu; Representatives Stark, Saxton, Maloney, English, Paul, Hill.

Staff Present: Donald Marron, Ike Brannon, Jeff Wrase, Chris Frenze, Robert Keleher, Brian Higginbotham, Kurt Schuler, Colleen Healy, Melissa Barnson, Gary Blank, Wendell Primus, Chad Stone, Rachel Klastorin, Nan Gibson.

OPENING STATEMENT OF SENATOR ROBERT F. BENNETT, CHAIRMAN

Senator Bennett. The Committee will come to order.

I have a prepared opening statement which has been distributed, and I don't back away from it. But I am going to deviate from it a little in the actual remarks that I make to kick off the hearing, because I think the best demonstration of the atmosphere in which this hearing is being held comes from this morning's papers.

Here is *The Washington Post* and its cover picture. And it says:

"In Holy City, Things Are Going Right. U.S. Forces and Iraqis Work Together In Shiite Stronghold of Karbala."

The New York Times, however, says: "G.I.s In Iraqi City Are Stalked By Faceless Enemies At Night."

And the lead says: "Since the American command quadrupled in military presence here last week, not a day has gone by without troops weathering an ambush, a rocket-propelled grenade attack, an assault with automatic weapons, or a mine blast."

Reminiscent of the war, when we won it on Fox, but lost it on CNN.

(Laughter.)

There is a constant sense of instant conclusion that goes on in the media. We must know, pre-season, who is going to win the World Series. We must know, pre-season, which two teams are going to go to the Super Bowl and which one is going to win.

We have national rankings of college basketball teams before the first dribble is ever bounced on a hardwood floor.

And we carry that same sense of determination to announce outcomes immediately over into politics.

So everything is going well in one newspaper, everything is a disaster in another newspaper. We're going to triumph. There is no hope.

Pick your paper. Pick your conclusion.

The purpose of this hearing today is to get above that kind of babble of voices one way or the other and recognize that we will not know whether we have succeeded in establishing a democratic, stable regime in Iraq for a year, two, or even longer.

The implications of that quest, the desire to replace a brutal tyranny and harsh dictatorship with a functioning, stable government ready to join the world and participate as a true partner in the world economic structure, has enormous implications for the United States. It has enormous implications for our economy. But it has even bigger implications for the world at large.

The establishment of a peaceful, stable, and economically-viable Iraq will transform the Middle East if it is successful. If it is not, we will pay a price that is almost incalculable at this point.

So I want to say to everyone who is listening -- I don't think I need to say it to our witnesses who are testifying -- that if you have come here to try to get the latest answer for are we making progress in getting the water turned on? Will the electricity be available by next Friday? Where are we in finding the latest artistic treasure? This is not the hearing for you. This is a hearing to be discussing very long-term prospects and very long-term strategies, to help the Congress and we hope through the Congress, the American people.

And yes, if I may be so bold, to help the Administration to understand some of the strategies that might work, some of the strategies that should be avoided, and overall, the opportunity and challenge that we are presented with.

There's never been a time in history where more is riding on a successful post-war engagement.

Now I say that looking back, that's probably not true if you look at the accomplishments that followed the Second World War. But the Second World War kicked off an entirely different international situation. As we followed the Second World War, we went into the Cold War, where there was a polarization of forces, with the United States and the other countries of the West on one side, the Soviet Union and its satellites on the other. And the successes that were achieved in Japan

and South Korea in taking what had not been a democratic society and turning it into a viable, modern state occurred within the framework of the Cold War challenge.

Now we are in a world where there is only one super-power, but there are a multitude of nonstate powers that would seek to destabilize the world through acts of terror. And how things come out in Iraq can have an incredible impact on whether or not we get on top of that new kind of world.

So that's the background against which we meet this morning. Those are the issues that we intend to explore. And we have assembled, I believe, an outstanding panel of experts to help us do that.

Now, with that, we're joined by Mr. Stark, the Ranking Member, and I will yield to him for an opening statement. And I would ask consent of the Committee -- our normal pattern is that we have opening statements only from the Chairman, the Ranking Member, and the Vice Chairman. But I would ask that Ms. Maloney be recognized for a brief opening statement because she has to leave us and wants to be part of this, to the degree that she can.

So if there is no objection, following Mr. Stark, we'll hear from Mr. Saxton and then Ms. Maloney.

[The prepared statement of Senator Bennett appears in the Submissions for the Record on page 43.]

OPENING STATEMENT OF REPRESENTATIVE PETE STARK, RANKING MINORITY MEMBER

Representative Stark. Thank you, Mr. Chairman.

I want to commend you and pay homage to your creativity in holding this hearing at this time. It's an important topic. And it's an important responsibility that the President has put on the shoulders of the American taxpayers -- or should I say, debt-holders, since this Administration doesn't believe in taxes.

As I was pondering my thesis for my doctorate in theology at Bob Jones University, I'm a humanist and therefore, the here-after doesn't mean much to me. I keep looking for heaven on earth.

One of the problems of doing that is that I could never find a place for right-wing Democrats or Republicans, either.

And it came to me as I was reading Hendrik Hertzberg's *New Yorker* article, which I'd like, Mr. Chairman, to put in the record --

Senator Bennett. Without objection.

Representative Stark. -- that describes Iraq. Why it's a supply-sider's dream.

There are no taxes. There are no environmental regulations to get in the way of you free-enterprises. Why, religion is the government. There's no separation of church and state.

I have never seen a place where a free-market economy is running amuck.

Charlton Heston would love to go there. Everybody's got a gun. He could organize the NRA and be there. Why, the Club for Growth ought to build their national headquarters there.

(Laughter.)

I just think, Mr. Chairman, that this is the nirvana for the supply-siders and the right-wing Republicans.

Now I'm afraid that's not what we're going to hear from our witnesses today. The facts are that Iraq's economy and their civilian society is a mess, and I suspect we have a long and expensive reconstruction ahead of us.

I don't think we should be surprised if the Administration put as much time into preparing for the inevitable problems with the reconstruction process, instead of preparing their public relations campaign to get us to invade and preparing the prime-time movie about Private Jessica Lynch.

Why, maybe we'd have had some ideas. But that's not what happened and we have to pick up the pieces.

So we'll hear some creative ideas from our panel. But I hope they won't lull us into thinking that this is going to be easy. I think it's going to be expensive and long-term, and I hope you'll be very honest with us so that we can be honest with the American public for a change, and tell them what the consequences are, because I'm afraid if we don't change our domestic policy soon, that our next hearing will be on restructuring the American economy.

Thank you, Mr. Chairman, and I look forward to the testimony of our witnesses.

[The prepared statement of Representative Stark appears in the Submissions for the Record on page 45. *New Yorker* article entitled Building Nations, Hendrik Hertzberg submitted by Representative Stark appears in Submissions for the Record on page 46.]

Representative Maloney. Thank you, Mr. Chairman, so very, very much.

Senator Bennett. I was going to Mr. Saxton.

Representative Saxton. She can go if she wants. That's okay.

Senator Bennett. All right. Mr. Saxton yields to you. So go ahead.

OPENING STATEMENT OF REPRESENTATIVE CAROLYN B. MALONEY

Representative Maloney. Thank you so much, Mr. Chairman, and Mr. Saxton.

At this point, I'm supposed to be at Financial Services Committee hearing in which I'm Ranking Member, but I feel that this is a tremendously important hearing and I ask permission to revise and extend my remarks and just briefly say that in this hearing, we will hear several approaches for setting the groundwork for reconstruction.

One issue that I believe should be a significant part of the discussion is debt relief.

As we have seen in post-war Germany, debt relief can be an essential tool in rebuilding a nation destroyed by war and humiliated by its leadership.

We have also seen in recent years that debt relief is an effective development tool that releases funds within a nation that can be used to address poverty and meet essential human needs.

The case for some debt cancellation is even more compelling in Iraq, given that much of the debt can be characterized as odious.

Odious debt is internationally recognized as debt that is taken on by a country for the personal benefit of corrupt leaders or for the oppression of a people.

Clearly, much of the Iraqi debt falls in this category.

To address the issue, this week I will introduce legislation in the House calling for debt relief from Iraq's international debts, including funds it owes the World Bank and IMF.

Who should pay debt that Sadaam owes? How can we ask the people of Iraq who lived in fear of Hussein's secret police to pay back the loans that supported these armed assassins?

You don't have to travel far outside of Baghdad to see a sprawling slum called Sadaam City that houses 2 million Shiite Muslims. The slum is overrun with garbage and children climb the mountain of refuse to look for scraps of food or things that could be traded for food or clothes.

In the face of this poverty, the Iraqi regime spent billions of loaned dollars on palaces and other luxuries. What better way to enhance our efforts at reconstruction and empower the people of Iraq than debt relief?

If Iraq is ever truly to be a peaceful and prosperous democracy, its citizens must be allowed to start anew. 50 years ago, 20 nations led by the U.S., England and France agreed to forgive half of Germany's pre- and post-war debt. The so-called London Agreement proved to be the

right course. Debt cancellation for Germany was a very important part of the Marshall Plan, which helped the country become a strong and prosperous democracy post-World War II.

This approach can aid Iraq as well.

In addition to odious and other debt that Iraq owes public and private world creditors, the IMF and World Bank are priority Iraqi creditors. When nations service their external debt, they will pay the IMF and World Bank first.

While estimates of Iraq's debt range from $100 billion to several hundred billion, the combined debt owed the IMF and World Bank is just over $150 million. These institutions have resources to relieve the debt, setting an important precedent for the rest of the world.

For this reason, I will be introducing the Iraqi Freedom From Debt Act, legislation to require the U.S. to negotiate in the IMF, World Bank, and other appropriate multi-lateral development institutions for the IMF and World Bank to relieve the debts owed by Iraq to these institutions.

Furthermore, this legislation includes a "Sense of Congress" that the President should urge France and Russia and all other public and private creditors to relieve the debts owed to them by Iraq.

By taking the lead on debt relief, we have an opportunity to do the right thing for Iraq's economy and to prove to the world that the major reason for war was to benefit the Iraqi people.

And I yield back the balance of my time and I thank you for this consideration and I would hope that you would consider looking at this legislation for the Senate.

[The prepared statement of Representative Maloney appears in the Submissions for the Record on page 49.]

Senator Bennett. Thank you very much. We appreciate your contribution and we will take a look at the legislation when it comes over.

Mr. Saxton?

OPENING STATEMENT OF REPRESENTATIVE JIM SAXTON, VICE CHAIRMAN

Representative Saxton. Thank you. It's a pleasure to join in welcoming the witnesses.

Before Ms. Maloney departs the room, I think her position and mine are fairly close on Iraqi debt. In fact, last week I introduced a bill which is H.R. 2338, which sounds very close to what you have just outlined and I'm going to speak a little bit more about that.

So I look forward to working with you.

Representative Maloney. I wish I could stay, but I must go.

Representative Saxton. That's okay. Mr. Chairman, during your opening statement, you referenced the development of a long-range strategy to promote Iraq's economy, which has been sinking for years under the rule of Sadaam Hussein.

I'd like to talk about at least one important piece of what could become that long-term strategy.

The economy in Iraq has for years been doing very poorly. Extensive ownership control and influence of business by the government, its officials, and political cronies undermined economic growth. Iraq's invasion of Kuwait resulted in economic sanctions and the Oil-For-Food Program.

And although the recent war has resulted in some economic damage, Iraq's economic situation today is quite similar in my opinion to the Eastern European countries after the collapse of the Soviet Union.

New institutions are needed that are compatible with a market economy and improved prospects for economic growth. The prospects for Iraq's economic recovery are clouded by an unsustainable debt burden that Ms. Maloney was just referring to.

One of the major challenges to improve the potential of the Iraqi economy is the heavy burden of foreign debt accumulated under the regime of Sadaam Hussein. The hated regime is gone, but the financial legacy should not continue to oppress the Iraqi people, undermining their economic potential.

Forgiving much of Iraq's foreign debt is the right thing to do. But foreign creditors may be hesitant if they anticipate an opportunity for a bail-out indirectly through the IMF or the World Bank.

A write-down of at least part of Iraq's debt would greatly improve Iraq's economic outlook.

Under legislation that I have recently introduced, Iraq's creditors would be encouraged to forgive much of Iraq's outstanding foreign debt rather than to wait for a potential bail-out from the IMF or the World Bank.

This legislation, of which this is a copy, would mandate that safeguards be in place to ensure that lending by these institutions could not be used to repay Iraq's creditors, thus encouraging a more timely write-down of some of Iraq's debt and protecting taxpayer money.

As I have pointed out many times before, the IMF should not be used as a bail-out agency, as this practice creates a potential for mis-use of IMF funds.

Taxpayer money should not be used to bail-out investors of high-risk ventures. There is a role for the IMF and the World Bank in Iraq, but it should be carefully defined to ensure that past mistakes are not repeated.

With adoption of appropriate institutional reforms and market-oriented economic policy, Iraq's people could look forward to a better future.

The IMF and the World Bank can be useful in this regard, but not if the money is to be just funneled through to Iraq's creditors.

Thank you, Mr. Chairman.

[The prepared statement, including H.R. 2338, of Representative Saxton appears in the Submissions for the Record on page 51.]

Senator Bennett. Thank you very much. We'll now go to our panel of witnesses, and I'm quite excited about the witnesses that have agreed to appear today.

I know you would all like to give us something of a seminar, and we would undoubtedly benefit therefrom. But if each witness takes 15 or 20 minutes, we'll be in some trouble time-wise. And we would hope to have some interaction with the witnesses.

Now our normal pattern is five minutes. Some of you may have a little more to say than that, and I'll be a little generous. But if you start tending towards ten minutes, why, I'll begin to tap the gavel and ask you to summarize if you can, so that we can get the kind of interaction that we would hope for from this panel.

Our panelists today are Mr. Basil Al-Rahim, who is of Iraqi heritage. I believe he was born in Iraq. He's an investment banker, founder of the Iraq Foundation.

Mr. Hernando de Soto of the Institute for Liberty and Democracy, a best-selling author and advisor to a wide range of governments.

Dr. David Ellerman. He is an economist, recently retired from the World Bank.

And Dr. Rachel Bronson, who is director of Middle East Studies from the Council on Foreign Relations.

So I think this gives us a wide spectrum of background and understanding and we look forward to hearing from you all.

Mr. Al-Rahim, we will begin with you.

OPENING STATEMENT OF MR. BASIL AL-RAHIM, FOUNDER AND BOARD MEMBER OF THE IRAQ FOUNDATION, MANAGING DIRECTOR OF MERCHANTBRIDGE

Mr. Al-Rahim. Mr. Chairman, thank you very much.

You asked me to speak on transforming the Iraqi economy. It's a huge subject. I'll try to summarize some salient points in five minutes or so.

I apologize that I will miss a lot of the details, obviously.

First, let me say that there are four points to my presentation.

One is that we need a full economic program and it cannot be a haphazard transformation of the economy. The program has to be well thought out, comprehensive, transparent, and elaborated to the public, both here and in Iraq.

I have called this program the Phoenix Plan because rehabilitating Iraq will be like rehabilitating an Olympic athlete that can compete, not rehabilitating a cripple that can, at best, just walk.

The second point is that oil alone is definitely not a panacea. While Iraq has huge reserves, these are underground and don't do the man on the street much good.

The third point is that the solution to transforming the Iraqi economy is empowering the private sector. There is no escaping this.

The fourth point is that the plan must be implemented by an independent commission of technocrats with the ability to fast-track the regulatory approvals necessary to underpin this plan.

Let us remember that Iraq has four very important resources. First is oil, which we all know about. Second, Iraq has water, two major rivers in an otherwise arid part of the world. Iraq has very fertile land and has achieved self-sufficiency in food production in the past, and can do so again.

Fourth, and most important, Iraq has a large technical professional labor force made up of engineers, doctors, lawyers, teachers, et cetera, and it has experienced a very severe brain drain which needs to be reversed.

The economic blueprint that I'm calling the Phoenix Plan is an economic model for Iraq, the region and the future. It will counter the regression that Iraq has gone into back into the 19th century and bring it back into the 21st.

By empowering the private sector and using oil revenue as a catalyst, I believe that this plan can be implemented.

It should have three phases -- an immediate phase, removing bottlenecks in the economy, a medium-term plan, five years, where we detail planned targets, such as production, industry, banking, health, education, with a target GDP per capita of $10,000. And it should have a long-term ten-year objective of a GDP per capita of $20,000, which is where Iraq should be had it grown normally during the last 20 or 30 years of the Baath regime.

The state should act as a facilitator and enabler. Monetary and fiscal policy have to be pro-active to support the plan.

Debt resolution is very important, as Mr. Saxton has mentioned. Debt has to be recognized in three categories -- bona-fide commercial debt, government debt, and war reparations.

Each one needs to be treated entirely separately and absolutely much of it must be forgiven.

The components of the plan fall into a number of sectors. Of course, the oil sectors is the major one. Big oil expertise and capital are definitely needed. However, the Iraqi private sector must be a partner in this exercise.

Though negotiations are difficult, they are between unequal partners. We must get the state out of the oil sector as the experience of the state in oil has been a bane to nations and never a boon.

There is the issue of whether Iraq should stay in OPEC or not, and that has to be thought through very carefully. Iraq has no interest to create price wars in order to obtain market share. But it cannot be tied to rigid allocations that no longer apply.

The downstream sector is also very important. But that also will require additional capital. The downstream sector is valuable not only in job creation, but also in improving the revenue-added value of exports.

The whole issue of privatization has to be explored. There are dangers and advantages to privatization. But this is the way to get what amounts to the majority of the productive assets of the country back into private hands.

There are many challenges, as to how do you value assets fairly at this time? How do you attract foreign investors? How do you achieve broad distribution? How do you avoid the problems that befell eastern Europe when people started out with a voucher and ended up with a bottle of vodka, and that was the extent of their participation in the economy.

Debt forgiveness and rescheduling, as I said, is critical. We see the three categories.

Commercial debt has to be renegotiated. Government debt has to be forgiven because it was extended to the old regime -- as Mrs. Maloney called it, the odious debt. And war reparations have to be

recognized because somebody did actually suffer at the end of this adventurism by Sadaam Hussein.

The plan proposes trading some of this debt for a point system that can be then used for concessions, licenses, contracts.

The point system itself would start having a market value and be traded between people who want to buy those points for use in Iraq on their own. Therefore, you don't eliminate the value of those points, but you shift them to the free market.

Attracting foreign direct investment, an aspect of the plan, is critical. And there are very many issues on this. One of the important issues is to avoid economic pillage of the country by foreign investment, which will definitely happen if we are not careful.

Restitution of private property has to be a part of that plan. And that has resulted from the 1963 nationalization and just continued through various waves of government.

Currency stabilization is critical. A new Iraqi dinar pegged to the dollar and the Euro has to be introduced.

The banking sector is very rudimentary. The banking sector is made up of two banks, two government-owned large banks and 18 small private banks.

This must be modernized, upgraded. Joint venture banks have to be attracted to help rebuild the banking sector, which is a critical part of any economy.

Finally, the component of the plan that we can look at is the capital markets themselves. There is something called the Baghdad Stock Exchange. It's been around for many decades. That has to be expanded, deepened and broadened. And that can be done by linking privatization with ESOPs, with IPOs, and with other forms of participation in the public market.

There are three other critical issues and I apologize if I am running over on the time.

First and foremost, critical to this plan is the employment and empowerment of the private sector. The private sector has been reduced to poverty subsistence over the past 20 years. The transition to a free market economy and full membership in WTO, which should be the objective of Iraq, cannot happen overnight because we need to protect the population to make sure not to disenfranchise them from the wealth of the nation.

Vocational training centers have to be set up so that 400,000 soldiers decommissioned from the army can be brought back in a productive manner into the labor force.

We have to avoid the problem of oligarches and cronyism that we've seen in other parts of the world. And these are already beginning to cluster around Iraq.

Vulture regional and international investors are looking very closely at Iraq and these have to be prevented.

Finally, while the WTO has to be the objective, the plan has to recognize how we move to that objective, step by step.

There has been much talk in the press about something called the Iraq Development Fund. We don't know what the mandate of that fund is. We don't know what the governance and oversight of that fund are. And I would suggest that the mandate should be synergistic with the overall plan.

The governance and oversight has to be transitioned to full local authority once a legitimate government is in place.

There are models that we can look at. The Alaska Fund has been mentioned as one model and some aspects of that fund are attractive, not all are relevant.

The Oil For Food Program has been a resounding failure, in my opinion, in the last number of years and should not be followed. But there's also something called the Iraqi Development Board which was set up in the 1950s, which has some very clear attractions because it was able to take part of the oil revenues away from the government budgets completely and use them only for development work. And that's a program that needs to be clearly examined.

We need to deregulate infrastructure, some parts of it fast, and get the states out of there. The fast parts can be transportation, telecom and media. Over the medium-term, the government should get out and deregulate power and water. And it should partially deregulate but stay partially involved in health care and education.

In closing, I would like to say, what is the role of the United States and other players in the transformation of the Iraqi economy?

It is critical that the United States does not abandon its leadership role in Iraq. Iraq needs a strong open-markets patron and partner with a shared vision for its transformation. It cannot become a beacon for the region without U.S. help.

G-8 countries do have a role and should be brought in because they can bring diverse values that can help rebuild the country.

The gulf cooperation countries, Iraq's neighbors, should be encouraged to supplement the limited financial and industrial absorption capacity of their own economies by participating in the Iraqi market.

And finally, in conclusion, I would like to say that the Phoenix Plan requires an independent technocratic commission with the ability to fast-track implementation and regulations.

A healthy economy in Iraq is a prerequisite for a stable democracy and both are mutually reinforcing. The domino effect can happen and we have to be careful which way it tips.

Empowering the private sector is the only solution. Albeit, important, oil is only one part of the equation.

The price of losing the peace is not limited to Iraq or even the region, and time is of the essence.

Thank you very much.

Senator Bennett. Thank you, sir. We appreciate that. Mr. de Soto?

[The prepared statement of Mr. Al-Rahim appears in the Submissions for the Record on page 54.]

OPENING STATEMENT OF MR. HERNANDO DE SOTO, PRESIDENT, INSTITUTE FOR LIBERTY AND DEMOCRACY

Mr. de Soto. Thank you very much, Mr. Chairman, first of all, I would like to tell you how much I appreciate your comments on the fact that so much is at stake in Iraq. All the eyes of the world are on Iraq. And, in effect, if there is not a successful transformation there, that will definitely bolster the arguments of all those people who are already marching on the streets against globalization, against the values of a free market society, and the possibility of creating capital.

And if you aren't able to do it in Iraq, the question then will be -- are all countries made for that kind of freedom? If they're not, obviously it can't even work, even if the foremost power of the world is involved.

So a lot is at stake.

And I think a very important comment was also made by Mr. Saxton, which is that the important thing here is not to repeat mistakes.

And that's why it's very useful to look at history and see where mistakes have been made.

One of the interesting things about listening to Mr. Al-Rahim, both in a conversation previous to this meeting and here, is that what he says about Iraq is well known and is absolutely true.

There is a large technical and professional class in Iraq, and there is an elite, like of course there was in Cuba and there was in my country and there was in Venezuela and there was in Egypt.

Now why did we get off the track 40 years ago, and I think that's important to remember?

We got off the track because the people who could actually participate in a capitalist society, were, nevertheless, an elite, a minority. And when there are minorities, when it's only 20 percent of the population, 30 percent or 15 or 5 percent of the population that is in an

elite position to benefit from a capitalist society, it usually becomes what I call mercantilism -- it becomes something that is politically unsustainable.

So if all it is about is restitution, in general, one must be very careful because what it could mean is restituting an elite. And the other people, feeling themselves on the outside, will then go for one of these isms, whether it's called socialism or whatever it is, to go for redistribution because that's the reason that though capitalism has been around for such a long time, it has failed in our countries.

It hasn't redistributed opportunities fast enough.

And that's really the history of the world -- in the United States, Japan, Germany, Switzerland, and France, capitalism came, but with large legal efforts to make sure that everybody could come inside the game.

In countries where there were elites that did not distribute these possibilities, whether it be Russia or any country that was part of the former Soviet Union, the system collapsed, and they will continue to collapse because they're not politically sustainable.

Nobody on the outside, as Marx said, will feel that they're participating. They will feel alienated. And that's how revolutions start, whether there's a Kremlin to organize them, whether Beijing is around to organize them, or whether they're not there.

However, we can learn from not only the bad experiences of history, but also the good experiences of history.

One of them, for example, is your own history in Japan, when the United States won the war against Japan and occupied Japan in 1945. What it did there that was good is useful to remember.

People sometimes forget what state Japan was in during the '30s and the '40s. For us Peruvians, of course, it's relatively easy because we had a president of Japanese origin from the year 1990 to the year 2000, President Fujimori, who was a member of one of the 1-1/2 million Japanese families who migrated to South America in the '30s and the '40s, especially to Peru and Brazil, which were open to Asian migration.

The reason the Fujimoris migrated to Peru, and the reason why the de Sotos did not migrate to Japan, was because our GNP per capita was higher than Japan's -- 20 percent higher in the case of Peru, 40 percent higher in the case of Brazil.

Now that President Fujimori has returned to Japan, he has found a Japan which is now ten times richer than any other Latin American country.

What did Japan do between 1945 and today to become ten times richer than us Latin Americans, who used to receive their migrants because they were poor?

The reply is that they created a capitalist system, but where everybody could participate. That required a plan. And that plan was originally set up by Americans working since 1942 in Honolulu to make sure that the feudal class did not recuperate all its privileges and that property rights were widespread.

As a matter of fact, they were already widespread, but at an extra legal level.

But the legal reforms that took place in Japan between 1946 and 1950 made sure that capitalism was a popular enterprise, the way it is today in the United States, instead of being an oligarchic enterprise, the way it is in most developing countries, and therefore, falters.

The ideas and virtues of your economy and political system have been around for more than 200 years and we've tried to imitate them.

One of the first things I think that should be done is to get the facts. What do you have to do to popularize a capitalist economy to make it democratic?

As you know, some of the work that we're doing in different countries, our think tank which you have so generously supported in the U.S. Congress, includes countries like Egypt, where we've been contracted by the government and the government has made public the numbers I'm going to give, therefore, I'm not breaking anybody's confidence.

Though I know that Egypt is not Iraq, Egypt is not very different from the other Asian and Latin American countries that we've been working in. We have found that in places like Egypt, the extra legal enterprises, small and medium enterprises, run by what are generally poor people, actually represent a large amount of assets.

The problem is their owners don't hold them within the law, and as a result, of course, their assets cannot become fungible or liquid. They cannot become capital.

But what we did find out is that the poor in Egypt own about $245 billion worth of assets only in small enterprises and land and buildings.

How much is $245 billion?

Well, it is 55 times the size of all foreign direct investment. In other words, a lot of the resources that Egypt and Iraq may need to get ahead are already within those countries. Their value is much higher than that of foreign direct investment.

Another interesting fact -- the $245 billion is 50 times greater than all World Bank loans given to Egypt.

So, no matter how much aid you give, public or private, the poor may already be holding their more, albeit, illegally. They can't really get

into the official market, the expanded market, and their assets cannot be traded in a way that they can be leveraged and actually create major wealth.

In the case of Mexico, for example -- and by the way, excuse me. One last point.

All the assets of the poor in Egypt are 30 times bigger than the Cairo Stock Exchange.

So it would be interesting to find out, in Iraq, in spite of all the turmoil and all the problems, already the poor have got a stake, and that stake, instead of being withdrawn, should be enhanced.

In the case of Mexico, which is another oil-producing country, it turns out that what the poor have, also outside the law, is about $315 billion worth of assets. And the interesting aspect of it is that, today, Mexico of course produces more oil than Iraq and has been doing so for over ten years.

These assets that belong to the poor are seven times higher than Mexico's known oil reserves.

So the mistake -- the important thing here that you said in your statement is that property rights are crucial. Who gets the property rights? How does the legal system recognize them or not?

Because, in the end, if people see that the law protects their rights and what they have today in assets, and allows them to leverage them, then, of course, the rule of law can come into place because I will understand the rule of law and the measure that protects whatever assets I have, whatever capital I have, no matter how incipient it is.

And the clue to all of that, of course, Mr. Chairman, is inclusion. There are exclusive capitalist systems, what Mr. Al-Rahim called oligarchies and cronyisms, and there are democratic and popular capitalism. And it's very important to ensure that now that the eyes of the world are on Iraq, that that's the kind of capitalism that you get.

[The prepared statement of Mr. de Soto appears in the Submissions for the Record on page 67.]

Senator Bennett. Thank you very much.

Dr. Ellerman?

OPENING STATEMENT OF DAVID P. ELLERMAN, PH.D., AUTHOR AND FORMER ECONOMIST AT THE WORLD BANK

Dr. Ellerman. Thank you, Mr. Chairman. I'm here to speak about some of the lessons learned from the transition economies of the former Soviet Union, in particular.

I think the short story is that the intervention of the international institutions of the World Bank, the Fund (IMF), western academics, the

economic profession in the former Soviet Union and the nation-building effort there was a disaster. It was a debacle.

The recently appointed head of the Council of Economic Advisers, Greg Mankiw, from Harvard, just published a piece on this and was a bit agnostic about assigning the blame. But he said, if in fact this shock therapy and the voucher privatization was wrong, then it was a blunder of historic proportions -- one of the biggest blunders in world history.

But he was a little soft on assigning responsibility because it involved a lot of his Harvard colleagues.

So the question is, what do we learn from that? What are the lessons that we can take away from that experience?

One has to go back to the sort of mentality of the intervention. It was one where it was after a revolution; socialism had failed. The west came in with sort of a cold warrior self-righteousness of let's wipe the slate clean of everything from the past. Let's try to start over. Let's try to create a new society, a heaven on earth.

This is something that conservatives know doesn't work. You can't do this overnight. The Jacobins tried this in the French Revolution. The Bolsheviks in the original Russian Revolution. And yet, the United States backed the “market Bolsheviks” that tried to do the shock therapy and tried to do the voucher privatization and created basically a form of chaos in these countries.

What people knew how to do was not supported. They felt helpless. They were disempowered. And in this chaos, the oligarchs and the criminal elements flooded in.

So one of the major lessons in this is to look at it from the point of view of the population. Are the population empowered or are they all tarred with the same brush as if all were stained from the past?

Many of the -- in Eastern Europe, particularly -- the exiles that came back, tried to say that everybody in the country should be disqualified from office, that everybody is communist and so forth. And this aggravates the chaos, makes it much worse.

And so one point here is there needs to be a line drawn so that the people above that line are suspect, but the people below that line, the professional class, the technical class, scientific engineers and so forth, are people that often had to join the party, the communist party in the case of Russia and eastern Europe, the Baath party in Iraq, in order to get the jobs.

If they didn't, then the nomenclature would have gotten the jobs.

So it was something that was done pragmatically. They're not ideologues, and they should be treated as technical people, professional people, and not with prejudice.

So that is certainly one of the lessons.

Secondly, because this is a time-consuming effort to try to make this sort of a transformation, the immediate thing is to try to get some sort of working order restored, not to say, well, we have to restart things only under a new premise.

So this means something like going back to what's the last time things worked. What's the last time that the ministries worked, the last time the industries worked, and try to restore some sort of an order, even though it would not be perfect.

And the thing not to do is, as was recommended to us in Russia, don't try to jump over the chasm in one great leap, that it's better to try to build a bridge over the chasm from the old to the new, even though one foot of that bridge always has to be on the old, and which is maybe distasteful.

But the thing to avoid is to aggravate this feeling of being totally disenfranchised, totally disabled, nothing works any more. Things didn't work well before, but at least I could tinker around and I could get things to work in a haphazard way. But now things don't work at all.

And this will feed into much greater chaos and extremism.

So I want to urge a real pragmatism there and getting away from this sort of self-righteousness of a conquering army that's going to disempower everybody there and try to set up a new regime overnight.

Let's be very pragmatic.

And also, we can talk about privatization and some of the lessons learned there. But certainly, this attempt at voucher privatization, to just try to wipe away everything from the past and start anew with equal rights, sort of like a primitive communism almost, didn't work, and that should not be even contemplated in the future.

There should be a large emphasis on restarting the enterprises that people see in everyday life, which is the small and medium-sized businesses, the retail businesses, the things that affect people's ordinary lives so that they get some sense that they're returning back to a state of normalcy.

And the overall mentality here, we're often told by the Russians that you treat us as if we were a conquered people. And the Iraqi people are in that position.

So I think that we have to be doubly careful in the whole projection of the American intervention there that they are not treated as the objects of benevolence, the objects of charity.

In some sense, the way to put this is to say that we should not give them aid in the sense of trying to do things for them, that we should try to put the tools in their hands and then let them rebuild their own

country as much on their own, than us to give out contracts and the like, which would, as it were, do it for them in a great show of American benevolence, which would only preserve them in this position of being powerless and humiliated.

And then one practical point I just wanted to raise which I think is very difficult to judge right now. But the Middle East is the only region of the world that doesn't have a regional development bank. There are development banks for all the other regions of the world.

For obvious political reasons, it's been hard to do that. But if in fact in the future we're looking for some means of extrication, then to have a regional bank that's a cooperative effort of the nations in the region, might as well be something to look at.

And finally, I want to just try to get you to look at the psychology of how this is viewed from the Iraqi people because I think they are in a very ambiguous position right now in their own psychology.

Do they want to make this occupation a success? Or do they not? They all want to rebuild their own country. But they're put in a position where if they cooperate with the occupying power, as in Germany and as in Japan, well, that was 55 years ago and we still have bases in Japan. We still have bases in Germany. And they didn't have oil.

So if you're an Iraqi looking at this situation and say, do I really want this to be a success and still 50 years from now have American bases in the country or not?

And so, the fundamental point has to be to somehow make that political switch so that they're not working to make the American occupation a success, they're working to rebuild their own country for themselves.

And that's very difficult. I can't emphasize enough that that's going to be fundamental to the success of this effort from the point of view of the Iraqi people.

Thank you.

[The prepared statement of Dr. David P. Ellerman appears in the Submissions for the Record on page 73.]

Senator Bennett. Thank you very much. Dr. Bronson?

OPENING STATEMENT OF RACHEL BRONSON, PH.D., OLIN SENIOR FELLOW AND DIRECTOR, MIDDLE EAST PROGRAMS, COUNCIL ON FOREIGN RELATIONS

Dr. Bronson. Mr. Chairman, Mr. Saxton, Mr. Stark, thank you very much for the invitation to speak with you today on transforming Iraq's economy.

I want to make four points. The transition in Iraq towards a successful economy and successful political situation will take time, it will be dangerous and will require our resolve, it will be expensive, but ultimately, it will be worth it.

I want to make sure that we don't leave this hearing thinking that the security situation that, Mr. Chairman, you highlighted by holding up the newspapers, is somehow distinct from the economic transformation of Iraq.

They are indeed linked. It is something that we have learned, case after case, particularly in the Balkans.

We need to focus on the security situation if we want all of our goals for the economic transformation of Iraq to succeed.

We must also remember that this is going to be very time consuming. Secretary of Defense Rumsfeld has pointed out that it took eight years for the United States to move from its period of revolution to a constitution.

In Germany, that experience took four years. And in Germany alone, it required $8 billion, in current dollars, between 1948 and 1952. Germany required a significant American and international security presence to help the Germans rebuild law and order in their society. And it took a lot of attention to the international context to help facilitate that outcome.

So we know from the experience in the United States, we know from the experience in Germany, we know from the experience of the '90s, this takes a long time. It requires international assistance. It requires serious attention to law and order.

I want to focus on law and order because it matters to this Committee, both because it will be very costly to the United States and the lack of attention has already set back Iraq's reconstruction.

Much of the looting and the chaos that we've seen in the streets has largely undone all of the good work military planners who carefully considered what to target and what not to target.

Areas that were originally kept off the target list, have largely been destroyed anyway by the looters and this will make everything more costly.

The lack of law and order also makes it harder for the Iraqis to go back to work. They are afraid to leave their homes because of what might happen to their families and their property.

We have to create a situation where they are more comfortable to go back to work.

Focusing on issues of law and order, goes to the heart of the difference between *The New York Times* and *The Washington Post* stories that the Chairman referred to.

The Washington Post stories are focusing on the slow building back of the basic law and order on the streets, very positive and the Administration can very much take credit for.

But the vacuum that was created in the weeks following the war has allowed Sadaam's security forces, loyalists, those in the Baath Party, to begin reconstituting. They are organized. They do not believe this war is over. And the Iraqi people will find it very difficult to work against them if they are not convinced that Sadaam and his sons are dead or that the security forces do not provide an organized opposition to the United States.

The average Iraqi is waiting to see who is going to win this, and right now for them, the jury is still out.

Law and order will be a very expensive proposition. Before the war, the Council on Foreign Relations, our task force, estimated that, at minimum, 75,000 troops would be needed to secure the peace and cost at least $15 billion a year.

We now know that figure is low. The Administration is on record as saying that 150,000 troops in Iraq are costing about $3 billion a month.

The longer chaos is allowed to reign, the more costly this will be and the more difficult this will be. That is why I want to be sure that we focus on the connection between law and order and economic reconstruction.

But even when we get to reconstruction, even if there had been a seamless transition from our authority back to the Iraqis, this still would have been expensive.

Iraq's reconstruction will not be self-financing. The oil industry is in dire straits.

Before the war, because of sanctions and poor political leadership in Iraq over the last decade plus, Iraq was losing about 100,000 barrels per day annually. We need to staunch the bleeding of Iraq's oil industry before we can even hope to get back to the levels that they were before 1990, 1991, or the heady predictions that were made before the war.

We must remember that before the war, Iraq was bringing in about $10 to $12 billion a year in oil. 70 percent of that was going to the humanitarian needs of the Iraqi people--food and medicine. $3 billion is required to go back into the oil industry just to keep it operating.

We estimated that the reconstruction of the oil facilities to get it back to the 3.2 million barrels per day that it was producing before the war could cost up to $5 billion.

To get its energy sector back up to where it was could cost as much as $20 billion. Iraq was a sophisticated society with a sophisticated infrastructure. It is not like repairing Afghanistan.

There are a number of other things that will be required and some of my fellow panelists, the witnesses here today, have made reference to them, and I will quickly go through them and then leave you.

First, there is a requirement to diversify Iraq's economy. Over 95 percent of its resources come from oil. This was not the case just a few decades ago. But relying on this sole commodity is bad for the Iraqi people and bad for the economy.

It also makes it very difficult to get to any sort of democratic future.

When the leadership owns the major resource, it doesn't depend on the people to participate. And so, we need to think about the transformation of its oil sector and its larger economy if we're trying to reach any different political outcome.

Restructuring Iraq's debt is going to be a massive undertaking and we need to show our own commitment to the process before those around the world are likely to forgive the debt.

And also, we have to support a stable, transparent political order. If we want investment to flow into Iraq or if we want to keep the Iraqi money at home, there has to be something to invest in.

This kind of political order will take time. If we move too quickly, the Balkans show us you get black markets, drug lords, and money-laundering.

The Administration was right to step away from the interim authority and trying to create one too early. But by bringing up the topic of an interim authority so soon after the fall of the Sadaam regime created unnecessary expectations.

The way forward is going to be very difficult in Iraq, but it is well worth doing. Iraq can be a model for the region. I receive calls from those around the region on a regular basis, from our dwindling number of supporters begging us to get this right.

Our supporters out there need a win that they can point to. And right now, their hopes are on Iraq. And I think we should make sure that their hopes are realized.

Thank you very much.

[The prepared statement of Dr. Rachel Bronson appears in the Submissions for the Record on page 78.]

Senator Bennett. Thank you. Thanks to all of you. I think you've given us the provocative insight that we had hoped for.

Now we have some members of the Committee who did not give opening statements. If you would like to stay and question, I will allow members of the Committee who did not give opening statements to question before the others do.

Do you want to take advantage of that?

Representative Hill. I'll take advantage of that.

Senator Bennett. Now, actually, having said that, Mr. Paul was here before you were. So I'd like to go in the order in which they arrived.

Mr. Paul, if you could do the first questioning. Or I'll let you two fight it out.

(Laughter.)

Representative Paul. I'll yield.

Representative Hill. Okay.

Senator Bennett. All right. Mr. Hill?

Representative Hill. Thank you, Mr. Chairman.

I don't know quite what to ask, to be honest with you. This problem -- and it is a problem -- of the state of the Iraqi people and what their future holds is obviously complicated.

I woke up this morning and went jogging with my friends. I knew where my meetings were going to be. I knew where the bathroom was. I knew that I had to go to my ATM machine and get some money.

None of that exists in Iraq.

First of all, when you talk about private property, how does that happen? How do people obtain this property? What mechanism is in place, what system is in place that can create private property rights for the people of Iraq?

Anybody?

Mr. de Soto. Well, I would say that one way of looking at it -- without knowing Iraq but knowing other developing countries and what happens -- is that, probably at this stage, after all the looting, the burning, the squatting that had taken place before the Baathist revolution, the adverse possession stakes, the creation of a large, small and medium enterprise situation, maybe a great popular part of Iraq, is similar to what California was like 150 years ago.

You had 800 mining jurisdictions that are being formed on the basis of squatting. Nobody really knew who owned what or where.

It took you 30 to 40 years to put that all together because most of the property was obtained in an extra legal fashion.

So regardless of what existed before, whatever legal system existed before, you have to think of creating a new legal system to accept all the new stake-holders within the system.

And that's why what I insisted upon before was how important it is to get an inventory of what has actually happened on the ground in Iraq over the last 30 years to find out where there are claims, where there are conflicting claims, to make sure whatever property system is redesigned and put into place, actually serves the majority of people's interests. Otherwise, you won't get the constituency to have a stable economy.

Very different than in the situation, for example, of Germany, because the property rights system or the legal system that defined property rights had already been defined in the 19th century.

So the occupation really didn't involve getting into the thick of that because there was a consensus on property.

In most developing countries, that consensus does not exist. What you will probably find are widespread markets and anarchy regarding the law and therefore, the need to re-adapt whatever law exists to reality.

Representative Hill. Well, I'll go back to something that Dr. Bronson had said, that the people are waiting to see who is going to emerge in leadership positions.

It seems to me that none of that can happen until there is some certainty in Iraq. Is that true or not true? And how long will that take?

What has to be done? What should we be doing?

Mr. de Soto. Well, the first thing that you did in Japan, which was very interesting, or rather, that the Japanese did under Gen. MacArthur's sponsorship, is have an inventory done of what the situation was all about.

It took about two years to put the inventory together.

In other words, underneath the feudal class of Japan there were people who held property, but they were not within the law, or their stakes were not recognized by the law.

It took two years to actually find out who owned what. It's the whole experience you had in all of the west of the United States. There were people that went around and tried to calculate how many trees were felled in Wyoming to create a cabin and then find out those that would be calculated improvements and create a property law that was adequate to it.

Your own Congress passed 32 pre-emption acts, the purpose of which was to violate an existing common law that no longer responded to the situation on the ground.

The first thing you did was an inventory, state by state, and then you put the law together.

Mr. Al-Rahim. Mr. Hill, if I can just jump in.

Iraq today is a lawless country. But this was a country that was well on its way to industrialization in the '50s.

There were extensive land records. There were extensive property-holdings, property rights. And we are not talking about complete breakdown of the system.

Mr. de Soto may be right that we need to take some inventory. But we're not talking about starting from scratch and a complete chaotic situation.

Yes, there has been looting. Yes, there has been squatting. But this comes only in the last couple of months.

The problem of restitution and property rights is really going a little bit further back in terms of what's happened since the nationalization and the waves of socialism that took over.

I don't think it's an insurmountable problem. It's one of the problems and there's a lot of problems that need to be resolved.

Representative Hill. Mr. Chairman, I see that my red light is on. But thank you for the opportunity to ask a few questions.

Senator Bennett. Mr. Paul?

Representative Paul. Thank you, Mr. Chairman.

In the Chairman's opening statement, he mentioned that we could be looking at Iraq either as being half full or half empty.

I tend to think that it probably is half empty, and I sort of identify a lot with Dr. Bronson's concerns about what's going on over there.

The other concern I have is it sounds like we're in the business of nation-building, which is something that a lot of us talked about in the past as not being a very good idea. And it's still very popular for me in my district in Texas to say that we shouldn't be in the business of nation-building, and that usually gets a pretty good response.

So I have a great deal of concern about the cost of this and how well it's going. And I appreciate the testimony of all of you because I think it gives us a lot of insight.

But I do see tremendous problems with this instilling property rights in this country. I think it's so much different than in Japan and Germany. These populations were so much more homogenous compared to what we have in Iraq.

So this tends to make me less pessimistic.

I'm just wondering if any of you have given any consideration to the restoration of private property rights on the original owners and the developers of the oil wells because, in Cuba, we're concerned about that all the time, even though it's been 40 or 50 years. There are still people who have claims about property ownership in Cuba.

And I'm just wondering -- I don't hear much talk about that and it seems like maybe we should give that some consideration.

Also, on the debt elimination, I think it's an academic question. They're not going to pay the debt. And it's always interested me that when we talk about debt repudiation, we always have to talk about an appropriation.

So if they owe us money and we can't pay it, why don't we just write it off the books? It makes me suspect that somebody is going to get paid off that probably really doesn't deserve it, or they should get in line.

So I'm always concerned about appropriating money for debt forgiveness.

But if we did have the restoration or the implementation of private property markets, I think the idea of capital is irrelevant. The money will go there. That's all there is to it. We don't need huge appropriations.

So it is more important that we have the right rules set up, of course, by those who are there.

But my question is a political question in many ways because it seems like it's going to be so difficult. To me it seems like we have three countries over there. Iraq was an artificial country. It was designed by Europeans. It was designed after World War I.

And is it conceivable that even with our occupation and our 150,000 troops, more troops now than we needed to liberate Baghdad. We need more troops and all these billions of dollars.

My question is, how long do you think we can do this? How long will the American people tolerate it? And is it achievable?

Maybe, in reality, if we knew right now it was unachievable because, already, we've had Rumsfeld say that, oh, well, we can't have an outright election because if it goes the wrong way -- and the majority would not vote what we want.

So it may well be that the only solution is going to be probably three different countries there. And maybe we're fighting a losing battle.

And I just wonder if you have some comments, especially how long do you think we can go without having success? I think Mr. de Soto said, we'd better have success and we need to have success.

So I'd like to hear your comments.

Dr. Bronson. Mr. Paul, thank you.

In terms of answering your constituency on nation-building, there's a counter-intuitive aspect to it that makes understandable why everyone is so confused.

The more committed and more present you are up front, the faster we can pull our men and women home. And the reason for that is Iraqis are looking to go back to work. They're looking to go on the streets. They need an authority there and a heavy American presence.

As long as chaos reigns, everything takes longer. Everything is more expensive.

The Administration's recognition that more military police, and more soldiers, were needed is actually a good sign. It bodes well that we may actually be able to pull out earlier because if you allow the sort of chaos because we don't have enough people and commitment there, it makes everything much harder.

Will Iraq break down into three distinct territories?

If we don't stay committed, there is the possibility of it. But I think if you look back to original meetings that the opposition was having in the early 1990s, there was a preference, for instance, in the Kurdish community, their first preference was to have their own independent state. They also recognized that that was unlikely to happen.

The second best alternative is participation in a full and free Iraq.

We need to keep them focused on that, that their first preference is unattainable, but their second preference is truly attainable. And that gets back to some of these economic and political issues we're talking about.

We need to think through how the oil from the north and the south goes back to the central government and then resources go back to the provinces.

As long as you can get that kind of system going where the money goes in and goes back out, you will keep Iraq whole.

But if there is no organization committed to that reality, people will start fighting over keeping that oil in the north and the south and that will be a problem for Iraq.

Representative Paul. You assume that it is crucial that it be kept whole.

Is that correct?

Dr. Bronson. That's right, I do. If it is not kept whole, all of the fears of the critics of this war will come to pass. And that is because if it starts fracturing, you will certainly see Turkey moving in because they will be worried about an independent Kurdistan on its border.

You will see the Iranians much more active than we are seeing now if there is going to be some sort of independent Shia state in the south.

It is crucial to the neighborhood and the United States that Iraq remains whole, but that's good news. There is a shared interest. And it's a second preference of the Iraqis themselves which gives us a good basis for moving forward.

We have to have a centralized authority with some independent autonomy in the provinces that allows them to benefit from that kind of vision.

Representative Paul. Thank you. Other comments?

Mr. de Soto. Yes. The only comment or reference to the issue of property claims, what has happened in many developing countries, practically in all developing countries, and many former Soviet Union countries, over the last 34 years, is that, in some cases, because of natural migrations, in other cases, because dictatorships, also need some kind of legitimacy and they go around redistributing land and redistributing property.

And they've done that and probably, Sadaam Hussein has had to do the whole thing to create legitimacy for his own regime. It is very surprising what you see once the dictator is out.

The first thing that you will have seen is that one person may have owned just one estate. Today, there are 15,000 people living on that estate.

And so, what do you do? Do you just restitute to where you were before? Do you give California back to 15 Mexican families or do you keep the 3 million people with big guns on them?

What do you do?

So what I'm saying that I think is important, and it gives you an idea of the time, is you have to make an inventory of what has happened.

I don't think that even Sadaam Hussein actually knows what was happening underneath his nose. It's a whole social process that's been going into place.

Take Egypt: The logical thing of course would seem restitution. There were rent controls. Property was redistributed at the time of the revolution.

The Egyptians want to welcome investment again. But they find out that it's impossible because the families that will be benefitted are a small minority and those that would be dislodged are the large majority that you need for the rule of law to come into place.

The plan for how you go about this cannot be designed until you have an inventory of who is where, who owns what, and what are the different claims within the land: Then you can start creating the kind of law that peacefully settles those conflicts and allows you to bring in stability.

And that's what you in the U.S. Congress did in your own country 32 times before you created the Homestead Act. There's always people who believe that the Homestead Act started the process whereby a large majority of Americans who had squatted now had a right to property.

It was actually the last of your acts. You had 32 going before, including when President Washington had a third of his farms invaded by what he called the Banditti.

But, first of all, you had to take stock of what had gone on. And in many cases in Iraq, I don't think that anybody really knows what's going on. And the process is going to take time.

Senator Bennett. Mr. English?

Representative English. Thank you very much, Mr. Chairman.

Starting with Mr. De Soto, given the natural potential of Iraq's mineral wealth, what options would you suggest to maximize the potential of the petroleum industry since we've brought it up, in order to spur investment and growth in the overall economy in Iraq?

And at the same time, how do you utilize that asset without leading to an imbalanced economy, such as you have in Venezuela, where petroleum had become pretty much the only driver in the economy.

Recognizing Mr. Al-Rahim's point that there has been an industrial base in Iraq, how do you use petroleum and at the same time, encourage a movement towards a strong mixed economy?

Mr. de Soto. Thank you for your question, but I'm afraid I know very little about the use of petroleum. I know about successful experiments, your own in the United States in Alaska bringing a wide amount of people to participate in the wealth.

I know what, for example, the Bolivians have done in terms of their gas industry and how they've made all citizens stake-holders. But I know very little about the headlines, sir.

Representative English. Mr. Al-Rahim, would you like to take a whack at that?

Mr. Al-Rahim. Mr. English, thank you.

Obviously, the oil sector is very important. But I see it as important only as a catalyst for the economy.

Just to put it in context, Iraq has 113 billion of proven reserves. The last count or assessment of those reserves is 20 years old.

Assume that if a new assessment is made, the reserves may be as high as three times that.

Putting reserves in the ground, proven reserves, 1-1/2 times those of Saudi Arabia and, in fact, the largest in the world.

However, reserves in the ground is something and oil revenues is something else.

As Dr. Bronson said, it takes about $5 billion to rehabilitate the industry and it will take probably another $30 billion to get up to six million barrels a day, which at that time will give about $35 billion of revenue a year.

You have to get the private sector to participate actively. The oil sector is not just about upstream production, of course. It's a whole world by itself as an industry. And it is a sector that will involve not just oil field services, midstream activities and downstream activities.

The way to do it is to invite foreign participation with special protection clauses because for a country the size of Iraq which today has a GDP of $25 to $35 billion, to negotiate with a company like Exxon-Mobil, which an annual turn-over five times that, this is not a level playing field by any stretch of the imagination.

But you need to attract the major players.

You also need to implement things that you will implement in the privatization program, which is local participation, employee share ownership programs, IPOs, so as to really get that broad wealth distribution out into the country.

But there are a number of methods that you can do this.

Representative English. Very good. Dr. Ellerman, I've been interested in the thrust of your remarks. And you have argued, as I understand it, for an incrementalist approach to building the Iraqi economy based on your experience in Eastern Europe.

Can you offer us what you think would be probably the best example of how that incrementalist approach has been successful in eastern and central Europe since the fall of the Berlin Wall?

Dr. Ellerman. Well, the general idea is to try to take what I would call the de facto property rights that people have -- their capabilities, their skills, what they know how to do, how they know to operate industry, how they know to make things, and so forth -- and try to then, as it were, shrinkwrap the ownership and control structure around that.

So the people who have to show up to work every day to make the thing work, they have to cooperate together, so they have the control in their hands to make it work.

It's very practical, don't try to set up great long chains of authority that has taken us decades and a century to work right.

Try to have something more like local ownership. And the ESOP, the employee stock ownership plan that's been mentioned, is an excellent way to do that.

Representative English. And which country in central and eastern Europe do you feel has most successfully undertaken that approach?

Dr. Ellerman. Well, all the countries use very mixed programs. You've got to almost go program by program.

But in Poland, for example, what they call privatization by liquidation program was a type of lease buy-out. And ESOP is like a lease buy-out, where the ownership goes to the management and the workers in it, but they have to pay it off over time.

So it's like a lease purchase arrangement where the company itself pays it off.

Something like that also happened in Hungary which was very successful. The country that I used to live in and worked in was Slovenia, and it was certainly very successful in Slovenia.

So something like that is a way of empowering people, a way of giving them a stake fairly quickly.

And for your question and for the previous question, this idea of us getting into nation-building, what I keep trying to say is we have to get the reconstruction effort conceptualized as their building their own nation, not as us doing nation-building to them.

And something like the ESOP, something like these programs where people can formalize their property rights and feel that they can then know what they can do, they're empowered to do it, and they can go further, that's the key thing to make it their effort and not ours.

Representative English. Thank you. And I need to head to the House floor, so I thank you, Mr. Chairman.

Senator Bennett. Thank you, sir.

Senator Sununu?

Senator Sununu. Thank you, Mr. Chairman.

Mr. Al-Rahim, you mentioned an organization established in the '50s or '60s you mentioned as a good model, a good structure for coordinating and maybe identifying prospective investment.

What is it about that model or that structure that works from an economic perspective or a cultural perspective?

Mr. Al-Rahim. Mr. Sununu, that was a development board set up in the '50s, independent of the government, staffed by technocrats, where, at the time, this was prior to the revolution, the government decided to allocate 70 percent of oil revenues to this board. And the board also had the benefit of a number of prominent international economists invited to it.

The attraction of that is that the revenues that came to this board were kept out of government budgets, so that people couldn't spill over and start using that money. And that money was really earmarked just purely for development work.

I just mentioned it as one example of something that could be interesting and could work.

Senator Sununu. Was the fact that it kept a large portion of the oil revenues out of the hands of government part of the reason for its success?

Mr. Al-Rahim. Yes, I would say that. You didn't have government overspending spilling onto its budgets because they were kept in completely separate boxes, as it were.

Senator Sununu. Mr. de Soto, you mentioned both Alaska and Bolivia. I'm familiar I think with the structure of the Alaskan trust.

What is the structure of the equity or revenue distribution of the Bolivian gas industry and to what degree has it been successful? And to what degree could it be a model for Iraq?

Mr. de Soto. I'm sorry, I wouldn't have a reply to that question.

Senator Sununu. I'm sorry. You did mention it, though, didn't you?

Mr. de Soto. I mentioned that I knew of the successful experiments, but I know no more than that.

Senator Sununu. Okay. Could you talk a little bit more about the experience with the inventory in Egypt? What's the scope of that effort? Is it nation-wide? Is it a pilot program?

How long has it been going on? When is it expected to be completed?

Mr. de Soto. It's a nation-wide exercise that the Egyptian government is carrying out and in which we are the technical support.

It began when there was a consciousness that may be a great part of their economy was an underground economy or an extra-legal economy. And we were brought in to quantify it, to try to find it to categorize it.

And the results were surprising. That's why I was saying that it would be interesting to also carry out that kind of an exercise in Iraq.

So far, we've reached the point in July that there is a plan now to carry out the reforms. There were two stages. One was the inventory, and then once you had the inventory --

Senator Sununu. The inventory is complete?

Mr. de Soto. The inventory is as complete as you can get it now.

And as I repeat, the interesting thing about the inventory that we found to be the extra-legal economy is actually the largest part of the

economy. It is bigger than their oil reserves. It is bigger than all the other industries, as I said before. It's 30 times the size of their own stock exchange and it's about 70 times the size of all the bilateral aid they've received ever.

So these are also like oil resources. They're huge human capital and asset resources that are simply not put within the legal system and therefore, they cannot be mortgaged and therefore they cannot be leveraged and they cannot create the wealth that they can in the United States.

Senator Sununu. Has the package of reforms been proposed and adopted?

Mr. de Soto. The package of reforms is being proposed now. Discussions for adoption will start taking place beginning the month of September.

Senator Sununu. To what extent are you concerned that there may be political forces that work counter to the potential economic benefits here?

We'll leave Egypt out of the discussion. It may or may not fall into this category.

But one might argue that, in some societies, the governing forces have some interest in people holding their land or being allowed to use their land, or being allowed to operate their business to a certain extent at the pleasure of the government.

Property rights that are protected empower individuals, make them less dependent on the whims or the political dispositions of the leadership.

So, to a certain extent, might you be concerned, whether it's an Iraq or anywhere else where these kinds of land reforms are undertaken that the governing forces don't really have an interest in establishing clear, quantifiable and protected individual rights?

Mr. de Soto. Well, sir, in the case of the countries we've been called to, including Egypt, and where we have been paid to carry out these studies, various millions of dollars, I supposed that we've been called in because people have been interested in the reforms.

What always spurs along the reforms is, as I repeat, the inventory.

If as a result of the inventory, for example, in the case of Egypt, as we were talking about, one finds out that 88 percent of businesses function outside the law, and 92 –

Senator Sununu. Leaving Egypt out. In the other case histories that you've looked at, I guess, have you seen this phenomenon or is it just a concern that hasn't been seen in the case studies?

Have you seen the phenomenon where sort of political forces desire to have a system where ownership rights are vague or not easily enforced?

Mr. de Soto. I was coming to that, sir. The thing is that when you are aware, if you're a politician, that in fact you are not governing 88 percent of the people who work in the private sector because they work outside your system, that you really don't know who is living where in 90 percent of your land, you have every political interest for that to change.

I have not found resistance for change coming from somebody saying, well, it's all right. 90 percent can live outside the law. I don't really care if they have property rights or not, because the consequences of not having property rights are not only the fact that you don't get development because credit, investment, is all based on property rights. But it's also that you can't even police these places.

You don't know where Osama bin Laden is hiding because you don't have a system of addresses. You cannot participate in the global economy.

Where the danger comes from, sir, is the following one. It has a lot to do with ideology and with cultural myths.

So let me tell you a little bit just how we work there in two minutes and why we're optimistic about the fact that these changes will be adopted.

For example, Egypt has been trying to pass a mortgage law for many years now and has been unable to because the forces of resistance say, how are you going to have a system whereby people are able to use their homes or their chattel, their goods, their animals, their equipment, to guarantee to secure a credit?

Because credit only functions where people have something to lose. That's what basically creates the trusts and that's what allows you also to enforce noncompliance. And therefore, the idea is you can't impose this on poor people. Therefore, you will not be able to pass a mortgage system.

That has been stopping them for years and years now, if not decades.

What we do is try and look at the dark side of the economy because it actually provides the answers in an unideological form.

So we start asking, for example, how do people in this large extra-legal sector of Egypt, but we could also be talking about Mexico, survive on a day-to-day basis within their small enterprises? Do they get credit?

And the reply is they do.

And the question then is, how is it guaranteed? And it's guaranteed by an instrument which, as a matter of fact, the Arabic culture created 700 years ago, which is the check system. I think it even comes from an Arabic word.

There were Arab checks circulating all the way up to Shanghai 700 years ago.

So the way it would work, sir, is that if you asked me for $12,000, I will say that the guarantee will constitute a check written against your account for that amount.

Excuse me -- not for that amount, but it will be drawn blank.

If you do not pay, I can get you in a month or two in jail because in all these countries, there is debtors jail. And a great amount of the prisoners are people who haven't paid their debts.

So what we do are the statistics, which are the following one:

How many people today of Egyptians actually -- there's no mortgage law, mind you -- but how many people to pay off the debt and not to go to jail, have had to sell their houses?

One point five percent.

How many people have gone to jail and anyhow had to sell their houses?

Another 4.5 percent.

How many people have had to flee the region which they live because they've not been able to pay their debts?

20 percent, and therefore, have had to sell their houses as well.

And then we put it next to, for example, U.S. statistics, that say -- the Fannie Mae statistics that I've got, at least -- only 0.3 percent of Americans lose their homes as a result of the mortgage system.

So then the argument becomes the following one:

Not having a mortgage system violates human rights and property rights much more than having a mortgage system. But the examples that you bring are not the examples from how good this works in the United States because then you get a Samuel Huntington telling you that there's something in the Anglo-Saxon gene that makes it work in the states.

What you do is you compare it to the credit system that already exists for most Egyptians, and in this case, for most Iraqis, show how badly it works, how many more little old ladies actually lose their homes under the lack of the rule of law, and that's how you get your rule of law passed.

Senator Sununu. Thank you. Thank you, Mr. Chairman.

Senator Bennett. Thank you very much.

Let me try to summarize some of this, at least for me.

Mr. Al-Rahim, I'm interested to have you say that, along with oil, Iraq has water and fertile land, as well as a technological and professionally capable labor force.

From the papers, we hear about the oil and we hear about the labor force. But we don't hear that Iraq has fertile land and water.

It would seem to me that that would be an enormously valuable resource in the Middle East, to have fertile land and the water to cultivate it, and that Iraq could not only become self-sufficient in food production for its own population, but begin to export food, if not in the Middle East, down into Africa or other places where food is desperately needed.

What are the chances in your view of that becoming a viable economic opportunity for the Iraqis separate and apart from the oil?

Mr. Al-Rahim. Mr. Bennett, I think it's a very viable opportunity within the context of the plan because Iraq has been self-sufficient in the past.

It doesn't even have to go as far as Africa to export because a lot of the region, for example, the Gulf states, are net importers of food, anyway. So it can just export to its own neighbors.

There are two major rivers in Iraq, the Tigris and the Euphrates. They are large rivers, and provided they don't get subjected to severe damming in the north, in Turkey and Syria, and there's been threats of that, those rivers can support a very large agricultural industry in Iraq.

That industry has not had any modernization brought to it like any other industry for the past 20 years for the reasons we all know.

So I don't think it would be very difficult to reactivate it.

I put in my paper which is now in the record, at some point, we need to re-establish a system of collective co-ops just to have the economies of scale that you need in modern agricultural operations.

But I don't think that that is going to be, again, something that is impossible or every difficult to achieve. I think it's a very viable component of the overall plan.

Senator Bennett. And Mr. de Soto, that clearly would go to the question once again of property rights, of who owns the land that could then be turned into agricultural activity.

Maybe we don't want small farms. Maybe we want more of an agri-business kind of approach. But that means the people who are in the way of an agri-business acquisition of large tracts of land would have to be compensated for moving. They'd have to sell their land the way the

small farmer in America sells his land to Archer-Daniels-Midland or whoever, and takes that money and goes off to the city and becomes an entrepreneur in some other kind of circumstance.

So it seems to me that there's a connection between that opportunity. And we should focus on that because we have become so pre-occupied with oil, we should recognize that there are many other opportunities.

I want to come back to you, Dr. Bronson, and a point which was your fourth one which I think has been lost in some of the specifics that we've gotten tied up with here.

When you say this is timely, dangerous, expensive and worth it. And I think we should focus on the worth it.

This is, after all, the Joint Economic Committee. We want to talk about the impact economically on the United States. And let me just philosophize for a minute and then get your reactions, any of you.

Dr. Ellerman, you're in this field as well.

Looking back at the examples that have been talked about here, Japan and Germany at the end of the Second World War, those were enormously expensive operations on the part of the United States of America.

Japan at least dealt with a very, very different culture. The Germans were used to a western style of entrepreneurial activity, the kind that would be compatible with their neighbors. The Japanese were a feudal empire.

Dr. Ellerman, MacArthur kept a bridge on the other side of the chasm. He did not eliminate the emperor. Indeed, when Japan was being bombed, they did not bomb the Imperial palace.

I remember as a businessman driving through the streets of Tokyo with my manager when I owned a business in Japan and looking at all of the buildings, some of which were modern skyscrapers and some of which looked much more traditional.

And I asked, how many of these buildings were built since the Second World War? And the answer was all of them, because every building in Tokyo, with the exception of the Imperial Palace and the Diechi Insurance Company was destroyed by the American bombs.

So MacArthur very wisely kept at least one toe on the old bridge by keeping the emperor in place, but eliminated the system of slavery.

We don't realize that the Japanese had slaves in the 20th century, in the feudal system that they had. The woman who managed my business in Japan was part of the team -- she was a translator for the American occupation forces and was part of the team that went into those areas and told these people, you're now going to have property rights. Told these people, you are no longer slaves.

How long did it take MacArthur to make that transition? Seven years? Five years? Something along that line.

How much did it cost us? I don't know. But it was huge. Dr. Bronson, it was obviously worth it.

Japan, even with its deflation and problems now, is still the second largest national economy in the world, a major trading partner. Most Americans love Japanese cars, if nothing else.

We have created an island of stability and prosperity in a part of the world that desperately needed it. And we have the opportunity to do the same thing here -- create an island of stability and prosperity, property rights, proper kinds of capitalism -- I remember the Russian ambassador saying to me when we were talking about some of their problems, we've had plenty of shock, but damn little therapy.

And you're right. We did not do the Russian thing right, and we need to learn from that and do the Iraqi thing properly.

Am I just a rosy-glasses idealist here who's looking at the best thing? Or is this in fact an enormously valuable opportunity, how difficult and dangerous and expensive and timely it may be?

Is Dr. Bronson really right, everybody, that this is overwhelmingly worth all of the challenge that we need to put into it, and the advantages -- being very selfish -- the advantages to America, to our children, in terms of what could happen out of this, could be as great as the advantages that came to us because our parents did what they did in Japan and Germany at the end of the Second World War?

That's a philosophical question, but I think that's what we really want to deal with in this hearing as a whole.

Responses? Mr. de Soto?

Mr. de Soto. Well, one reply to your question is, regardless of whether that's the way it should have taken place or not taken place, your occupation of Iraq, the fact is that it's done and you're there.

(Laughter.)

And now that you're there, it is an opportunity, not only because, Senator Bennett, it's an island of stability, but it's because these islands of stability are very contagious.

Senator Bennett. Yes.

Mr. de Soto. In the case of China, you didn't get it at the first throw with Chung Kai Chek. But by leaving behind the Brits two ports, with market economies and freedom, at least economic freedom, Singapore and Hong Kong, by allowing widespread property in all of these places, including Japan, what is today South Korea and what is today Taiwan, after 40 years, now the larger continent is also following.

It's very contagious. If it fails, that's also contagious as well. When, for example, you've done similar things in Latin America, but only for the purposes of just occupation, then withdrawing, that has not been contagious at all.

So I do believe, Senator Bennett, that what happens in Iraq since the eyes of the world are upon you, is going to very much determine the future of the whole Middle East, and will bolster the arguments that markets and freedom are something that transcends cultures or, on the contrary, will strengthen the hands of all of those people who say, we're not all built for those kinds of systems.

Senator Bennett. Dr. Bronson?

Dr. Bronson. For the record, let me say that I think that Dr. Bronson is right.

(Laughter.)

It is very important that we get Iraq right. Iraq is in the heart of the Middle East. With all the troubles and problems that we've had since certainly September 11th, with the region, but even before, getting Iraq right is going to be very important to the security of the United States.

We need to remember that, historically, Iraq has played a major role in Middle Eastern and inter-Arab politics. Economically, it has been an engine for the region. And culturally, we often forget this, the universities and the religious establishments of Iraq have shaped the thinking of hundreds of thousands in the region.

This is why many were nervous about us going into Iraq, but this is why it is so essential that we do get it right, because the eyes of the world are on us.

Think about the challenges we're facing in the Balkans, the black markets, the drug lords, all of the problems. Multiply that for Iraq in the region of the Middle East.

It will be catastrophic.

But getting it wrong, as I said in my statement, I have people calling me, begging for us to get this right. Our supporters need a win in this region and we are there -- one of my colleagues has made the point, we are occupiers. We might as well be good occupiers.

There is a lot to be done, but it is do-able and possible. We have to stay committed to it, though. If we don't, it all falls apart.

Senator Bennett. Yes. Getting it wrong -- go to Haiti and see what happens when we come in. It turned out we replaced a brutal dictator, much beloved of American conservatives, with a brutal dictator, much beloved of American liberals. And left. And the people of Haiti are worse off than they were before.

Mr. Al-Rahim, you had a comment.

Mr. Al-Rahim. Mr. Chairman, I have to tell you that I agree, not just fully with Dr. Bronson, but even more than she imagines because Iraq is so geo-politically important. And I'm not talking just about the benefits to the Iraqis.

This country made such a fuss about going into Iraq. The trumpet of changing the face of the region. There's a serious commitment to the world, not just Iraq, that was made about America's intentions, American abilities, and their visions of the future of this whole planet.

I think to get Iraq wrong, if nothing else, is egg on the face of this nation for the next 20, 30 years.

It's not like eastern Europe. When the wall fell down, everybody looked around and said, we won, turned their back and walked away. The western Europeans had to come in because they had to worry about primarily migration problems.

So they stepped in very quickly.

Today, if America does not get Iraq right and Iraq will start the domino effect. The domino effect will start from Iraq under all circumstances. The real question is which way is that domino going to tip?

And if it tips in the wrong way, don't forget Iraq's neighbors are Iran, Turkey, Saudi Arabia, Syria -- Israel is not very far down the road.

It's a volatile region. And if it tips the wrong way, everybody's going to feel it. We're not just talking about the Middle East any more.

And so, I think that's an added incentive of what you just very clearly and eloquently mentioned, that in Japan, you created an island of stability, of growth, of prosperity, as an example, because the tiger nations that eventually emerged in Southeast Asia really followed the example of Japan. That was closer to them.

And you can see that same thing happening again.

I can tell you, it's no secret -- much of the Middle East is still living in the 14th and 15th century, whether it's politically, whether it's systems of ownership, whether it's a feudal mentality, et cetera, et cetera. And that has to change.

The only question is, will that change happen violently and in the wrong direction, or can it happen peacefully by seeing the right example.

And that's one thing that we should all be concerned about.

Senator Bennett. I don't think there's any question but that we are in it for the long haul. We have to stay in it for the long haul. We have to do everything that we possibly can to get it right.

And at the risk of speaking out of school, but the Democrats have all gone --

(Laughter.)

I was at the White House yesterday. And at least based on the President's attitude and comments and general posture, this President is determined to stay however long it takes, spend whatever amount it costs, to see to it that we get it right.

And he is determined that we will not turn and leave, and we will not abandon that which we have begun. I think he understands, Mr. Al-Rahim, exactly what you're saying, that the domino can fall either way. And if it falls the wrong way, that will be a permanent stain on his presidency that George W. Bush is not willing to accept.

So, based on the conversations that we had at the White House yesterday, I think the President would agree with the consensus that has emerged from this panel.

Mr. Paul, do you have any final comments of your own? You've been very faithful all the way through here.

Representative Paul. I have a very brief question, if I may. I would once again like to direct it towards Dr. Bronson, since she's always right.

(Laughter.)

But we're talking about long and costly. Would you be willing to give us an estimate because we have to do some of the budgeting around here, how many troops will we have in Iraq in five years from now?

Dr. Bronson. I think the level of 150,000, where we are now, will be necessary not just for a matter of weeks, but months.

And then the numbers will start to drop after a year or so. But you're not down to this sort of golden number of 30,000 very quickly. It is going to take time and numbers.

To the extent to which we can work with our partners and allies who have constabulary forces and paramilitary forces, the exact kinds of forces that you need, our numbers can drop, because they will both supplement our numbers, but they also have the exact expertise that is needed.

And so, therefore, you can have fewer.

But to the extent to which we have to do this alone, we will be required to stay in there with those numbers because we don't really have that expertise. We have been resistant to nation-build and therefore, haven't built the kinds of forces and troops, security services, that you need.

I don't know the exact number, but I think the notion that we cannot go down below 75,000 probably for a few years. We don't get to that number of 30,000 three to five years, maybe even longer.

Representative Paul. Thank you.

Senator Bennett. Thank you all very much. This has been a most enlightening panel.

The Committee is adjourned.

(Whereupon, at 11:22 a.m., the hearing was adjourned.)

SUBMISSIONS FOR THE RECORD

PREPARED STATEMENT OF SENATOR ROBERT F. BENNETT, CHAIRMAN

Good morning and welcome to today's hearing. Amidst the cacophony of voices in this town talking about our actions in Iraq, let us humbly add our own. Our intent with today's hearing is to push the focus of the debate away from the short-term management of Baghdad and toward the implementation of policies that can ensure a long and prosperous free-market economy in the cradle of civilization.

To be sure, everyone in this room realizes that the current environment in Iraq is frustrating for many of its citizens and needs to be improved upon soon. However, there is little value in debating here how to get the Baghdad electric grid functioning or the resumption of garbage pickup in the country. Able men and women are dedicating themselves to this problem as we speak, under the careful scrutiny of other congressional committees and the ever-watchful gaze of the press.

However, we should not focus on the present to the exclusion of the future, which I submit we are in danger of doing.

Today we ask a fundamental question: what practices and reforms need to be underway in the next two years to ensure a prosperous Iraq in the future?

The only exception to this myopia has been the debate over how to develop and use Iraq's vast oil reserves, and thus far I am not encouraged by its tenor. Various pundits have suggested that the rebuilding of Iraq is as elementary as making a modest investment in oil industry infrastructure and using the proceeds to "pay" for the reconstruction of the economy. This overly-simplistic notion of "letting the oil wealth pay for it" borders on *naiveté.*

Oil wealth, economists tell us, has been more of a curse than a blessing for countries. I suggest with tongue only partly in cheek that the best thing that could happen for the Iraqi economy might be to suspend the production of oil for the next decade. Failing that, we need to think long and hard about how to ensure that natural resource wealth in Iraq is developed efficiently and invested prudently. I trust that our witnesses will address this issue in their testimonies today.

The plight of dealing with Iraq's oil wealth illustrates the essential conundrum of putting a decrepit economy on the path to

prosperity. There is no one magical formula that we can employ nor one model we can point to in this task. The United States has a mixed record in the endeavor of rebuilding economies. While we succeeded admirably after World War II in transforming the Japanese and German economies into vibrant and productive markets, our efforts in assisting the former Soviet economies were less than successful. A half-hearted attempt to assist Haiti in the 1990s can be called little else other than an abject failure.

From the missteps in the 1990s economists have learned a number of lessons, the first of which being that it is not enough to mouth the words "free markets" upon entering a country and leave it at that. We now know that formal institutions need to be in place so that property rights are recognized. While a government's role in the market needs to be limited to ensure prosperity, a government must also guarantee the rule of law and efficiently collect the revenues necessary to provide the basic services expected of all governments, such as police protection and transportation infrastructure. It is also beneficial to have an entrepreneurial class in place with the knowledge of what it takes to compete in a free market.

The goal should be to reform Iraq as a beacon for market democracy in the Middle East. Every Arab country possesses some version of the corrosive, quasi-socialistic economies that have failed to materially improve living standards for nigh on two generations.

A prosperous Iraq would give lie to the dubious proposition that Western oppression, combined with geographic circumscriptions and cultural idiosyncrasies, make capitalism and its attendant prosperity untenable. History is not yet over in the Middle East; if we want market democracy to vie with radical theocracies for the hearts and minds of its denizens we need to present them with a model that works in their neighborhood.

I am pleased to have a panel of esteemed witnesses to discuss the nuts and bolts of transforming the Iraqi economy. Our panelists today are Mr. Basil al-Rahim, an investment banker and founder of the Iraq Foundation, Mr. Hernando de Soto of the Institute for Liberty and Democracy, Dr. David Ellerman, an economist recently retired from the World Bank, and Dr. Rachel Bronson, Director of Middle-East Studies from the Council on Foreign Relations. To our witnesses today we say welcome; we look forward to hearing your testimony.

PREPARED STATEMENT OF REPRESENTATIVE PETE STARK, RANKING MINORITY MEMBER

Thank you, Chairman Bennett. I would like to commend you for holding this hearing on "Transforming Iraq's Economy." It's an important topic, and an important responsibility that President Bush has put on the shoulders of American taxpayers—or maybe I should say debt-holders, since this Administration doesn't believe in taxes. It is clear, instead, that the Bush Administration prefers the easy route of arguing that taxes are an unnecessary burden rather than accepting that taxes are a necessary means to meeting important responsibilities.

As I was thinking about this hearing, I was reminded of an interesting piece in the latest *New Yorker*. The author, Hendrik Hertzberg, observed that in many ways Iraq right now is a conservative's paradise, with limited government, limited regulation, limited gun control, and so forth. I would say, in addition, that if the theories underlying President Bush's economic policies are correct, Iraq should be poised for a robust economic recovery, since there is no meaningful government and no tax burden.

I suspect that this is not the testimony we will hear from our witnesses today. In fact, Iraq's economy and civil society are a mess. And we have a long and expensive reconstruction ahead of us. Should this outcome have been a surprise? Of course not. Should the Administration have put as much time and effort into preparing for the inevitable problems we would face in postwar Iraq as they did into developing an elaborate P.R. campaign to justify the war? Of course. But that is not what happened, and now we have to pick up the pieces.

I am sure we will hear some creative ideas from the economists at this hearing, but I hope they won't try to lull us into thinking that the transformation of Iraq's economy will be a cakewalk, and that all we need to do is set up the right conditions for the free market to flourish. The American public deserves honest answers about the task that lies before us so that we can make wise choices. The Bush Administration does not have a very good record of looking down the road and telling the public about the future consequences of its policies. If that doesn't change soon, we will be having a hearing on "Reconstructing the American Economy."

Thank you Mr. Chairman and I look forward to the testimony of our witnesses.

The New Yorker
June 9, 2003

SECTION: THE TALK OF THE TOWN; Comment; Pg. 39

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HEADLINE: BUILDING NATIONS

BYLINE: Hendrik Hertzberg

BODY:
The other day, the *Times* quoted one of that ever-helpful breed, a "senior administration official," as expressing surprise at the horrendous condition of Iraq's "infrastructure," even before the destruction brought about by the war and its aftermath. "From the outside it looked like Baghdad was a city that works," the senior official said. "It isn't."

The quintessential city that works (or, at least, has a cleverly cultivated reputation for being the city that works) is, of course, Chicago. The ward heelers and aldermen of that city understand (or, at least, are celebrated in song and story for understanding) that political power flows not from the barrel of a gun, and not even, necessarily, from the ballot box (whose contents can change in the counting), but from the ability to fix potholes. Garbage that gets collected, buses and trains that take people places, cops that whack bad guys upside the head, taps that yield water when you turn them, lights that go on when you flip the switch, all lubricated by taxes and a bit of honest graft-these are what keep streets calm, voters pacified, and righteous "reformers" out of City Hall.

By Chicago standards, Baghdad, along with almost all the rest of Iraq, is a catastrophe. For that matter, conditions are disastrous even by the looser standards of places like Beirut, Bogota, and Bombay. Reports from the scene are in general agreement on the essentials. Iraq is well rid of the murderous regime of Saddam Hussein. But the blithe assumptions of the Iraq war's Pentagon architects-that a grateful Iraqi nation, with a little help from American know-how and Iraqi oil cash, would quickly pick itself up, dust itself off, and start all over again-are as shattered as the buildings that used to house Saddam's favorite

restaurants. In Baghdad, and in many other Iraqi cities and towns, civic society has degenerated into a Hobbesian state of nature. Despite the heroic efforts of a scattered minority of midlevel Iraqi civil servants, the services that make urban life viable are functioning, at best, erratically. More often, they do not function at all. "In the most palpable of ways, the American promise of a new Iraq is floundering on the inability of the American occupiers to provide basic services," the *Times's* Neela Banerjee reported a few days ago. (Perhaps with an eye to educating her White House readers, she added that Baghdad is "about the size of metropolitan Houston.") Telephones are dead. Electricity and running water work, if at all, for only a few hours a day. Because the water pumps are hobbled by power outages, raw sewage is pouring into the Tigris River and is leaking into the fresh-water system, spreading disease and making the city stink. Hospitals that are secure enough to remain open overflow with patients, but they are short of food, medical supplies, and personnel. (Only a fifth of prewar health staffs are showing up for work.) Worst of all is the pervasive, well-founded fear of crime. Armed thugs rule the streets, especially in the pitch-black nights. "Amid such privations," Banerjee writes, "one of the few things that thrives now in Baghdad, at least, is a deepening distrust and anger toward the United States."

It's tempting to suggest that the Bush Administration is failing to provide Iraq with functioning, efficient, reliable public services because it doesn't *believe* in functioning, efficient, reliable public services-doesn't believe that they should exist, and doesn't really believe that they can exist. The reigning ideologues in Washington-not only in the White House but also in the Republican congressional leadership, in the faction that dominates the Supreme Court, and in the conservative press and think tanks-believe in free markets, individual initiative, and private schools and private charity as substitutes for public provision. They believe that the armed individual citizen is the ultimate guarantor of public safety. They do not, at bottom, believe that society, through the mechanisms of democratic government, has a moral obligation to provide care for the sick, food for the hungry, shelter for the homeless, and education for all; and to the extent that they tolerate such activities they do so grudgingly, out of political necessity. They believe that the private sector is sovereign, and that taxes are a species of theft. To paraphrase Proudhon, *les impots, c'est le vol.*

In a way, Iraq has become a theme park of conservative policy nostrums. There are no burdensome government regulations. Health

and safety inspectors and environmental busybodies are nowhere to be seen. The Ministry of Finance, Iraq's equivalent of the Internal Revenue Service, is a scorched ruin. Museums and other cultural institutions, having been largely emptied of their contents, no longer have much use for public subsidies. Gun control is being kept within reasonable limits. (Although the occupying authorities are trying to discourage possession of heavy munitions, AK-47s and other assault weapons-guns of the type whose manufacture Tom DeLay and most of the House Republicans plan to re-legalize back home-have been given a pass.) And, in the absence of welfare programs and other free-lunch giveaways, faith-based initiatives are flourishing. The faith in question may be Iranian-style militant Shiism, but at least it's fundamentalist.

The Bush Administration no longer flaunts its contempt for nation-building abroad, but it remains resolutely hostile to nation-building at home. Its domestic policy consists almost solely of a never-ending campaign to reduce the taxes of the very rich. Not all of this largesse will be paid for by loading debt onto future generations. Some of it is being paid for right now, by cuts in public services-cuts that outweigh the spare-change breaks for less affluent families which the Administration, in selling its successive tax elixirs, has had to include in order to suppress the electorate's gag reflex. The pain is especially acute at the state level, where net federal help is in decline. States are cancelling school construction, truncating the academic year, increasing class sizes, and eliminating preschool and after-school programs. Health benefits are being slashed, and a million people will likely lose coverage altogether. In many states, even cops are getting laid off.

As it happens,these are the very kinds of public services that America's proconsuls are promising to bring to Iraq. Of course, being nice to Iraq does not necessarily require the United States to be nice to itself. Nor does denying medicine to kids in Texas require denying it to kids in Baghdad. The connection is more karmic than causal. But it's also political. Whatever one may think of the global democratic-imperial ambitions of the present Administration, they cannot long coexist with the combination of narrow greed and public neglect it thinks sufficient for what it is pleased to call the homeland. At some point-the sooner the better-a critical mass of Americans will notice.

LOAD-DATE: June 9, 2003

PREPARED STATEMENT OF REPRESENTATIVE CAROLYN B. MALONEY

I thank the Chairman and Ranking Member for calling this hearing on the post-war rebuilding of Iraq and its economy. In the aftermath of war, the immediate problems of restoring order and basic infrastructure for the people of Iraq have proven daunting. It seems that every morning the newspapers carry demoralizing stories of the latest attacks on American troops and of growing resentment of U.S. forces by the people. Given this atmosphere in the country it is particularly important for Congress to focus on ways that we can boost the Iraqi economy so the people can see that the U.S. action will have a substantial long-lasting positive impact on their daily lives.

In this hearing, we will hear several approaches for setting the groundwork for reconstruction of the country. One issue that I believe should be a significant part of the discussion is debt relief. As we saw in post-war Germany, debt relief can be an essential tool in rebuilding a nation destroyed by war and humiliated by its leadership. We have also seen in recent years that debt relief is an effective development tool that releases funds within a nation that can be used to address poverty and meet essential human needs.

The case for some debt cancellation is even more compelling in Iraq given that much of the debt can be characterized as odious. Odious debt is internationally recognized as debt that is taken on by a country for the personal benefit of corrupt leaders or for the oppression of a people. Clearly much of the Iraqi debt falls in this category. To address this issue, this week I will introduce legislation in the House calling for debt relief from Iraq's odious debt and relief from the debt Iraq owes the World Bank and IMF.

Who should pay debt that Saddam owes? The dictator who incurred the debts or those he oppressed and brutalized? How can we ask the people of Iraq who lived in fear of Hussein's secret police to pay back the loans that supported these armed assassins?

You don't have to travel far outside of Baghdad to see a sprawling slum called Saddam City that houses two million Shiite Muslims. The slum is over-run with garbage and children climb the mountains of refuse to look for scraps or things that can be traded for food or clothes. In the face of this poverty, the Iraqi regime spent billions of loaned dollars on palaces and other luxuries.

What better way to enhance our efforts at reconstruction and empower the people of Iraq than debt relief? If Iraq is ever truly to be a peaceful and prosperous democracy, its citizens must be allowed to start anew.

Fifty years ago, twenty nations, led by the U.S., England and France, agreed to forgive half of Germany's pre- and post-war debt and to renegotiate the remaining debt at favorable interest rates. The so-called "London Agreement" proved to be the right course, providing a much needed economic and spiritual boost to a country ravaged and humiliated by years of war and defeat. Debt cancellation for Germany was a significant part of the Marshall Plan which helped the country become a strong and prosperous democracy post-World War II. This approach can aid Iraq as well.

In addition to odious and other debt that Iraq owes public and private world creditors, the IMF and World Bank are priority Iraqi creditors. When nations service their external debt they will pay the IMF and the World Bank first- and at any cost. Thus it should be our priority to call on the IMF and the World Bank to relieve Iraq's debt, freeing the people of Iraq from the obligation to pay down debts that we accrued by dictatorial regimes.

While estimates of Iraq's debt range from one hundred billion to several hundred billion, the combined debt owed the IMF and World Bank is just over $150 million. These institutions have the resources to relieve this debt, setting an important precedent for the rest of the world.

For this reason, I am introducing the Iraqi Freedom from Debt Act. This bill will require the U.S. to negotiate in the IMF, World Bank and other appropriate multilateral development institutions for the IMF and World Bank to relieve the debts owed by Iraq to these institutions. Furthermore, this legislation includes a sense of Congress that the President should urge France and Russia and all other public and private creditors to relieve the debts owed to them by Iraq.

By taking the lead on debt relief we have an opportunity to do the right thing for the Iraqi economy and to prove to the world that the major reason for war was to benefit the Iraqi people.

I thank the Chairman and I yield back the balance of my time.

PREPARED STATEMENT OF REPRESENTATIVE JIM SAXTON, VICE CHAIRMAN

It is a pleasure to join in welcoming the witnesses before us today. The economic reconstruction of Iraq poses many policy questions that merit the attention of this Committee.

Iraq's economy had been shrinking for years under the rule of Saddam Hussein. Extensive ownership, control, and influence of business by the government, its officials, and political cronies undermined economic growth. Iraq's invasion of Kuwait resulted in economic sanctions and the oil-for food program. Although the recent war has resulted in some economic damage, Iraq's economic situation today is similar to that of the Eastern European countries after the collapse of the Soviet Union. New institutions are needed that are compatible with a market economy and improved prospects for economic growth.

The prospects for Iraq's economic recovery are clouded by an unsustainable debt burden. One of the major challenges to improving the potential of the Iraqi economy is the heavy burden of foreign debt accumulated under the regime of Saddam Hussein. The hated regime is gone, but its financial legacy should not continue to oppress the Iraqi people, undermining their economic potential.

Forgiving much of Iraq's foreign debt is the right thing to do, but foreign creditors may be hesitant if they anticipate an opportunity for a bailout indirectly through the International Monetary Fund (IMF) or World Bank. A write-down of at least part of Iraq's debt would greatly improve Iraq's economic outlook. Under legislation I have recently introduced, Iraq's creditors would be encouraged to forgive much of Iraq's outstanding foreign debt, rather than wait for a potential bailout from the International Monetary Fund (IMF) or World Bank. This legislation would mandate that safeguards be in place to ensure that lending by these institutions could not be used to repay Iraq's creditors, thus encouraging a more timely write-down of some of Iraq's debt and protecting taxpayer money.

As I have pointed out many times before, the IMF should not be used as a bailout agency, as this practice creates a potential for misuse of IMF funds. Taxpayer money should not be used to bail out investors in high-risk ventures. There is a role for the IMF and World Bank in Iraq, but it should be carefully defined to ensure that past mistakes are not repeated. With adoption of appropriate institutional reforms and market-oriented economic policies, Iraq's people could look forward to a better future.

108TH CONGRESS
1ST SESSION

H. R. 2338

To prevent loans for Iraq from the International Monetary Fund or the International Bank for Reconstruction and Development from being used to pay off Iraq's creditors.

IN THE HOUSE OF REPRESENTATIVES

JUNE 4, 2003

Mr. SAXTON introduced the following bill; which was referred to the Committee on Financial Services

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A BILL

To prevent loans for Iraq from the International Monetary Fund or the International Bank for Reconstruction and Development from being used to pay off Iraq's creditors.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. PREVENTION OF LOANS FROM IRAQ FROM THE**
4 **INTERNATIONAL MONETARY FUND OR THE**
5 **INTERNATIONAL BANK FOR RECONSTRUC-**
6 **TION AND DEVELOPMENT FROM BEING USED**
7 **TO PAY OFF IRAQ'S CREDITORS.**

8 The Bretton Woods Agreements Act (22 U.S.C. 286–
9 286oo) is amended by adding at the end the following:

1 "SEC. 64. PREVENTION OF INTERNATIONAL MONETARY
2 FUND LOANS FOR IRAQ FROM BEING USED
3 TO PAY OFF IRAQ'S CREDITORS.

4 "The Secretary of the Treasury shall instruct the
5 United States Executive Director at the Fund and at the
6 Bank to use the voice, vote, and influence of the United
7 States to oppose the making of a loan by the Fund or
8 the Bank, respectively, to the government of Iraq unless
9 the Secretary of the Treasury determines that there are
10 sufficient safeguards in place to prevent the loan proceeds
11 from being used to reimburse persons or governments
12 holding debt arising from credit extended to the govern-
13 ment of Iraq, and outstanding as of the date of the enact-
14 ment of this section, for any losses with respect to the
15 debt.".

PREPARED STATEMENT OF MR. BASIL AL-RAHIM, FOUNDER AND BOARD MEMBER OF THE IRAQ FOUNDATION, MANAGING DIRECTOR OF MERCHANTBRIDGE

I. Intro

Good morning Senators, Congressmen, ladies and gentlemen. First let me thank you for inviting me to speak on this important topic. "Transforming the Iraqi Economy".

The subject is important not only because the fate of a nation and its people located in a supremely geo-strategic and volatile region is at stake, but also because the prestige of this country and its leaders (both administrative and legislative) will be judged in the present and for many years by the outcome and face of the new Iraq.

My career has been spent in commercial and investment banking in the Middle East, the United States and Europe. My sources are publicly available information, what little research that I could get my hands on, interaction with Iraqis both within the country and from the exile community and of course my personal experience and preferences. I have not tried to get the most precise numbers because I do not believe they are available from any definitive source at this time.

While I will attempt to cover a very broad area in my testimony I cannot possibly do it justice in the brief time available. The subject is too large simply because so many things need to be done, but that is also the advantage. We are starting from scratch with a nation anxious to get on with it and in possession of the means. If the program is successful it will be akin to the rehabilitation of an Olympic athlete who can compete again, not a cripple who at best will just walk.

To start with I would like to add two important provisos to this presentation. First, that Transforming the Iraqi Economy requires a pre-requisite of civil security; i.e. an efficient police force to maintain basic law and order, plus eventually an army potentially built on the Swiss model of an effective defence force. Second that the economic transformation will be far more achievable if it is led by an independent body, staffed by qualified technocrats combining certain functions of the ministries of Finance, Economy, Trade and Planning, with ability not just to develop and oversee the various programs but

also and critically, the ability to fast-track approval of the regulatory framework necessary for the success of such programs.

II. Resources

There are four major resources available to the country that can be immediately recognized:

a. Oil: The last reliable estimate of proven reserves dates back over 20 years and put such reserves at113 billion barrels. This is from a limited number of fields and wells where exploration work has been carried out. More recent and informed guesstimates put the reserves at three times this number and this does not take into account gas reserves. If this is accurate Iraq's reserves are 1.5 times those of Saudi Arabia and represent a significant portion of world reserves. The other very important fact is that Iraqi oil is one of the cheapest in the world in terms of production costs at about the $1 per barrel.

b. Water: Iraq has two major rivers running through it. Assuming historic water rights are respected and these rivers are not subjected to extensive dams in the north this resource is critical in a generally arid part of the world.

c. Fertile Land: In combination with the water, the country can easily achieve self-sufficiency in agricultural products and livestock. Indeed Iraq can again become a net exporter of farm produce given the right circumstances.

d. People: Lastly and perhaps most important the country possesses a large professional and technically competent labour force (doctors, engineers, lawyers, etc.). While this body of people may have gotten rusted over the past 10 years and has certainly been subject to a severe 'brain drain' these factors can both be quickly rectified. It is worth noting that the country had already started its industrialization program as early as the 1950's but hit the progressive calamities of nationalization, Baathism, two decades of war and sanctions. The professional and mercantile classes within the country are eager to update their skills and many of those abroad, the majority of whom are successful in Western countries, are ready to return to help rebuild the country in the right environment.

One of the most critical issues is the ability to quickly address the problem of high unemployment rendered more severe since the de-commissioning of the army. This is an energetic and skilled young labour force that can become a main engine for growth.

III. Economic Blueprint: The Phoenix Plan

Over the past 23 years Iraq has slipped back into the 19th century while the rest of the world has moved on to the 21st. Examples of this economic regression abound, one needs to only look at per capita GDP, telephone penetration rates, internet access or any other plethora of indicators. It is imperative to develop a well thought out and comprehensive economic model for Iraq in which all the parts fit and work together in a synergistic manner.

We must immediately acknowledge two very important factors; first, that no economic rejuvenation and vitalization can happen without empowering the Iraqi private sector, therefore the role of the State has to be that of a facilitator and enabler to create the framework for a new economy. Second, that oil revenues alone are insufficient to lift the economy; the oil sector itself requiring significant investment, and therefore oil revenues are only a catalyst and not a panacea for the solution

The Plan will be implemented in three phases:

A short-term plan outlining immediate actions that can help to kick-start the economy, remove bottlenecks, clarify the regulatory environment, encourage the return of exile skills and attract foreign direct investment.

A medium-term five-year plan detailing expectations for each sector of the economy has to be clearly spelled out setting forth production levels, capacity, consumption and penetration rates as well as health coverage and education. Target GDP per capita should be about $10,000 (in 1979 it was about $7,140) enabling a phasing-in of open markets.

A long-term ten-year plan with per-capita GDP objectives of about $20,000 must be targeted, with a deregulated economy and full access to WTO.

Fiscal policy and monetary policy have to be designed to act in a supportive manner to achieve the desired objectives of the plan in a pro-active not a re-active manner.

Outstanding debt has to be broken down into its three categories, bona-fide commercial debt, government debt incurred by the Baath regime, and war reparations resulting from Saddam's adventurism. Each category has to be resolved in the corresponding manner.

IV. Components of the Phoenix Plan

A number of sectors have to be specifically addressed in the plan and are set out below. Due to the scope of this testimony only the most critical aspects of each are elaborated. Countless other details are important and their omission is not intended to downplay them but rather an admission of the complexity of each and the need for specialist experts. However, the following are the over-riding issues:

A. The Oil Sector:

The conventional wisdom holds that Iraq's rejuvenation program will be largely taken care of by the country's abundant reserves. While reserves may be plentiful, oil in the ground means nothing in the circumstances. Prior to the recent war Iraq produced 2.8 mbpd, with annual revenues of about $17 billion (about one or two month's turn-over for General Electric or Exxon-Mobil). It is estimated that up to $5 billion will be needed to restore this production capacity in the short term and up to $30 billion will be needed over the next five years to produce 6.0 mbpd. At that production level (in five or so years) and using the Shell Oil long-term projections for prices at $15 per barrel Iraq's revenues could be about $35 billion at the time. Given the overall needs and condition of the country and the size of the population it becomes very quickly clear that oil alone is not the solution.

Evidently Big Oil expertise and capital is necessary. Production Sharing Agreements may be appropriate but how those are structured and worded is critical. Experience has shown that oil in the hands of governments is a bane not a boon; however abdicating ownership to foreign interests under any circumstances is unthinkable. The Iraqi private sector itself must be encouraged to become a player and there are a number of methods of achieving this. Negotiating on a level playing field is not easy given the size of the respective negotiators (i.e. Iraq or Iraqi's vs. the oil majors). It is imperative that any agreements keep majority control in the hands of local ownership and fair and equitable exit clauses (put and call options) are available to keep both sides honest and working in the best long-term interest of the economy. While such clauses may not be standard and are novel in this

context, they are not unusual in other transactions and can be easily adapted for the purpose.

The matter of whether Iraq should stay in OPEC or not has also been debated. It is obviously not in the country's interest to trigger a price war to achieve a pyrrhic victory. By the same token current quota allocations no longer have relevance in light of current needs and circumstances. A new formula has to be agreed that helps maintain market stability for consumers and viability for producers.

Finally Iraq should move quickly into the downstream sector, which in itself will require additional capital. This will not only benefit the economy directly through expansion and employment but also improve the added value of oil sales. In order to do this, agreements need to be put in place with end-user countries that receive some advantage for opening up their markets and removing trade barriers in advance of full WTO entry by Iraq.

B. Privatisation

It should be recognized that the Baath State, through inherited nationalisation and progressive expropriation, owned about 80% of the productive economic assets of the country. This, of course, must be brought back into the private sector. However, it is easier said than done since after all, this not only represents the wealth of the nation but arguably also the forfeited economic value of a population short-changed for the past three decades by the Baath State and reduced to living on rations. An economic programme must therefore be careful not to be accused of handing the economy over or selling assets too cheaply to a handful of oligarchs and foreign investors as the average Iraqi citizen does not have the means to participate in such programmes. The two problems, that of broad distribution of the wealth (assets) and 'fair' valuation must be solved simultaneously and quickly to get the economy firing on all cylinders and in a long-term socially and politically acceptable manner.

First, addressing fair valuation the problem is:

i) The current condition of the assets is seriously degraded, true both for machinery and equipment that is out of date or poorly maintained (i.e. for hard asset companies), as well as market share that has been lost or is weak (i.e. for service companies);

ii) Country risk as assessed by the major rating agencies will be near the bottom of the ratings;

iii) There is significant competition from a number of

countries in the world all vying to attract privatisation money making it very much of a buyers market – witness the failure of both the Egyptian effort over the past six years and the more recent failure of the Saudi gas initiative.

Given the above factors fair valuation means that today 'auctions' will not do the job! Better to develop a programme that values assets progressively over the next few years using a set of pre-agreed benchmarks; e.g. EBITDA, Gross Sales or market share etc. This would give the buyer the assurance of the acquisition through an executed purchase and Sale Agreement, while giving the seller (the government) part of the cash price today and part at a later date when the full value of the asset is more properly measurable. Such Agreements can also incorporate Put and Call options between the parties that further ensure a "fairness" to both sides.

Second, as regards the broad distribution of the assets it is important to learn the lessons of Eastern Europe to avoid the economic disenfranchisement of the lower economic classes (essentially the overwhelming majority of the population in Iraq today) and prevent the emergence of a handful of oligarchs. This can be accomplished both through an extensive system of ESOPs and Trusts. For example, at every privatisation full vesting of any ESOP shares would be gradual, for example start paying dividend but delay conveying ownership (and thus the ability to sell) until full value was better reflected by actual performance and understood by the stakeholder. Alternatively, shares to be distributed to the population may be held by a specially created fund e.g. in the case of capital-intensive industries with small employee numbers. The Fund can then administer the assets until such time as value is realisable and it can find an equitable or attractive distribution strategy not only to the direct employees but also perhaps to a wider base of beneficiaries (e.g. regional or geographic within certain proscribed guidelines).

A. Debt Forgiveness & Re-Scheduling

An important feature of the economic plan is clear and final resolution of the debt issue as it impacts almost all aspects of the program. New lenders need to know what other creditors are owed before extending new facilities. Investors need to understand the solvency status of the country, the local government must properly budget to meet its obligations and individuals must achieve a level of confidence before they start investing or saving.

Bona-fide commercial debt should be re-scheduled in conjunction with the Paris Club. Government debt extended by the old supporters of the Saddam regime must be totally forgiven for obvious reasons. War reparations incurred as a result of Saddam's adventurism must not be allowed to become an albatross around the neck of future generations. Part of such forgiveness can be traded for a points program that the old creditors would receive; these points can then be used (redeemed) to enhance bids for licenses, contracts, concessions or other agreements. As the value of such points becomes recognized a separate market in these points will develop internationally (e.g. amongst the oil companies) thereby creating value to the original holders of these points.

B. Foreign Direct Investment

Funds need to be attracted from a variety of foreign sources, government, private, multi-national and multi-lateral; both commercial profit-motivated and charitable aid-related. If the economic plan is structured correctly the need for aid should be minimal and is better allocated to other countries in serious need. Already foreign investors are lining up at the gates of the Iraqi economy armed with know-how and capital. A proper regulatory framework and a clear path to open markets must be elaborated to encourage the making of such investments in the country. The conventional wisdom is unanimous in its view that if the Iraqi economic experiment is successful, it will result in a major economic boom that can spill over into the whole region.

However by the same token it is critical to avoid economic pillage by foreign investors. It should be recognized that while a lot of emphasis will be placed on the indigenous private sector, it will take some time before the local population is up on its feet and able to participate as an equal partner with foreign players. Here also it is imperative to establish a level playing field that gives breathing room and establishes safeguards for the local population during the first phase (five years) of the Plan.

C. Restitution & Private Property

During the past four decades respect for private property has been virtually non-existent. Starting with the nationalization in the early sixties the situation became progressively worse as the Baath regime could expropriate any property for any value or no value at any time and for any reason. Lack of respect for human life extended indiscriminately to property and ownership.

An independent Property Restitution Authority must be set up to look into all legitimate claims and provide proper compensation or restitution. In this regard the experience of Eastern Europe is valuable and needs to be carefully assessed to provide guidance. In addition to being ethically correct such action will have two added benefits; first, it will go some way towards redistributing assets away from the state and its cronies and second, it will inject a measure of wealth back into the middle class which having been totally dispossessed and decimated, will be able to revive and participate in the economy again. While the work of such an Authority may not be straightforward, nevertheless a concerted and consistent effort has to be made.

F. Currency Stabilization

A stable local currency must be created as an ongoing tool of monetary policy and the creation of credit in the banking sector. The new currency should be pegged to a basket of the US dollar and the Euro reflecting the country's primary import and export position. Such currency stability will not only help the average Iraqi feel secure but also help to allay the concerns of foreign investors. At a later point in time and subject to the building up of adequate reserves the Central Bank may decide on changing the basket mix or free market floatation.

G. The Banking Sector

At present there is no proper banking sector to speak of. There are two large government owned and about twenty minuscule commercial and investment banks. The sector is utterly rudimentary by almost every standard. It is imperative to develop a strong and modern banking infrastructure to support economic growth both at the retail and the corporate level. A vibrant banking sector will accelerate the circulation of money, promote investment and capital expenditure to boost every sector of the economy, encourage consumer spending and saving, and contribute to an active deeper stock market.

Specialized lending such as consumer credit, leasing, mortgage lending, trade finance, agricultural finance and micro lending must be introduced and vigorously promoted. Foreign expertise will also be required in this sector and international banks should be encouraged to participate in a dynamic manner. Here again the participation of the Iraqi private sector must be safeguarded at the initial stage, which can be done by requiring foreign investors to have local partners with a minimum ownership during a pre-agreed initial period. As with other sectors involving large international players, ESOP and/or public listing requirements can be built into the license agreements as a partial means of providing such safeguards.

A. Capital Markets

Underpinning the whole economy a program to re-invigorate the country's stock market is of paramount importance. Such a market already exists but it is small and shallow. An independent regulatory authority is needed to promote and develop this vital aspect of the economy resulting in three main benefits; first, it will allow for a broader participation in economic activity and the resultant distribution of wealth. Second, it will allow for the classic ability of enterprise to raise capital. Third, it can be an efficient tool in the privatisation program, its ESOP features, the listing requirements and put/call options that may be negotiated with large foreign buyers.

The Capital Markets can be brought to a reasonable size fairly quickly if a requirement is imposed on certain large privatisation industries to list within a specific time frame. These industries can include oil, petrochemical, power and telecom as an example. Strict requirements on transparency, disclosure, collusion and insider trading must be put in place to avoid the "oligarch syndrome" experienced in other countries both in the region and internationally.

VIII. Other Critical Issues

In addition to the above a number of other issues have a critical impact on the Phoenix plan, these are:

A. Employment & Empowerment: the Private Sector

The local professional and mercantile segment of the population has been reduced to poverty subsistence over the past 20 years. It is not realistic to expect them to participate in the economic program in any meaningful manner very quickly. This needs to be taken into account during an interim period (the first 5 years) while a reasonable amount of intrinsic wealth, self-confidence and skills are accumulated.

Vocational Training Centres (VTC) need to be established across the country to deliver technical training in a variety of skills with a very heavy emphasis on IT. This will not only help absorb the youth, significantly upgrade the quality of the labour force but also indicate to the population at large the start of new economic horizons. Vocational training will also play a key role in harnessing and re-directing the energy of the recently de-commissioned army, channelling this energy into a productive force in the economy.

Real and effective protections need to be put in place during the first five years of the plan to achieve a proper distribution of wealth to the population at large, limit the emergence of oligarchs and avoid economic pillage by cronies of the old regime and foreign vulture investors. Furthermore, specific provisions and benefits programs need to be introduced that start the process of reversing the "brain drain" and attracting competent professional Iraqi exiles back to the country. One example is that followed in the GCC whereby regulation requires that 51% of any business activity is locally owned.

Furthermore it is not enough to limit control to Iraqi ownership, but in certain cases the identity of the owners must also be vetted. Already dubious characters and vulture investors are beginning to circle. The first category is more dangerous as it comprises many local cronies of the old regime who quietly accumulated large amounts of clandestine wealth in shady deals on their on behalf and on behalf of senior members of the Baath regime. Large and unaccounted for amounts of money held by persons with no discernable business backgrounds or worse still from unsavoury business backgrounds are waiting to transform their liquid assets into legitimate businesses in Iraq. Some of these characters are teaming up with gullible international investors, to gain legitimacy, by selling their supposed access and knowledge of the country. This also must not be allowed to happen. As the international community has cracked down on money laundering activities in other parts of the world, it must remain vigilant that another equally virulent strain of this activity does not happen in Iraq.

B. The Iraq Development Fund

There has been talk in the press of plans to set up an Iraq Development Fund that would receive all the oil revenues and be responsible in a transparent manner for reconstruction expenditure. While this sounds acceptable in theory there are two major questions that have to be answered.

First, what is the mandate of the Fund? If the Fund is just an accounting body, albeit transparent, then that is of very limited use. The Fund if it is to be set up must become a synergistic organ of the overall economic plan. It must work within the parameters and guidelines of the economic blueprint and must have some authority to make decisions not just take instructions to write checks and pay bills.

Second, what is the governance and oversight of the Fund? The Fund must have an un-conflicted and qualified Board with local participation. Such governance should have a phased transition to full local authority over a specific period of time. It is intelligent not to

repeat the problems and inefficiencies that plagued the Oil For Food Program partially resulting from the governance of that program.

Finally thought should be given to The Iraq Development Board that was set up in the country in the 1950's, whereby 70% of oil revenues were allocated exclusively, outside of government budgets, to the fund to be expended towards economic development. Such a model or a variation thereof may be very relevant in the present circumstances.

B. Infrastructure De-Regulation

There are certain infrastructure sectors that would benefit from phased de-regulation and expedite the economic revival of the country. These include; power, water, transportation and telecommunications initially, to be followed by other sectors such as education and healthcare. The objective is to either get the state completely out of these sectors, fast (e.g. telecom & transportation), or over the medium term (e.g. power & water), or at least to run in parallel with the private sector (e.g. education & healthcare).

There are a number of well-documented examples one can learn from such as the successful British experience with extensive infrastructure privatisation under Margaret Thatcher; the minimal role of the state from the healthcare system in the USA which is one of the best in the world; and the recent mixed experience with de-regulating the power sector again in the USA.

In the context of de-regulation a separate note must be made of the role of the Media, which in the past was dominated by the Baath state and used solely to serve their purposes. A number of different media outlets have already started springing up, however all controlled by the different political parties. It is important to encourage independent and non-political outlets in radio, television, newspapers and the Internet not just for education and information but also for entertainment and especially for the young.

IX. Role of the USA & other International Players

The US must continue in its leadership role in the reconstruction of Iraq; it is critical not to abdicate it to any other single or multinational authority. This leadership role is important for Iraq but also for the US. From the US perspective what was started must be successfully completed and should not be left half-baked. As the vision for the new Iraq was explained to Iraqis, the region and indeed the world only the US can bring it about. It is no secret that many

countries, some overtly and some covertly are looking for the United States to stumble and be ultimately humiliated in the bold and noble initiative it has undertaken to remove tyranny and bring freedom and stability to the "cradle of civilization" and ultimately to the whole region. Only the close and continued involvement of the US can shoulder the burden and transform this vision into reality.

For Iraq this relationship is equally if not more critical. Devastated by a pathological tyrant, war and sanctions; surrounded by hostile and sceptical neighbours, the country must and can rebuild itself into a vibrant free market peaceful economy in record time. For this it needs not only a strong patron, but also one who shares its vision. From a practical perspective this translates to a number working arrangements including assistance in drafting a new constitution to using a number of the regulatory models in transportation, telecommunications, banking, securities and anti-trust laws amongst others. At another level assistance will be required in re-negotiating debt, free trade agreements where applicable, providing loan guarantees in the short term, technology transfer and other tools that will enable the country to leapfrog into the 21st century.

Iraq can be the beacon that transforms the region but will need US help to do so.

Other international countries can and should be given a role in the reconstruction of the country. Most notably other members of the G8 countries can make an important contribution and should be encouraged to come forward. In a similar manner these countries can provide financial resources, technical skills and know-how in areas as diverse as banking to education and oil-field services to water and sanitation.

Members of the Gulf Co-operation Council who share a destiny with Iraq want and should also be encouraged, to participate in the reconstruction effort. Many of the GCC countries have limited absorption capacity in their own economies relative to their wealth and are in a state of both excess financial liquidity and excess capacity in industry and services. A dynamic Iraqi economy will represent an interesting new market and can act as an economic spark to the regional insipid economic environment.

X. Conclusion

1. The Phoenix Plan must be managed by an independent "Commission" combining certain functions of various ministries as Finance, Economy, Planning and Commerce & Trade. The "Commission must be staffed by technocrats and

have the authority to draft regulations that can be fast-tracked for approval.

2. Any acceptable political system (let alone a vibrant democracy as a beacon to the region) will fail if it is not quickly underpinned by a healthy economy; these two are interlinked and mutually reinforcing in both directions.
3. Oil alone is not enough given the scale of the problem. While it is a big help it is definitely not a 'cure-all'. Empowering the private sector in a comprehensive, transparent and publicly elaborated manner is the only solution.
4. The price of 'losing the peace' is not limited to Iraq or even the region. It will stab at the heart of America's leadership in the 21st century and certainly there are a lot of parties, alone and in collusion, waiting to push and twist the dagger. The "Domino Effect" can start in Iraq; better make sure it tips in the right direction.

There is not much time. At most the honeymoon in Iraq (if one could call it that) will last three to six months. Already other suitors (some unsavoury) are making 'courting' noises. A population, long oppressed, having recently found freedom will turn desperate without productive occupation and basic means of earning a livelihood. Immediate gainful employment is of the highest priority.

The Phoenix Plan is a way to get people off the streets and to work, fill their time, minds, stomachs and pockets in a constructive manner and start the "virtuous cycle" of economic growth.

PREPARED STATEMENT OF MR. HERNANDO DE SOTO, PRESIDENT, INSTITUTE FOR LIBERTY AND DEMOCRACY

The Property Challenge in Iraq

After 20 years of experience analyzing the world's property systems, the ILD has found that the property recording organizations in most developing and former communist nations tend to be in decent working order. Like their counterparts in the West, they have departments specializing in surveying, mapping, and digitalization of real estate and business registries. The odds are that up until Operation Desert Storm in 1991 Iraq's property records were also in good condition (at least for Baghdad). Since then, however, these records have probably degraded. And many or most of them, it is now feared, may have been looted and torched after the fall of the Iraqi regime. If so, they will have to be reconstructed —and fast— to help settle real property claims and provide space for displaced persons and returning refugees.

The real problem, however, is that even if that Humpty-Dumpty can be put together again, Iraq's records are still unlikely to reflect the reality of Iraqi property, much less provide authorities with the legal tools to build an inclusive market economy. History has shown us, again and again over the past two centuries, that once an existing authoritarian legal and administrative system breaks down, it is impossible to reconstitute the previous order. What automatically followed the collapse of the age-old patrimonial system, of feudalism, and, more recently, of communism was not a market economy but anarchy and widespread black markets, or another form of authoritarianism to rein in unruly behavior.

In the Ukraine today, for instance, 14 years after the end of communism, 60% of the people operate in the underground economy. Unable to adapt to burgeoning markets and emerging new practices, the Ukrainian system cannot provide affordable and thus enforceable rules, leaving people no alternative but to make their living in the extralegal sector. And while the Egyptians may have invented surveying and mapping 3,000 years ago to calculate and virtually represent boundaries after the Nile overflow, today 90% of Egyptians operate their businesses and hold their assets outside the law. The same kind of underground economic activity is bound to thrive in Iraq, including the transactions taking place in a vast extralegal micro and small enterprise sector that is probably now one of the largest absorbers of unemployed Iraqis, particularly young people.

The consequences for a genuine property system and the future of capital formation in Iraq are profound. A spanking new computerized property database, neat maps, and property claims commissions do no good if the records they contain do not reflect real possessory rights on the ground. And even if Iraq's legal system could be jump-started tomorrow, it is doomed to failure because its laws will not connect to the reality of how most people do business when freed from authoritarianism and will thus be unenforceable.

Throughout the developing and post-communist world, from Russia to Brazil —and now in Iraq— the real challenge of creating a property system is to design it in such a way that the poor and middle class citizens holding extralegal assets will voluntarily register those assets and transactions and bring them under the rule of law of a market economy —not because they are forced to but because they recognize that it is easier and more profitable to comply with the law than to work outside it. Law will have to be redesigned and adapted to the changing needs and expectations of common people no longer controlled by a dictatorship. That is the only way a property system can work in a non-authoritarian country.

Why Property is so Important for Creating the Rule of Law in Iraq

Creating a property system is more than just building a system to record ownership; it is the cornerstone of the rule of law and the market economy. We believe that a property system has to be designed so that it can integrate *all* of a nation's assets and provides the framework of rules that organize the market, the titles and records that identify economic agents, and the contractual mechanisms that allow people to exchange goods and services in the expanded market. It is property law that provides the means to enforce rules and contracts along with the procedures that allow citizens to transform their assets into leverageable capital. Therefore, if the property system is not designed to enable owners to enter into the market economy, property will be reduced to its ownership protection function and the poor, even with titles in hand, will be excluded from the market economy.

That is also why the ILD program to create an inclusive property system is more than just about land. We want everything that people use and possess to come under the rule of law so that everyone is not partly "legal" and partly in the shadows but fully governed by the rule of law. A property system should be able to represent all kinds of assets —not only land, but also businesses, chattel, and whatever other things people own— in standardized and universally accepted

records that allow owners to use their belongings and track records to guarantee credit and contracts. We make sure that beneficiaries of property programs are also in a position to access the instruments that store and transfer the value of their assets, such as shares of corporate stock, patent rights, promissory notes, bills of exchange, and bonds. We design the property system so that addresses can be systematically verified, so that assets can be described according to standard business practices, so that people can be made to pay their debts, and so that authors of fraud and losses can be easily identified in a expanded market.

That is how the rule of law begins —with property law that protects what poor people cherish the most and leads them quickly to understand the value of a system of rules that applies to everyone.

What needs to be done before implementing an Inclusive Property System for Iraq

The ILD program rests on a strategy whose objective is not just to consolidate the legal rights of those who had property under the Baath regime or its predecessor but to give all Iraqis the right to have property rights. Bestowing such "meta rights," emancipating people from bad law, and creating an inclusive property system is not about drafting elegant statutes, interconnecting shiny computers, or printing multicolored maps. Iraqis know all about that. What Iraqis need is a property program supported by a well-thought-out political strategy that motivates Iraqi leaders to be deeply committed to putting property and capital in the hands of the whole nation, thus giving citizens the incentives to create the institutions of a democratic and free society which they can use to safeguard and advance their objective interests.

That is exactly what the Western nations did – create legal property systems supported by well-thought-out political strategies. That is, for example, what Thomas Jefferson did in Virginia at the end of the eighteenth century, when he increased the fungibility of property by abolishing, among other things, the practice of entail. Similarly, when Stein and Hardenberg set the stage for universal property rights in Germany at the beginning of the nineteenth century, when Eugen Huber in Switzerland at the beginning of the twentieth century and the Japanese reformers after World War II began to integrating the dispersed property systems of their countries, they too employed carefully planned strategies to storm the barricades of the status quo. They also made sure they were armed with astutely aimed legislation that permitted government to create popularly supported, bloodless revolutions that could not be halted.

That is why the program we propose for Iraq takes the form of a transformation strategy that is based not only on our experience in the field but on the lessons that the ILD has learned from the successful transitions to market systems in the USA, Europe, and Japan during the 19th and 20th centuries.

Before creating a new property system for Iraqi authorities, it is important to get the facts: all extralegal and legal assets must be identified, located, quantified and classified according to the different rules —formal and informal—that govern the right to possession and exchange.

The rule of law can be established only if the new property law: reflects the extralegal customs and practices of the poor and middle classes; and gives them more easily enforceable rights than they can obtain through bribes and protection provided by extralegal organizations.

The program will begin by identifying, locating and classifying extralegal rights over assets, whether they are created by feudal, tribal, refugee, or black market organizations. Such information is an essential prerequisite for writing modern law and shaping recording procedures that will be enforceable and respected in practice.

Simultaneously, we will investigate the current laws and regulations that thwart Iraqis who try to gain legal title to assets they are holding, forcing even honest people to operate in the extralegal sector and continue to conduct business in a corrupt environment. The ILD has found that in most developing countries such obstacles to playing by the rules can be truly Sisyphean. Today, in Egypt, for example, which helped set up the Iraqi civil code of 1953, titling a bakery can take up to 540 days of moving from one bureaucracy to another at a cost of 84 times the average wage. In Mexico, even after 15 years of structural adjustment, foreclosing a mortgage takes no less than 43 months.

With the information obtained above, we will acquire the material and criteria needed to create an official property law that is more efficient at protecting rights and creating capital than the fragmented extralegal rules and bribes that characterize the shadow economy. In this manner, records and maps can be transformed from quickly outdated snapshots into "living" cadastres. Instead of slipping back into the corrupt practices of the extralegal economy, owners will have the incentive to keep registering their subsequent transactions, thus maintaining current official property records (and the legitimacy of the market economy law).

We would be very surprised if the information obtained would not confirm that a substantial amount of the poor and middle classes of Iraq are already working within a market economy, albeit an extralegal one and constitute a wide-based constituency for market reforms. This diagnosis would debunk any myth about a market system being incompatible with the local culture.

In our experience, presenting proof to a government that the extralegal sector of its nation is enormous and composed of private firms run by ordinary people loaded with potential capital motivates the leadership to move quickly towards reform. For instance, the ILD diagnosis in Egypt found that 90% of the population holds their assets and does business outside the law. We also estimated that these assets were worth about $245 billion —55 times larger than all foreign direct investment in Egypt and 30 times the value of the nation's existing legal business. Egyptian leaders were astounded. They were no less amazed by another ILD discovery: that the cost of legalizing those assets was prohibitive for most Egyptians: typically, it took 2 years to license a business and 17 years to title a home that could work as collateral, thus depriving the poor of access to their capital. The ILD diagnosis demonstrated that the reason most Egyptians worked outside the law and refused to enter a legal market economy was not due to an Islamic or Arabic cultural trait but to bad law. We are now helping the Egyptians reform their legal property system.

Faced with evidence of such vast potential wealth held by ordinary people, leaders in Iraq will have to recognize, sooner or later, that: The poor are not the problem, but the solution. That they are the most important constituency to create a market economy based on a rule of law compatible with their needs. The poor are vibrant, creative entrepreneurs. The poor already hold the assets required to create capital.

The lack of liquidity for entrepreneurial purposes is the result of a bad legal structure that can be reformed to create an acceptable rule of law. Property reform will allow their macroeconomic policies to work because legal incentives become meaningful and assets and transactions can be taxed.

Reform will defeat terrorism rather than incite it. If the new property law emphasizes the protection of the assets and transactions of the poor, given the fact that they are the majority, this will create a solid constituency for the rule of law in a market economy. (This is in contrast with other countries where market reforms are driven by —and mostly beneficial to— small elites and therefore do not have widespread support.)The best way to win elections and stay in power is by creating an inclusive market economy.

The goal would be to produce a common bedrock law for all citizens. The current extralegal rules that govern most Iraqis should be deconstructed in order to identify the principles that underlie them and see how they can be integrated into a new property law that can be trusted by everyone. One can then proceed to design and help enact a legal property system that consolidates the meaningful aspects of the disparate and dispersed extralegal arrangements (including procedural regulations for refugees and displaced persons) into one modern, codified system that Iraqis will freely choose to abide by and that will meet with a minimum of resistance from official bureaucracies and the formal sector.

In this way, the new government can begin to catch the wave of rising expectations instead of being engulfed by it.

Lawlessness is terrible, but the whole notion of security is far more complex than what would be achieved by putting a cop on every corner. The rule of law is not the iron fist imposed from above, it is a consensus about people's respect for one another's person and property. It is a social contract that people agree to keep because it protects the sources of their lively hood, their assets, and the customs that they respect and obey.

PREPARED STATEMENT OF DAVID P. ELLERMAN, PH.D., AUTHOR AND FORMER ECONOMIST AT THE WORLD BANK

Mr. Chairman, members of the Committee, I am David Ellerman, recently retired from the World Bank[1] where I was an economic advisor to the Chief Economist. Prior to joining the World Bank ten years ago, I started and ran for two years a consulting firm in East Europe to assist in the transition. While in the World Bank, most of my work was on the post-socialist transition with only a small part on the Middle East and North Africa region. The bulk of my remarks today will be based on the many hard lessons learned in trying to help the post-socialist countries make the transition to a private property market economy. While I am not an expert on Iraq, I imagine that many of these lessons would also apply to the post-Baath-socialism transition in that country.

1. The Case for Humility, Caution, and Incrementalism. Western economic advice to the former Soviet Union was partly responsible for the debacle in that region. Professor N. Gregory Mankiw of Harvard, the newly appointed head of the Council of Economic Advisors, noted in a recent book review that the book's author blamed much of the debacle in Russian on the shock therapy advice which came from some of the best and brightest of the economics profession (mostly from Harvard in this case). While Mankiw was more agnostic about the blame, he noted that if the advice "was a mistake..., its enormity makes it one of the greatest blunders in world history."[2] After a debacle of such historic proportions, surely we should have some humility about "nation-building" and be skeptical of those academic economists, brimming with self-confidence from building castles in the air, who now think they can socially engineer a new "shock therapy" program for a quick economic transformation in Iraq.

2. Pragmatism about Party Affiliation. The disastrous advice for institutional shock therapy in the FSU arose partly out of very understandable concerns that most of the people in positions of any power were in the Communist Party. Hence much of the western

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[1] My remarks are solely in personal capacity.

[2] Mankiw, N. Gregory 2003. Review of: Reinventing the Bazaar (book by John McMillan). *Journal of Economic Literature.* XLI(March): p. 257.

policy advice was wrapped in a cloak of Cold War self-righteousness: "Let's wipe the slate clean of the evil from the past to make a fresh new beginning." But we might recall the results of the Jacobins in the French Revolution or of the Bolsheviks in the Russian Revolution. For whatever reason, the U.S. supported the slate-cleaning "market Bolsheviks" in Russia to use the same methods for the reverse transition from Communism to the Market—with predictable results. Yet many of the professional, scientific, technical, and otherwise educated people were in the Party because it was the only way to get the jobs. If the qualified people hadn't join the Party, then the jobs would have gone to complete Party hacks. In Iraq, an organizational line should be clearly drawn so that above that line are the people who have to go. Below that line are the people whose professional knowledge and best energies will be needed for the reconstruction. They should not be thrown out along with the "dirty Baath water."

3. New Leaders Should Come from Within. It is important to understand the "returning-exiles" dynamics that played itself out in Eastern Europe and the FSU. When the old system collapsed, many who had been in exile (including various types of internal exile) returned to try to take over. They lead the chorus to demonize everyone who was a Party member, even those who had stayed in the country and worked for decades for reforms from within. Only those who were outside were presented as being sufficiently "clean" and untainted by involvement in the old system. By disqualifying those in the country who had any capabilities, the returning exiles tried to fill the power vacuum. But it did not work. Those in the country, in effect, said: "We who stayed suffered under the old system and tried to get along as best we could with passive resistance and active reforms. You got out and had a wonderful life in the West. Now that the system has finally collapsed, you want to come back in and take power." In all the post-socialist countries (with a few minor exceptions that were quickly discredited), the new governments were run by leaders who had grown up from within.

4. Avoid Symbolic Cargo-Cult Reforms. During WWII in the Pacific, the natives on many of the islands saw wonderful cargo being disgorged by the huge silver birds that came from the sky. After the war ended and the refueling stations were gone, the natives started cargo cults to "go through the motions" to get the cargo. They ran crude model airplanes up and down runways and talked into leftover orange crates with vines attached to "radio" to the birds to come back—but all to no avail. After the post-socialist revolutions, many

aid agencies promoted similar Hollywood-storefront "stock markets" along with voucher privatization so people could "go through the motions" of trading vouchers and shares—and thus "get the cargo" like in the West. What better photo-op for aid officials than cutting the ribbon in front of the Great Totem of the Stock Market? Never mind that after a century of perfecting the watchdog institutions, the U.S. still has its ENRONs. Aid officials should not have been surprised when their voucher privatization schemes and ersatz stock markets quickly degenerated into wall-to-wall ENRONs. People who lost their national patrimony in voucher ripoffs and lost their savings in Ponzi schemes expressed their despair with black humor: "Everything the Communists told us about communism was false, but everything they told us about capitalism was true."

5. Reverse the Disenfranchisement of War/Revolution/Shock-Therapy. The revolutions in the socialist countries and the shock therapy that followed in many of them quickly destroyed the "old way of doing things" but then found that it would take years or decades to construct new working institutions. A type of chaos ensued and a variety of economic and political thugs took over. The old system had never worked well but people got along in a twilight system held together "with chewing gum and baling wire." They knew that if they did X and Y, they could get something like Z. But after the old way was destroyed, they were disenfranchised and discombobulated. Things that never worked right, now didn't work at all. The helplessness and despair that followed in many countries lead to extremism and the election of neo-communist governments. Instead of going down this road again by naively trying to socially engineer new institutions overnight, it is better to start by seeing what worked before in some tinkered way and to see how it could be revivified in some more legitimate retinkered way—which can then evolve. Instead of trying to jump over the chasm between the old and new institutions in one great leap forward (only to fall into a chasm of chaos), it is better to incrementally build a bridge—even though one foot of the bridge must always rest on the old ground.

6. Promote Small and Medium-sized Enterprises. In the current situation, the Iraqi people feel helpless. The first aim of economic transformation should be to promote and stabilize small and medium-sized businesses where people can regain some measure of control over their lives. Small business support organizations such as chambers of commerce can give businesses an organized voice, incubators can help new firms get going, domestic franchising can

rapidly multiply successes in the retail businesses, and business education can give hope to a new generation. Instead of setting up cargo-cult stock markets, what is required is quiet and patient work with the banking system so that it can serve small businesses. Where businesses are informal and property rights are *de facto*, they should be formalized and protected as urged by Hernando de Soto so that people can use these "erector sets" to build more. In the small business and family farm, ownership is closely tied to control. There is no long hard-to-police and ripoff-prone chain of authority from shareholders to boards of directors to managers to middle managers and finally to workers. People feel they are empowered and responsible. For larger firms or organizations to be restarted and privatized, the same principle applies. Try to find pragmatic arrangements so that the formal structures of ownership and responsibility are "shrink-wrapped" around the set of stakeholders who have to co-operate in order for the firms to function again. On that basis, they can build a better economy.

7. Don't give aid to the Iraqi people; give them the tools to help themselves. Lincoln said he would like to be neither a slave nor a master. In like manner, just as Americans would not like to receive charity from others, so we should not aspire to bestow charity upon others. Instead we should aspire to get the tools into the hands of the Iraqi people so they can sow and reap on their own—so they can help themselves. Aid recipients in the former Soviet Union sometimes complained that they were being treated like a conquered people. Since the Iraqi people are in that unfortunate position, we must be doubly careful to show respect rather than benevolence. Charity corrupts, and long-term charity corrupts long term. For instance, there is the short-term rush to supply aid in commodity form (e.g., food and supplies) but that will tend in the longer term to undercut the markets that might provide those goods. Phasing in something like a food stamp program would help to restart the Iraqi supply chain of businesses that used to supply those goods. Or, for another example, there will be the temptation to demonstrate American goodwill and know-how by paying U.S. firms to do the reconstruction work. But the Iraqis will see this as adding the insult of presumed helplessness to their injuries. Instead the contracts should go to the Iraqi organizations and firms that can reconstruct local infrastructure perhaps with some additional learning as the work goes along.

8. A Regional Bank for Reconstruction and Development. One of the strokes of genius in the Marshall Plan was that the resources for European reconstruction were channeled through the Organization for

European Economic Cooperation where the European countries had seats but not the United States. The Europeans had to come to a *modus vivendi* and justify to each other how the scarce resources would be allocated. The U.S. role was indirect. If we look at the Middle East and North Africa (MENA) region today, it is the only region in the world without a regional development bank. The idea is an old one but there have been a few problems with "regional cooperation." Perhaps the time for this idea has finally come. Reconstruction efforts will be more successful if they come from within the region as part of regional self-help rather than from Washington. I suspect that the direct strategy: "We'll stay here until we have finished the job" is not viable for Americans and is not welcomed by Iraqis. Perhaps the U.S. Government should adopt an indirect strategy: help the countries of the region work out a *modus vivendi* in the concrete form of a regional development bank so that those countries can better help themselves.

PREPARED STATEMENT OF RACHEL BRONSON, PH.D., OLIN SENIOR FELLOW AND DIRECTOR, MIDDLE EAST PROGRAMS, COUNCIL ON FOREIGN RELATIONS

Mr. Chairman, thank you for the invitation to speak before the Joint Economic Committee about the challenges confronting Iraq's economic transformation. As you may know, I co-directed "Guiding Principles for U.S. Post-Conflict Policy in Iraq," a December 2002 report co-sponsored by the Council on Foreign Relations and the James A. Baker III Institute for Public Policy. Ambassadors Edward P. Djerejian and Frank G. Wisner co-chaired the report. In addition, during "Operation Iraqi Freedom," and the weeks prior to it, I traveled twice to the Persian Gulf to discuss the war and its aftermath with those in the region. Although the Council on Foreign Relations makes my research possible, it bears no responsibility for these remarks.

MAGNITUDE OF THE CHALLENGE

The task we confront in Iraq is enormous. Iraq sits in the strategic heartland of the Middle East. Historically, Baghdad has been a major player in Middle Eastern affairs and has been at the center of inter-Arab politics since its independence in 1932. Economically, Iraq has the second largest proven oil reserves in the world, estimated at 112 billion barrels, with as many as 220 billion barrels of oil resources deemed probable. Culturally, Iraq's universities and religious seminaries have shaped the thinking of large sectors of the region's citizenship. In short, what happens in Iraq matters immensely to millions of people in the region and beyond, as it does, of course, to the Iraqis themselves.

We have set high expectations for ourselves and the Iraqis. But even establishing a basic level of stability, security and economic recovery will be time-consuming and expensive. As Secretary of Defense Donald Rumsfeld has pointed out, after the American Revolution "it took eight years of contentious debate before [the United States] finally adopted a Constitution and inaugurated our first president." In Germany, it took four years to move from the end of the war to a constitution. The German experience, of course, also benefitted from approximately $8 billion of Marshall Aid money (in current dollars), a robust American and international security presence, and an international political context that America organized around Europe's recovery. Time, money and security were required in Germany. In Iraq, there is no reason to expect it will take anything

less. If anything, it could take more.

The challenge confronting the United States is to initiate a process that creates a reasonable level of security, maximizes international political and economic support, addresses the aspirations and needs of Iraq's various ethnic and religious groups and allows as many Iraqis as possible to participate in the positive political and economic transformation of their country. Such an Iraq could provide the region with a new political and economic model. It would supply a win for America's dwindling base of support throughout the Muslim world. But it will require a strong and serious American commitment. Failure to stay committed, politically, militarily and financially would have pernicious effects throughout the Middle East, North Africa, South Asia and beyond. The costs of getting Iraq right will be exceedingly high, second only, perhaps, to the costs of getting it wrong.

THE COMPONENTS OF ECONOMIC RECOVERY

Unfortunately, hard economic data or statistics for what is needed in Iraq are few and disputed. Still, the obstacles confronting recovery are many and include:

Re-establishing law and order. Iraq's recovery is challenged primarily by a lack of law and order. The looting and violence that has occurred, and is still occurring, has all but undone the hard work of military planners who largely tried to avoid targeting sites necessary to Iraq's reconstruction. Destroyed infrastructure along with missing documents and equipment are delaying reconstruction projects and attempts to get Iraq's oil flowing.

Iraq's economic recovery depends on its workforce returning to productive economic activity. But today a large portion of Iraq's workforce remains sequestered in their homes, fearful that leaving would risk the safety of family and property. Others simply can not go back to their jobs because of the damage done by the war, the civil disorder that followed, or both. Unless this situation is reversed, the time-table for Iraq's recovery will continue to slip.

Worse, the breakdown of law and order and the resulting power vacuum is providing Saddam's loyalists from the Ba'ath party, the military and other armed groups the opportunity to reconstitute. Knowledgeable Iraqis suggest that Saddam's security forces, that melted away during the fighting and that have not been disarmed, are trying to hasten an American withdrawal by inflicting a steady stream

of low-level casualties. The use of guerilla tactics that is beginning to emerge in western Iraq is an ominous warning of things to come. Unless America and its partners deal firmly with such opposition, and make clear their commitment to provide for a better future for all Iraqis, all other goals for Iraq will be illusory.

A heavy security presence will be necessary to fill the power vacuum left in Iraq. Prior to the war, a Council on Foreign Relations task force estimated that a stability force of 75,000 American troops would cost no less than $15 billion per year. This estimate did not include reconstruction and humanitarian costs. U.S. administration officials now estimate that the current force levels of about 150,000 (and expected to remain steady for the near future) are costing in excess of $3 billion per month. The original hope of reducing American presence to 30,000 by this fall is no longer viable given the chaotic reality on the ground.

The Administration deserves credit for the growing evidence that law and order is slowly being restored. Maintaining large number of soldiers in the country, supplemented by military police and Special Forces, is helping to stabilize the situation. However, the looting and violence that occurred unchecked during the first weeks of the post-conflict phase has set back Iraq's reconstruction.

Recovering Iraq's oil potential. Even if law and order had seamlessly transitioned from occupational authority to local control, Iraq would still require considerable outside assistance.

Iraq's reconstruction will not be self-financing. Oil is its major source of government revenue. Iraq's oil infrastructure is in decline. After years of sanctions and poor political rule, Iraq's production capacity is decreasing at an annual rate of 100,000 barrels per day. Prior to the war, Iraq generated $10-12 billion in oil revenue per year. Over 70% was spent on basic humanitarian assistance such as food and medicine that still is required today. While official assessments have yet to be concluded, repairing and restoring Iraq's previously used oil facilities may cost $5 billion, in addition to the $3 billion needed for annual operating costs. Up to $20 billion may be required to restore Iraq to its pre-1990 electricity capacity.

Before the war, questionable assumptions were made about the cost of the conflict, and the likely speed of reconstruction. Despite heady predictions for Iraq's recovery, there are limited short-term resources available for repairing Iraq's oil industry and decaying infrastructure. Considerable American and international support is required. It is unlikely that the Administration's one time request of $1.7 billion will produce the stable promising Iraq that many advocated before the war.

Diversifying the economy. To get Iraq back on its feet economically, greater attention must be given to diversifying Iraq's economy. Over 90% of its export earning comes from oil. In 1980, Iraq relied on oil for only 39% of its gross domestic product. Reliance on a single source of revenue makes Iraq vulnerable to the chronic corruption, monopolistic behavior, under-development, and under-employment that have afflicted other energy-reliant economies in the region, while leaving Iraq hostage to the whims of the market. Throughout the twentieth century, the value of economic output for those working with raw materials, in this case energy has declined by 50%, relative to skilled labor.

Re-structuring Iraq's debt. Iraq shoulders a massive debt load. While the exact debt amount is unclear, it is generally agreed to be between $100 and 200 billion. Iraq's debt is largely a result of the Iran-Iraq war of the 1980s, reparations from Desert Storm of 1991, and payments for pending contracts with foreign companies.

UN resolution 1483 "welcomes the readiness of creditors, including those of the Paris Club, to seek a solution to Iraq's sovereign debt problems." When possible, incentives will be required to encourage debt forgiveness. Unfortunately, even if they wanted to forgive Iraq's debt, some of Iraq's creditors are by law unable to do so. In such cases, generous refinancing conditions should be encouraged.

Supporting a stable, transparent political order. The Middle East has been woefully unable to attract foreign direct investment. Opaque authoritarian leadership has chased away such funds. To successfully attract capital and keep local capital at home, Iraq will require a transparent, stable, rule-based political system. While a transfer of power from the occupiers to local leaders is necessary, it will not happen quickly. America must plan to remain actively involved until local political experiments in places such as Mosul and Kirkuk can be replicated at the national level. A speedy transition will either return to power the scions of the old system, as happened in many former communist societies, or result in the assumption of power of a regime viewed as an illegitimate puppet of the occupiers. Neither alternative is attractive to foreign capital. For this reason, the Administration's decision to delay the selection of an Iraqi Interim Authority was a correct one. Initially raising the possibility of an early transfer unnecessarily increased expectations and distracted Iraq's potential leadership from the difficult tasks of recovery.

MANAGING EXPECTATIONS

We must remember that the pre-Saddam Iraq that many hold in their memories is not the Iraq of today, nor will it be the Iraq of tomorrow, even under the best of circumstances. With high unemployment and 42% of its population below the age of 15, Iraq's economic base is considerably worse off than it was before Saddam took office and during the first few years of his rule. At all times, America must make clear to the Iraqi people the reason for our actions and seek to include them in the implementation of policies to the greatest degree possible. Inflated expectations will only lead to discontent and instability.

THE WAY FORWARD

If done well, the reconstruction of Iraq holds the promise of a better and more enduring security situation for the entire region. Successful reconstruction is a hope that many around the globe share with the United States. To the greatest extent possible, the United States should harness the capabilities of those who are able to contribute to the Herculean task we have set before us. The road to Iraq's reconstruction will be long, difficult, dangerous and costly. We can travel it alone, or we can travel it with others. It is our choice.

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TECHNOLOGY, INNOVATATION AND HEALTH CARE COSTS

HEARING

BEFORE THE

JOINT ECONOMIC COMMITTEE CONGRESS OF THE UNITED STATES

ONE HUNDRED EIGHTH CONGRESS

FIRST SESSION

JULY 9, 2003

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TECHNOLOGY, INNOVATION AND HEALTH CARE COSTS

WEDNESDAY, JULY 9, 2003

CONGRESS OF THE UNITED STATES,
JOINT ECONOMIC COMMITTEE,
Washington, DC

The Committee met, pursuant to notice, at 9:30 a.m., in room SD–628 of the Dirksen Senate Office Building, the Honorable Robert F. Bennett, Chairman of the Committee, presiding.

Present: Senator Bennett.

Staff Present: Donald Marron, Mike O'Grady, Jeff Wrase, Angela Brimhall, Colleen J. Healy, Melissa Barnson, Wes Yeo, Rebecca Wilder, Frank Sammartino, John McInerney, and Nan Gibson.

OPENING STATEMENT OF SENATOR ROBERT F. BENNETT, CHAIRMAN

Senator Bennett. The hearing will come to order.

Perhaps it's appropriate in a hearing dealing with health care that I have a summer cold.

I apologize for the way I growl this morning, but there's not much I can do about that. We welcome everyone to today's hearing on how technology and innovation affect health care costs.

The United States has a health care financing problem, one that goes well beyond the budget challenges posed by Medicare. For many years, our health care spending has grown at a significantly faster rate than the economy. Projections indicate that this will continue. Any financial arrangement where expenses grow significantly faster than income is truly on very shaky ground.

In other sectors, new technologies usually lead to greater efficiencies and ultimately, lower costs. Yet, it's unclear whether the same is true for health care. So what's different about health care? Is it the technology or the way we pay for it?

How can we strike the right balance—providing access to the latest breakthrough technologies, while limiting an open-ended raid on the public and private treasuries that fund our health care?

During this hearing, we will explore these issues, bringing together some of the best minds from the public and private sectors to help shed some light on this situation.

We should first question whether technology and innovation have truly added to health care costs, as some claim, or have reduced health care costs through enhanced efficiency.

And second, we should examine whether new technologies are disseminated in an efficient and effective manner, and if there are

areas where they are being overused or underused. For example, some have expressed concern that advanced imaging technologies may be overused, in part, because of poor incentives in the payment formulas used by Medicare and other insurers. At the same time, an article in this week's *Health Affairs,* highlights how new technologies may be underused in treating people who lack health insurance.

We need to find the right balance. We need to judge the cost-effectiveness of new technologies so that we can properly fund this critical work, without overpaying and without adding additional upward pressure on health care spending.

Unlike most of the recent congressional debate on health care, this hearing is not about Medicare or its coverage of prescription drugs. However, this issue is crucial to Medicare and every other health care purchaser that faces the dilemma of how to add innovative new benefits without setting off an explosion of health care costs.

[The prepared statement of Hon. Robert F. Bennett appears in the Submissions for the Record on page 37.]

Senator Bennett. On our first panel, we're privileged to welcome Dr. Mark McClellan, the Commissioner of the Food and Drug Administration, who has testified before this Committee before.

Dr. McClellan, we're delighted to have you back.

Dr. McClellan. Thank you.

Senator Bennett. And Dr. Carolyn M. Clancy, who is the Director of the Agency for Healthcare Research and Quality. Dr. Clancy, you're a new appearance here, but we're also delighted to have you.

Dr. Clancy. Thank you.

Senator Bennett. Congressman Stark is unable to be with us this morning because of a conflicting schedule. But he has an opening statement which will be made part of the record at this point.

[The prepared statement of Representative Pete Stark appears in the Submissions for the Record on page 37.]

Senator Bennett. We are expecting several other Members of the Committee to show up as their schedules will permit. And as they do show up, I will recognize them for an opening statement or questions as is appropriate.

With that opening and background, Dr. McClellan, again, we welcome you and look forward to your testimony.

OPENING STATEMENT OF DR. MARK McCLELLAN, COMMISSIONER, U.S. FOOD AND DRUG ADMINISTRATION

Dr. McClellan. Good morning, Mr. Chairman. I welcome this opportunity to testify before this very important Committee. It's a pleasure to see you again and I want to thank you for your broad interest in health and in issues touching the FDA.

We've talked before about the importance of nutrition and we're working on ways to help people improve their diet.

In fact, we have an important announcement on this topic coming later this morning.

I'd glad to be here today to talk with you about the critical questions you just raised on the effects of technological innovation in health care on the cost of health care.

It doesn't take an economist to appreciate that new technologies often lead to higher costs of medical care. Millions of Americans are struggling today to afford the rising cost of what medical technology can do for them.

Many new medical technologies do lower costs, such as drugs for treating depression that can be less expensive than non-drug approaches to effective treatment.

Recently, FDA has approved new, simpler tests for HIV exposure that can be done quickly in a doctor's office, as well as less costly implantable defibrillators that can reduce the risk of sudden cardiac death for many patients.

But many technologies do result in increased costs. First, when a treatment becomes less expensive and safer, more patients may decide that it's worth the risk and unpleasantness to get it.

Second, many treatments exist today that do things that were simply not possible in the past. Patients with heart disease, cancer, AIDS, arthritis, cystic fibrosis, low birth weights, and countless other conditions are living longer and better lives because medical innovation has transformed fatal illnesses, or illnesses that could only be treated with supportive measures, into conditions that people can live with and often live well.

The important fact that Americans are living longer lives and better lives doesn't show up in any direct way in a country's national economic accounts, like health care spending does. But that doesn't mean that these health benefits aren't worth a lot.

So from an economic standpoint, one key issue is whether the benefits of medical innovation are rising faster than the costs.

In recent years, a number of economists and doctors and other health care experts have addressed this question. It's hard to answer since it's hard to put a value on better health and since there are many things besides medical care that influence health.

Perhaps the best evidence comes from studies of changes in treatments and associated changes in costs and outcomes for patients with specific illnesses over time, like patients with heart attacks or cataracts or depression.

While none of these studies are completely convincing in themselves, they generally show that medical innovation have been of great value to the public. That is, the value of the improvements in health are much greater than the increases in spending.

Another way to look at this is if you are a patient with heart disease or at risk for breast or colon cancer with rheumatoid arthritis or with many other conditions, you'd generally be much better off with the treatments that you can get today compared to the inferior treatments you could get a decade ago, even though in all of these cases, treatment for your condition is much more expensive than it was a decade ago.

But just because our leadership in medical innovation in America has added great value in the form of longer and better lives for millions of Americans, it doesn't mean that we should just be sitting back and doing nothing.

Just because changes in medical technology have been good overall doesn't mean that we can't do better. There are lots of examples of medical treatments used inappropriately or erroneously or in other ways that add to costs without providing much, if any, bene-

fits. And in addition, many people can't afford some of the valuable new treatments and that's a public health problem, too.

We must work hard to find better ways to increase value in the development and use of medical technologies. We must work to keep modern care affordable while still encouraging medical innovation.

I'm quite concerned about threats to valuable innovation in health care today. On the one hand, the process of medical innovation, turning sound ideas from insights in the biomedical sciences into safe and effective treatments for patients. This process has become steadily more expensive, more time-consuming and more uncertain.

That means it's getting much more expensive to get new technologies to patients.

On the other hand, we are also under more pressure than ever to find ways to bring health care costs down, and some of the ideas for reducing health care costs would unfortunately reduce the financial incentives needed to bring valuable, life-saving technologies to patients.

We're facing this crisis at a critical time from the standpoint of medical innovation. The number of new technologies coming to patients is down.

For example, we got fewer applications for truly new drugs last year than at any time in the past decade. But this is happening at the same time as the investment in research and development by the National Institutes of Health and by the private sector is higher than ever—over $80 billion, with the promise of new breakthroughs ahead from understanding the human genome and many other sciences like genomics and medical nanotechnology.

If the cost of developing new products that are safe and effective keep going up, while short-term efforts to control costs increasingly focus on controlling payment rates, we may not get more valuable new treatments in the years ahead.

I think there's a better solution, one that means better health and greater value for medical technology in the years ahead.

We can take steps today to improve the development and use of medical technologies and find creative policy solutions that both support innovation and make health care more affordable, particularly for those with limited means and great needs.

As part of a new FDA initiative on improving medical technology announced in January of this year, the FDA is taking many steps to help foster more efficient innovation, especially in emerging areas or those with great medical need.

We are working not only to reduce the time for reviewing new products and determining whether they are safe and effective. We are also working with partners at the NIH and with product developers to find ways to make the development process less costly and more predictable. For example, by providing clear guidance on what it takes for a product developer to show that a new treatment is safe and effective.

Lower costs and more certainty in developing new medical technologies means more safe and effective treatments can reach more patients faster.

In order to get more value from the medical technology we use, however, after new technologies are approved, we also need to work to do more to help doctors and patients use new medical innovations more effectively. And so, we're working closely with many participants in health care, including with the Agency for Healthcare Research and Quality, led by my friend and colleague, Dr. Carolyn Clancy, who I'm delighted to testify with today.

We're working with health care organizations to collect more information, automatically, on potential safety problems with products after they've been approved.

We're implementing new bar-coding requirements to make sure the right patient gets the right treatment, avoiding costly medication errors.

And we're conducting more post-approval studies to develop better, more up-to-date evidence on safety and effectiveness, the risks and benefits of medical products after they are approved.

We're working on a daily med program for physicians using an electronic version of our product label for physicians that is easier for them to use to get the treatment information they need for each patient they're treating. And it can be updated daily to include the most current information about the risks and benefits of the drug after it's on the market.

Only by facilitating development of complete, timely, and easily used information can the FDA help make sure that people are making the best decisions about their health based on the best available information.

Mr. Chairman, the FDA is working with AHRQ and with our partners throughout the Federal Government and the private sector to promote increased access to high-quality, safe and effective medical technologies, including drugs, biologics, devices and combinations of all three.

This is the best way from a public health standpoint to make health care more affordable and to make sure that we get the most value for medical technology.

I'm sorry we don't have any more products coming along sooner for the common cold, but I would appreciate the opportunity to have my written testimony read into the record and I'd be very pleased at this point to hear what Dr. Clancy has to say.

[The prepared statement of Dr. Mark McClellan appears in the Submissions for the Record on page 38.]

Senator Bennett. Thank-you. Your written testimony will be part of the record.

Dr. Clancy.

OPENING STATEMENT OF DR. CAROLYN M. CLANCY, DIRECTOR, AGENCY FOR HEALTHCARE RESEARCH AND QUALITY

Dr. Clancy. Good morning, Mr. Chairman. I'm very pleased to be here today to discuss the important issues of how we can facilitate, sustain and promote health care innovation and ensure that we have a health care system that is affordable.

And I'm also quite delighted to be here with Dr. McClellan.

I wanted to start off by just telling you a little bit about the Agency for Healthcare Research and Quality (AHRQ).

Our focus is improving the effectiveness, quality, safety and efficiency of the health care delivery system. So our work complements that of the Centers for Disease Control, which focuses more on public health, for example, through the use of public health ad campaigns.

To improve health care, we focus both on the clinical content of the care, as well as the systems or settings where people receive care.

So it's that dual focus that is a unique focus for the agency.

We contribute to efforts to speed the diffusion of effective medical breakthroughs. Through effectiveness in cost-effectiveness research, we can extend the findings of biomedical research to populations not included in clinical trials, determine whether patients in daily practice actually achieve the promising benefits seen in clinical trials, and identify which people benefit most and least.

So, for example, if a new breakthrough came along for the common cold, we would be able to help clinicians understand which patients were most likely to benefit and which patients might be harmed or not likely to benefit at all.

Our expanding portfolio of implementation research develops effective strategies to facilitate the rapid adoption of effective services and technologies.

We also facilitate adoption of new knowledge by putting into perspective available scientific evidence so that clinicians and their patients can better assess the importance of recent breakthroughs, an issue of increasing importance as new interventions appear almost daily in the media.

So, for example, where the FDA determines that a drug, biologic or device is safe and that it has an impact, usually when compared to a placebo, those making coverage decisions and those making clinical decisions need more information regarding its relative effectiveness and relative cost—how does it compare to the other options I have?

For example, our evidence reports and technology assessments assist Medicare in making coverage decisions of new clinical interventions.

One area of increasing importance that's relevant to this discussion is in assessing safe use and minimizing unintended harm of health care interventions.

While FDA plays a key role in ensuring the safety of drugs, biologics and devices, their inappropriate use can still lead to patient harm, and that's an area where our agencies are collaborating closely.

But there are other innovations in health care, such as new surgical procedures and medical interventions, or new applications of existing technology, for which there is no comparable up-front evaluation of safety.

While some of these innovations offer unprecedented breakthroughs for some patients, they may also result in unintended harm, if not used appropriately.

And this unsafe use is both a personal tragedy for individuals and their families, as well as a big source of unnecessary costs as clinicians struggle to repair the damage and as medical liability expenses mount.

This is a growing focus for AHRQ, and the area of drugs, biologics, and devices is an area where we work closely with the FDA.

Mr. Chairman, the pace of health care innovation continues to accelerate. It's increasingly difficult for clinicians and patients to assess their options adequately.

Many of these developments offer patients the potential for greatly improving the quality of life for patients, as Mark has noted. In other cases, the improvements are marginal at best.

Some innovations lead to significantly lower costs, while others are cost increasing.

The big challenge underlying this is to effectively sort through the increasing array of clinical care options to develop objective scientific information so that those making decisions—policymakers, systems leaders, insurers, employers, clinicians and patients—can make informed choices.

Whether you favor our current insurance-based system or favor a more consumer-driven model of care, the need for objective evidence is compelling and remains constant throughout.

The resurgence of health care cost inflation, combined with expected growths attributable to the investments that Mark McClellan noted in biomedical research, will only accelerate this demand for objective information.

So I wanted to tell you five ways in which AHRQ can help.

First, AHRQ research identifies what's effective and cost effective in daily practice.

Experience suggests that new drugs, technologies and medical or surgical interventions are seldom equally effective for all types of patients.

For example, will a breakthrough for the treatment of arthritis tested in clinical trials for patients who only have arthritis work as well with patients who also have diabetes, heart failure and hypertension?

Or how well will it work in patients whose racial, ethnic and demographic characteristics differ from those enrolled in the original trial?

My written testimony provides two examples that demonstrate the importance of avoiding simplistic judgments about new technologies.

In one case, treating middle ear infections in kids, a very common cause of seeing physicians, we demonstrate the value of using the low-cost option, generic antibiotics.

In contrast, in a study of the use of very expensive, but highly effective drugs to treat AIDS, we demonstrated that the long-run savings that result from the use of these much more expensive drugs more than warrants their use.

Second, AHRQ research identifies strategies for overcoming barriers to the use of effective services.

Two weeks ago, you may have seen a lot of headlines about a study that was published in the *New England Journal of Medicine* from the Rand Corporation saying that getting quality of care in this country was effectively a little bit better than flipping a coin—about 54 percent of the time is what they found.

The vast majority of the areas that they measured in quality of care related to underuse of effective treatments.

Great opportunities for improving health developed through biomedical research are easily lost if physicians and patients aren't able to make the best use of that knowledge in every-day care. And that is a big focus for the agency.

Third, AHRQ facilitates the use of evidence-based medicine.

Developing and synthesizing evidence and objective information about various clinical options is important. Making it useful in real time is essential.

In recent years, AHRQ has focused increased attention on the development of technologies and tools to facilitate the use of evidence-based medicine.

For example, every year, tens of thousands of patients go to an emergency department with chest pain and they're worried, as are their clinicians, that they might be having a heart attack.

We developed a tool that has now been incorporated into EKGs that helps clinicians make better decisions and which we estimate could prevent 200,000 unnecessary hospitalizations and 100,000 unnecessary coronary care unit admissions a year, saving over $700,000 million annually in costs.

Fourth, AHRQ research assesses the effectiveness of cost containment and management strategies.

Medicaid pharmaceutical costs are increasing at about 20 percent a year and obviously are the source of great focus and attention by states right now.

As an example of how our past research was helpful to today's decisionmakers involved a study of a strategy used by one of the New England states. And what they did was that they limited Medicaid prescriptions to three drugs per patient.

Indeed, they saved money on pharmaceutical costs.

The only problem was that they spent more than 17 times what they saved in unnecessary admissions to emergency rooms, nursing homes and to the hospital.

So that was of an unintended harm or unwanted aspect of an intervention that was intended to control costs.

When I actually mentioned this to state legislators in Dr. McClellan's home state, their eyes got really big because I think they had been thinking about this strategy as well.

The results from this study led nine other states to change their policies.

Finally, AHRQ has a role to play in speeding the pace of evaluation of health care innovation.

One of the critical roadblocks to coverage of innovation interventions is the lack of solid scientific evidence regarding their effectiveness, especially in contrast to existing interventions.

This is often frustrating to those whose creativity leads to the development of new breakthrough interventions and then come to realize that they have to get through FDA and CMS scrutiny, that that's only part of the journey toward seeing their innovation and widespread use.

I wanted to give you an example of a surgical procedure because that does not come through the FDA.

We work very closely with the Centers for Medicare and Medicaid Services and they asked us several years ago to evaluate a new surgical procedure called lung volume reduction surgery.

We did an assessment using existing data and found that some patients benefited enormously, near-miraculously. Others were harmed.

And what we said to the Medicare program was we can't say with confidence ahead of time which patients are most likely to benefit. We think conditional coverage linked to a randomized clinical trial might be the way to go here.

As a result, the Medicare program turned around and said that they would only pay for this procedure for the patients enrolled in a clinical trial.

What happened was that we now know which patients are likely to benefit and very importantly, we identified a very high-risk subgroup of patients who are likely to be harmed. That is to say, they are likely to die from their end-stage lung disease, much more rapidly, which I think is a very important contribution to the public's health overall.

There are at least two other ways in which we can improve how we work as a science partner to promote private-sector innovation.

First, we want to work closely with industry trade associations to assist their members who have products moving to the end of the FDA review process to better understand the types of studies that will be needed to assess the effectiveness of their products.

This simple step will facilitate more timely assessment of health care innovations.

Second, as our existing investments in patient safety come to an end, we want to expand our focus on human factors research. This is research that helps us idiot-proof our technology—for example, making sure that the controls on all new machines and devices work consistently in the same way that a pilot, any time that he or she steps into a 747, knows that the dials are all in the same place.

That way, even if health care professionals are distracted, stressed or, sometimes, sleep-deprived, they will provide safe care.

By ensuring that this type of critical information is in the public domain, we can be a science partner for these private industries to develop even more effective and safer health care technologies.

Before I conclude, I just want to say a few words about the future directions of AHRQ.

We're determined to make the agency even more of a problem-solving agency. This will entail a greater focus on implementation research to help overcome barriers in the adoption of clinical interventions that are both effective and cost effective.

We've developed closer linkages throughout the research process between the ultimate customers of our work and our researchers to ensure that we're addressing their highest priority challenges.

We're also giving greater emphasis to identifying strategies for eliminating waste, assuring that evidence-based information is current and up-to-date, bringing our health care infrastructure, particularly information technology, into the 21st Century, and redesigning work-flow so that health care professionals can work more efficiently and effectively. And finally, evaluating financial and other incentives to encourage safe, high-quality care.

In conclusion, let me just say that a series of studies have demonstrated that the timeframe for approval of a research grant that

ultimately leads useful findings to the widespread diffusion and adoption of those results was, on average, about 17 years.

We consider this timeframe unacceptable.

Now this study did not actually look at the products developed by the private sector, but I can tell you that there are many other studies that would suggest that they're probably not all that much far ahead of the curve.

We're prepared to play an important role in identifying effective interventions and increasing the pace of their diffusion.

Thank you very much.

[The prepared statement of Dr. Carolyn Clancy appears in the Submissions for the Record on page 45.]

Senator Bennett. Thank you. Let me give you a personal example of the dilemma that we face here when we're looking at the overall system.

My wife used to jog. She's gotten more sensible in her later years, and she doesn't do that anymore.

She tore the cartilage in her knee. And went in, got examined, and was called for surgery. She spent, my recollection is, a week in the hospital. She has a scar on her knee as a consequence.

Obviously, the surgery and hospital stay were expensive.

Some years later, she had to have the same kind of surgery on her other knee. Arthroscopic surgery done as an out-patient took about an hour. I waited in the waiting room while it was done and took her home the same day.

Obviously, there was no increase in cartilage injury by virtue of the invention of the arthroscopic procedure. So you can't say that the technology stimulated enough new procedures to take the cost up.

The number of injuries were the number of injuries were the number of injuries.

So the dramatic cost savings in arthroscopic knee surgery entering the overall economic picture would indicate that the cost would come down.

Now, when you look at the fact that costs go up while this kind of innovation is going on, and there are a number of other examples like that, you come to the issue that I think you addressed a little, Dr. Clancy, that there must be some parts of the system where the cost has gone up exponentially, because it's not just gone up the 15 percent per year that we're looking at right now.

In those areas, it has gone up enough more than the savings to eat up all of the savings and produce on top of the savings a 15-percent per year increase.

Now, is there ever any prospect in the future that we're finally going to catch up with this, whether we do it through evidence-based medicine—which is a great phrase that I like—or through the analysis, Dr. McClellan, of the benefits outweighing the costs so that we can continue to justify doing this?

At some point, will the impact of the—if I can put it in these terms, the arthroscopic surgery lowering of costs—catch up with whatever it is that's driving the increase of costs so that the overall number levels out?

Do either of you have a view of what the next 5 to 10 years might bring in that regard?

Dr. McClellan. I think there are many examples like the one that your wife experienced where innovations in medical technology and capabilities have made it safer and less expensive to achieve a given treatment, to achieve a given improvement in outcome for a patient.

In your wife's case, it was repairing some damaged cartilage.

There are a couple of reasons why, even though that's less expensive in terms of both the procedure itself and hospital time and complications, that may not even in itself translate into lower health care costs overall.

One reason is that when the procedure gets easier to do, more patients tend to decide that it's worth having it. So that people with milder injuries, for example, may be more likely to undergo arthroscopic surgery when they would never consider going into the hospital for that more miserable week's stay and major surgery that your wife experienced some years ago.

Senator Bennett. So you're saying that knee or cartilage injury is a case of elasticity of demand.

Dr. McClellan. If you look at the number of procedures, it has gone up a lot.

And in fact, picking up on something that Dr. Clancy talked about earlier in terms of appropriate use, there have been some studies recently, including the study in the Veterans Administration, that showed that, in a number of cases, arthroscopic surgery may be being performed where the benefits don't outweigh the costs or the risks to the patient.

And that's why developing better information, as Dr. Clancy and I both emphasized, on risks and benefits of a new technology for a particular kind of patient, can be very helpful.

And it's also why the linking up of incentives for using those technologies in certain patients so that people think about the costs, might be helpful as well. And that's where a lot of health policies have been directed in recent years.

There also have been a number of new treatments coming along for knee injuries that just didn't exist before. It's now a lot easier to get a knee replacement for people with severe arthritis who couldn't walk or couldn't walk easily, so that they can get around and even take up jogging again.

The technology has gotten a lot better.

So, previously, that wasn't very expensive if people just sat around at home and didn't do much because their knee was gone.

Now, they can have a much better quality of life in getting around, but it's added to our health care costs.

All this just goes to show, as you said, that we need to make sure, or do more to make sure that we're getting a lot of value out of the new treatments when they're actually used in practice.

Senator Bennett. So your answer to my overall question is no, there's not going to be a time in the future when it starts to level off?

Dr. McClellan. Well, I think a lot of people have been reluctant, a lot of economists have been reluctant to predict that because they look back on 50 years of experience of health care costs growing significantly faster than our overall economy, and then they look down the pipeline in terms of new treatments being developed as

a result of genomics and other sciences that are just now starting to have an impact on medical care.

They see a lot of conditions that are either not treated today or not treated well—Alzheimer's, many forms of cancer, other illnesses where people really do have to live with a lot of disability, if not die, because they suffer from it.

And that gives them reason to think that costs can go up.

On the other hand, I wouldn't be completely pessimistic that we can't do a lot better if we make the right policy choices.

There are a huge number of examples, and Dr. Clancy talked about many of them, of us spending a lot of money on health care for treatments that don't do much or anything for patients' health outcomes and may even, in the case of medical errors and preventable adverse events, make outcomes worse and add to costs.

And by some estimates, the savings could be in the many billions of dollars per year.

So if we can find ways to get the new technologies, the valuable new technologies, moved along, while at the same time reducing the spending on treatments that don't really do much for patients, we can have a much more viable health care system, one that does more for patients.

It may cost more overall. It may cost less. But we'd be getting a lot more for our money. And that's what I think we need to focus on.

Senator Bennett. Dr. Clancy.

Dr. Clancy. Yes, I would agree with all of Dr. McClellan's comments, and we've confirmed this, his observation that if you make a procedure much easier and less painful, that more people are likely to want to do it.

For example, we had a research team in place when the new procedure for gallbladder surgery was introduced, which made an incredibly miserable operation far more bearable and much more faster recovery.

Since I'm a physician, but not an economist, unlike my colleague who is both, I don't have to be quite so embarrassed about predictions, I don't think.

[Laughter.]

But if I were to look at the population's health and demographic changes affecting our population, what you see is a general aging of the population here and in all developed nations.

I think the great opportunity for savings is two-fold.

One is waste in the health care system and that's a big focus of the agency's efforts.

The second, though, is really improving the quality of life for people who now suffer impairments in quality of life.

If you look back over the 20th Century, the huge achievement was the expansion in life expectancy. What that has not translated into far enough is improvements in quality of life in the later years.

So that mantra of adding life to years does make a lot of sense and I think actually has an enormous opportunity for us to be able to save money downstream.

What this will mean is a lot more focus on helping people with chronic illnesses, whether that's arthritis, who benefit from joint

replacements, or people who benefit from new drugs for treating a variety of conditions.

And I think the other contributor here that will be very helpful is information technology. I think as more and more people become engaged as partners in managing their own care, whether it's diabetes, high blood pressure, or other things, that will help us actually obtain greater value from our investments in health care.

Senator Bennett. Let me go to the question of waste. It's something that you dealt with in your testimony, which again triggered another personal experience.

I woke up in the middle of the night one night having some, for me, unique and a little bit strange and ultimately frightening kinds of symptoms.

Finally, my wife woke up and said, "Do you think we need to go to the hospital?" And I said, "Yes."

She drove me to Georgetown Hospital in the middle of the night. I just presented my Federal employee's card and was very impressed with how excited everybody got about taking care of me in the midst of what was an apparent heart attack.

I commented to her about how somebody just off the street that they'd never seen before was being taken care of. And she made it very clear, she told everybody I was a United States Senator.

The head of the cardiac department at Georgetown University showed up immediately.

It turned out what I had was known as an esophageal spasm, which has exactly the same kind of symptoms as a heart attack, particularly for somebody who has never gone through it. But it's not life-threatening and, indeed, disappears. As mine did.

They thought I was having a heart attack and the reason that it disappeared is because they put a nitroglycerine tablet under my tongue. In fact, it had nothing whatever to do with my condition.

I was in the hospital for, I think, 3 days, on all kinds of monitoring machines, et cetera.

Finally, they decided after the most extensive and obviously expensive series of tests, that, no, this wasn't a heart attack at all.

Now you referred in your testimony to some kind of technology that can determine that. Right at admission, they could have patted me on the head and given me a purple pill and sent me home that same night and everything would have been fine.

I've had some of those symptoms since, and all I do is take Prilosec and it goes away.

According to the latest stress test that I had at the Bethesda Naval Hospital, they said, "We don't need to see you for another 10 years. Your heart is as sound and solid as any we've seen."

So that raises—you talk about waste being one of the major problems. We think of waste, fraud and abuse as a continuum, and there's something sinister about it.

Here was a case of waste where there was nothing sinister whatsoever, and there was certainly no fraud and there was no abuse of the system.

They didn't know and they were taking every intelligent precaution to see to it that I stayed alive. Because if it had been a heart attack and they had not done the things they had done, they would have been guilty of malpractice.

What are the prospects of dealing with waste through technology? The Federal bureaucratic mentality, as I say, is that waste, fraud and abuse are all a single thing. So we simply say, we're not going to pay, like the example you gave of the state legislature saying, well, you can only have three prescriptions. You may need five or six, but we're not going to pay because doctors are overusing and overcharging and engaging in waste, fraud and abuse.

We'll fix that by passing a law that says that you can only have three. But this ends up costing the system a whole lot more in another area that doesn't get counted as you're congratulating yourselves on how much you've brought down your prescription drug cost.

What are the prospects of dealing with what I would call from the example I've just given you, benign waste, well-intentioned waste, through greater technology, bringing down the cost of that kind of waste through greater technology?

Dr. Clancy. I want to make a distinction between diagnostic uncertainty, which in your case, even though in retrospect you could have just gotten your purple pill and gone home, it sounds to me from how you've described it that they did everything appropriately. And I don't think anyone would have wanted them to do one thing less.

Senator Bennett. I wasn't complaining.

Dr. Clancy. Yes.

[Laughter.]

Dr. Clancy. One big source of waste or increased efficiency that I think is achievable is in the care of people with chronic illnesses.

There was a study published a couple of months ago, also in the journal, *Health Affairs*, that surveyed people in five countries with various chronic illnesses.

And what you heard consistently—it's interesting, sort of a global phenomenon—was that many of these folks saw multiple doctors. They tended to have the same test ordered twice. After all, I might know that Dr. McClellan has ordered a test on my patient or my patient might tell me that. But if I can't find the result or if I'm not really sure, I'm going to order it again. They also had medication errors and that were lots of opportunities for miscommunication.

I think that's where investments in information technology can make a huge difference because I don't have to look for the result. I can actually just check on it in the computer.

Very recently, the Department of Veterans Affairs has shown that those types of investments can pay off huge benefits in terms of improving the quality of care.

So that's one obvious source.

There are lots of opportunities I think to make our health care systems more efficient and that is a big focus of our research right now.

Senator Bennett. A central repository of information about every patient would lend itself to what you've just described.

Dr. Clancy. That would be one model.

Senator Bennett. It raises all kinds of privacy implications.

Dr. Clancy. Right.

Senator Bennett. And confidentiality of medical records. And I've spent a lot of time on that issue, too.

The technology exists, I believe, to do what I'm about to describe. Let's follow that road for a minute.

I step off the curb in New York City, don't look the right way, and get hit by a taxicab and become unconscious. No one has the slightest idea who I am or anything about my medical records, but I am rushed to a hospital.

They find in my wallet a card, which they can put into a reader somewhere, where my entire medical history is available on a chip.

All of a sudden, they not only know my name and my social security number, but they know the level of daily medications that I take, they know that I've had two hernia operations, an appendectomy, that my EKG is abnormal, but my heart is not, et cetera, et cetera.

They know all about me instantly.

And you say you didn't have the information of the latest test. On that chip, on the card in my wallet, they can know the date of my latest stress test at Bethesda Naval Hospital, dial it up somewhere, and instantly get those results.

So that as they work on this unconscious, unknown individual at Bellevue Hospital or wherever it is I'm taken in New York City, they have everything in front of them, everything available to them, and presumably, can then make not only the best diagnosis, but save huge amounts of money and give me the right kind of treatment.

The technology to do that exists. Let's set aside the confidentiality and privacy issue for just a moment and ask ourselves what would be the economic benefit if that technology were implemented and everybody carried such a card?

Would health care costs go up or down?

Dr. McClellan. It would certainly help avoid some of the kinds of duplicative costs of delivering health care that Dr. Clancy has emphasized exists too often today. And that could lead to some improvements in costs through less duplicative tests and higher quality of care for exactly the reason that you mentioned.

That's a more efficient system.

There are some obstacles to implementing that system.

Senator Bennett. There are a few, yes.

Dr. McClellan. You know, the department has implemented a strong new privacy regulation. I think it has given people much more confidence about how their electronic sensitive medical records are being handled.

There are some other obstacles in terms of standards and different institutions and organizations store their electronic data in different ways, using different codes.

Dr. Clancy and the rest of the Department of Health and Human Services and the rest of the Federal Government have been involved recently under Secretary Thompson's leadership to try to get more standardized systems for keeping track of medical information so that it can be shared across health care systems effectively.

But there's another type of benefit from using health information more effectively and that's it can let us learn more about what treatments are working and which ones aren't, which ones may ac-

tually be causing safety problems and harming patients in actual use.

It can be difficult for us to get that kind of information today.

For example, at the FDA, we've long relied on reports from manufacturers of products to tell us when something is going wrong. They in turn have to rely on increasingly busy and harried health care professionals to send information in to them when something goes wrong with a drug or device.

With the kind of information system that you described, we'd have a way of capturing automatically in real time or close to it information that could put us on to an important safety problem or maybe even an important benefit that's not well understood for patients. And we can in turn get that information out to doctors much more effectively by using that information system going the other direction.

So it should be a two-way street.

So there are a lot of potential benefits there. There are some obstacles along the way, including confidentiality and standards and providing the right kinds of incentives for health care organizations to adopt these modern information systems.

But there is a tremendous potential there.

Senator Bennett. Well, you get to the question of common database protocols. I think that's what you're describing here.

Another example.

Intermountain Health Care in Salt Lake City ran a series of hospitals—still does. And I believe I have these numbers right. It's been a while since I dredged up this particular example, but you've triggered it with this testimony.

The question of infections after operations is a serious question. People go into the operating room. The operation goes well, but they get an infection.

The standard that was established was 2 percent. If you could get your infection rate down to 2 percent of the operations, you were labelled as an acceptable and, indeed, admirable, kind of operation.

At Intermountain Health Care, they decided that they were going to experiment a little, not with the patients, but with the data. And they started checking various things that happened in the operating room to discover if there was any correlation between certain things and the elimination of infection.

I can't remember exactly what they discovered. My memory tells me that it had something to do with the timing of the injection, or the introduction of antibiotics, or whatever, that if they waited past a certain period of time, then there were infections. And if they did it within a certain period of time, there were none.

They changed the protocol in the operating room to correlate with the information they had discovered by virtue of their research and they brought the infection rate down to 2/10ths of 1 percent.

Now industry standard would say, if you meet the 2 percent, you get the seal of approval and everybody accepts that as being normal.

And they were able to bring that down to 2/10ths of 1 percent.

So, naturally, if you're going to have an operation, you want to be in one of IHC's hospitals with respect to the infection problem.

Is there some way that could be devised or adapted to where you work where that kind of discovery—it's not a research discovery in the sense that you've got a new drug or a new device. It's simply a statistical discovery of examining what's going on and saying, wait a minute. It really matters whether you do this in the first 20 minutes or the first hour.

To create a central repository of that kind of information that could then produce a national protocol that says, this is the way every hospital ought to do it, and take that example and spread it out over all of the things that can be discovered that you're talking about, Dr. Clancy.

Respond to that and see if that is something that the government should be involved in.

Dr. Clancy. Well, I'm very proud to say that we actually funded the study you're talking about at Intermountain Health Care.

Senator Bennett. Oh, did you?

Dr. Clancy. [Continuing.] Which identified just how important it is to get the timing of the pre-operative antibiotics right.

They also demonstrated that information technology can be a very important part of reinforcing and making sure that that happens.

The type of research that you're describing, the systems research, how do we make sure that what we know works is actually what happens, is very much a focus of the agency's work right now.

This fall, we're going to be putting out a big report on quality of health care, sort of a national report card, if you will. And in preparation for that, we're beginning to review all the evidence about what we know works best and are also hoping to use that as a launching pad for improvements.

So we'll make sure that you get one of the first copies.

Senator Bennett. That's nice to know that there's a report. But just to pick a city at random, suppose I go into a hospital in Detroit, where they haven't read the report.

Is there any system for getting the information out other than we published a report and hope somebody picks it up?

Dr. McClellan. Dr. Clancy emphasized that AHRQ and other Federal agencies, including us, are trying to get better information developed so that doctors would have access to the best and latest information on risks and benefits for a particular patient of a particular treatment.

And I think that the kind of system that you're talking about may not come together as just one single global database, but there are a lot of programs out there that can help doctors get more accurate information for treating patients.

I'd like to emphasize, though, that that's not enough. As you emphasized, this is something that happens at the local level when doctors and nurses and other health professionals delivering care to individual patients, just having an attitude and having the support they need to make the right decision at the right time and avoid errors is something that needs to be part of the system, part of the environment in which health care practitioners are functioning.

And having access to information technology can help with that. But other steps are necessary, too.

For example, one barrier that many institutions cite about trying to develop that same kind of information so that they can keep track of why infections are occurring and how we might prevent them, is concerns about liability.

They're afraid that if they write down what might go wrong—what went wrong or might have gone wrong for a particular patient, that's going to end up being held against them in court.

And I'm pleased to say that there's bipartisan legislation working its way through Congress, at least the House, which I know AHRQ and we strongly support that would provide liability protections that are needed to encourage the environments that promote safe and effective medical practice.

And also financial incentives matter as well.

Some institutions still today get paid more for treating a patient for not only the condition that brought him into the hospital, but for the infection that might keep them there longer or get them readmitted to the hospital.

Incentives should be in the right place for getting patients well and preventing errors in the first place. There are more supporting things that need to help, that if you get them in the right place, would help make that kind of national data that you're talking about be used much more effectively.

Senator Bennett. You're not suggesting that anybody rejoices or deliberately does things that would cause a patient to stay in the hospital longer?

Dr. McClellan. Not at all. I'm just pointing out that financial incentives to help people stay healthy can make a big difference.

Dr. Clancy. And just to build on that. In your home state again, at Intermountain Health Care, Brent James has a long and impressive list of examples where they have improved quality and the safety of health care and have lost money.

Now they're doing it because it's the right thing to do. And the reason they've lost money is related to payment policy and the fact that we pay institutions more for taking care of sicker patients.

Actually, treating patients more effectively, they have lost some money and they can provide very clear evidence of that.

So one of the pieces of this puzzle will indeed be payment policies to make sure that institutions that do a better job for a lower cost don't lose. Because for some institutions, that's not going to be a sustainable approach.

Senator Bennett. How do we deal with that? Back to my example of my non-heart attack.

They diagnose me instantly as having an esophageal spasm and they've lost money. I rejoice. They rejoice. How do we get some kind of financial incentive into the system to do just what you've described and say to people that if you do it right and come up with the right diagnosis, you get a bonus of some kind?

And what are the implications of that because people would say, oh, this would be great. That is, somebody who is disreputable would say, this will be great. I'll tell them that they don't have any real problem. I'll get the bonus for not having done the other proce-

dure. They'll walk out of here. They'll have the heart attack. They'll be back and I get two dips at the ice cream dish on that basis.

Do you have any ideas?

I agree with what you're saying, but do we have any ideas practically as to how we can do it?

Dr. Clancy. We're getting there. And it's an area of intense focus for my agency, for CMS, and for other parts of the department, including FDA.

How do you create the right incentives? At 20,000 feet, we would all love to pay for quality. We'd pay more for better quality care.

It's drilling down to make sure that we do that in the right way.

What I can tell you, Mr. Chairman, is that we recently developed a summary of the best evidence that we have, short on how IT information technology can be part of that solution.

And I'd be happy to submit that for you.

Dr. McClellan. I think that, in building on that, there are a lot of things that can be done to make the kind of care that you got even more efficient.

First, we need better treatment so that you don't have to stay in the hospital 3 days to make sure that you don't have heart disease. It can be done more quickly.

Earlier this year, for example, FDA approved some new diagnostic tests for the presence of the enzymes that go along with a heart attack that make it possible to get patients determined whether they've got a heart attack or not more quickly.

It's uncommon for someone to stay in the hospital as long as 3 days to make sure that they don't have a heart attack.

We need better incentives for payments, as you and Dr. Clancy have mentioned. A lot of people are concerned these days about the rising amount of costs that people have to pay out of pocket.

But that has made some people more sensitive to the overall cost of care that they're getting, doctors and patients, to try to work together to find ways to keep those total costs down.

And it would be nice to have added incentives as well to prevent the diseases in the first place. If there are a lot of steps that people can take to keep them from getting heart disease in the first place through a good diet, through regular exercise, good nutrition, that significantly reduces the chance of developing heart disease and many other chronic diseases that are extremely costly today in the first place.

That's the kind of health care system that we need. And the kinds of incentives that we've been talking about would help us move in that direction.

Senator Bennett. Now you opened the door to another whole area, which is the possibility through technology to do screening and thereby be in a position, A, for preventive care or, B, maybe a subset of A, counseling, where you could not in the pre-technology age justify the cost of screening tests for everybody.

You'd have to wait until you have some kind of symptom before you run the test because the test is so expensive.

When you've got a screening test that is very, very cheap, you could go into a school, for example, and screen all the high school seniors and tell 4 percent of them that they are going to be at risk

for this, that, or the other in their lives, and they have no symptoms yet.

And, presumably, the long-term benefit of identifying those that are at risk for a variety of reasons, and then treating it before the symptoms start out would bring down the long-term societal cost of health care, would it not?

Dr. McClellan. Well, it would certainly help people get longer and healthier lives for the same, if not less, money.

I think it would be worthwhile from that standpoint to encourage the development of these technologies.

You mentioned, you're obviously on top of what's going on in new medical technology. But there are a lot of technologies coming along as a result of breakthroughs in genomics and understanding how gene function works that will potentially allow us to have much more individualized therapy.

So we can tell for people, not only which drugs or medical treatments may be indicated to prevent diseases or keep them at bay based on their specific molecular basis of disease, but this goes beyond medicine as well.

People are increasingly going to have information about specific changes they can make in their diet and there are increasingly going to be foods available that are tailored to people that have particular nutritional needs to help them prevent diseases.

So there's a lot of potential there for more individualized high-value medicine. That's not the kind of health care system that we have now.

Senator Bennett. No.

Dr. McClellan. Those technologies are not yet in place. We need to think carefully about how the policies that we're implementing today might encourage or discourage the development of that potentially better future.

Senator Bennett. Since this Committee has no legislative authority, we can go anywhere we want. And that's what we're trying to do with this hearing, is to get an understanding of what the ideal health care system might be, which we could then recommend to the committees that have legislative authority.

And of course, underpinning it all is the overall economic impact.

Let's take an example that we don't think of as technology, but that's an example of what we're talking about—inoculation.

We routinely inoculate every child in this country with a variety of shots. Now, we have some problems in some areas of the country where the parents or guardians, whatever, don't bring the children in.

I remember we had this debate at the beginning of the Clinton Administration when they very appropriately said the Federal Government ought to finance inoculations for everybody.

All of the concern about the people who are left out, the uninsured, which has become the shorthand name to describe those who don't have health care. And the government is going to pay for all this.

And then we discovered, somewhat to our chagrin, that money is not the problem, that the inoculations are available everywhere to everyone, and the problem is that the parents or guardians, if there

are some—in many cases, there are neither—don't bring the kids in to be inoculated.

The technology is there, but in this case, it's not used. They don't have access. They don't take advantage for a variety of socio-economic and other reasons.

But that's an example. Let's just set the non-participation issue aside for just a minute. That's an example of where the cost has come down so low, that society can afford to fund a 100 percent participation. And we've stamped out smallpox. We've stamped out a lot of the things that were normal when I was a little kid growing up.

We've done it universally. It is a form of universal health care, to pick a phrase.

Could the day come when stepping up from that level to screening tests and diagnostic examinations would be universal in the same fashion, and be administered through the school system and produce the kind of economic benefits that come from the fact that we no longer have the epidemics of many of these diseases that have been taken care of through vaccination?

In this case, there wouldn't be a vaccine. There would be a treatment. There would be a tailored drug, the kind of thing that you're talking about.

Is that something that we can envision and maybe drive toward as policymakers down the line? I understand that there are going to have to be all kinds of cost studies and examination.

But is that an idea to which we should aspire or is that a stupid idea that we should forget?

Dr. McClellan. I think it's a great idea to aspire to. But I do think that it's a long way off. There is a tremendous amount of research going on now in terms of what kinds of impacts the latest genomic sciences have for patient care.

But the problem is that we really don't know a lot of the answers yet. Virtually every pharmaceutical company and biotech company is now doing extensive testing of all of their compounds in development on what are called micro-rays—chips that have literally hundreds, if not thousands, of genes on them, to see how the genes are up-regulated or down-regulated.

And these are genes that might be involved in disease processes like cancer, heart disease, or genes that might be involved in toxicities from drugs, like liver enzymes or something like that.

So we're getting a lot of information in now. The problem is we don't have much translational research yet to tie what happens with these gene expressions to what it actually means for a patient's outcomes, for impacting the course of the disease or determining whether or not a treatment would be harmful to an individual patient.

And that's what I meant when I talked earlier about a lot of research going on more than ever before in biomedicine that is moving in this direction of a more individualized, highly effective health care system.

But we don't yet know, we're not yet there and we're still a ways away.

One of the main things that we're focusing on at FDA is to try to make that, what could be a long process and a costly and uncertain process, more certain and less costly.

But even if we get those technologies developed, and that's iffy at this point, there needs to be financing mechanisms in place, incentives in place to encourage the adoption of these more individualized treatments rather than the one-size-fits-all policies.

Senator Bennett. Well, we've examined a whole series of what-ifs here, and I appreciate your willingness to take this journey with me.

Commissioner McClellan, I understand that you have to leave at this point.

Dr. McClellan. Thank you.

Senator Bennett. We've probably reached the point of diminishing returns in our speculation as to what might happen.

Let me thank you both very much for being with us today. And if you have any additional thoughts that this conversation may have triggered, we'd appreciate hearing from you and we'd be happy to make them part of the record.

Dr. Clancy. Thank you. We'd be delighted.

Dr. McClellan. We're going to, obviously, keep working closely together on many of these issues and would hope to be able to keep in close touch with you as well.

I've learned a lot from this session and maybe the most important thing is your good cardiology report.

Glad to know that you'll be up there for quite a while working with us on this.

Senator Bennett. Mitch McConnell gave us all a scare when he took his stress test and ended up having a triple bypass.

He's 10 years younger than I am and said, "You'd better have one." I went to the same place where he had his and they said, "you don't need to come back for another 10 years."

Dr. Clancy. Well, I was going to say, I would agree with Dr. McClellan's comments and also say that it's really unusual to be told that we don't need to see you for 10 years. That's about the highest approval that you could get.

Senator Bennett. Yes. Thank you both very much.

Our second panel will provide further insights on health care innovation. We're privileged to have Dr. Peter Neumann, who is the Associate Professor of Policy and Decision Sciences at Harvard School of Public Health, and Dr. Neil Powe, Director of the Welch Center for Prevention, Epidemiology, and Clinical Research at Johns Hopkins Medical Institution.

We have Harvard and Johns Hopkins. The only thing that's missing is the University of Utah.

[Laughter.]

But at least we have two of the three.

[Laughter.]

We very much appreciate your both being here. We welcome your thoughts on the challenges. And we'd be happy now to hear from you in your opening statement, and then continuation of the dialog that we had with the first panel.

Professor Neumann, let's start with you.

OPENING STATEMENT OF DR. PETER J. NEUMANN, DEPUTY DIRECTOR, PROGRAM ON THE ECONOMIC EVALUATION OF MEDICAL TECHNOLOGY, HARVARD SCHOOL OF PUBLIC HEALTH

Dr. Neumann. Well, thank you very much, Mr. Chairman, for your invitation to speak before this Committee on the topic of technology, innovation and their effects on cost growth in health care.

My name is Peter Neumann. I'm Associate Professor of Policy and Decision Sciences at the Harvard School of Public Health.

I would like to speak today about how we can better understand the value or cost-effectiveness of medical technology.

Broadly speaking, medical technology contributes to growth in health care expenditures, as we've been hearing.

But as we've also heard, this research says nothing by itself about the benefit side of the equation. As we consider medical technology, it is important to address not just how much medical technology contributes to health costs, but whether the investments in medical technology are worth the health benefits produced.

We would all like to get good value for our money when we pay for new drugs, devices and procedures. How do we get there? What tools do we have to use and what policy options are available?

Formal economic evaluation can help us answer these questions.

The field of economic evaluation of health and medical interventions has been an active area of research in recent years. It includes cost-effectiveness analysis, which shows the relationship between the total societal resources used, the costs, and the health benefits achieved, the effects for an intervention compared to an alternative strategy.

Often, a standard metric such as life-expectancy or quality-adjusted life expectancy, is used as the measure of health benefits.

In part, with funding from the Agency for Health Care Research and Quality, my colleagues and I have compiled a list of over 1500 cost-effectiveness ratios covering a wide variety of medical technologies and public health strategies in many disease areas.

More information is available on our website.

These data underscore several important points about the cost-effectiveness of medical technology.

First, a great deal of information on the topic has become available to policymakers in recent years. Unlike many unsupported assertions about the cost-effectiveness of drugs and other medical technology, these studies quantify costs and health effects using data and a standard, well-accepted methodological technique.

Second, according to peer-reviewed articles, many technologies are indeed cost-effective. Examples include warfarin therapy to prevent stroke in those with atrial fibrillation, immuno-suppressive drugs for those with kidney transplants, and treatment with mood-altering drugs for those suffering from depression.

These interventions provide good value in the sense that they produce health benefits for relatively little cost, or may actually save money for the health care system, despite their sometimes high pricetag.

Third, cost-effectiveness does not mean cost savings. Over the years, people have sometimes confused these terms. But restricting the term cost-effective to cost-saving interventions would exclude

many widely accepted interventions which do not save money, but are cost-effective in the sense that their additional benefits are worth their additional costs.

A related point is that a critical aspect of any medical technology's cost-effectiveness involves the manner in which the question is framed. A technology is not intrinsically cost-effective or cost-ineffective.

It is only meaningful to say that a technology is cost-effective compared to something else.

A drug prescribed to lower an individual's blood pressure may in fact be cost-effective compared to the option of no treatment, but not necessarily when compared to an alternative intervention such as an intensive program of diet and exercise or other medication.

Similarly, claims of cost-effectiveness often depend on the population under investigation.

For example, statin drugs used to lower an individual's cholesterol have been found to be relatively cost-effective as secondary prevention in persons with existing heart disease, but considerably less cost-effective as primary prevention.

Well, does anyone actually use cost-effectiveness analysis?

Logically, cost-effectiveness analysis should be used by private insurers and state and Federal policymakers. However, many payers, including Medicare, have shied away from using cost-effectiveness analysis in coverage and reimbursement decisions.

But why?

Cost-effectiveness analysis promises to inform decisions and enhance population health in an explicit, quantitative, and systematic manner. Medical journals, including the most prestigious ones, routinely publish cost-effectiveness analyses.

Furthermore, many other countries have incorporated cost-effectiveness analysis into their policy decisions.

How do we explain this paradox?

Studies point to a couple of explanations. Some of them fault the methodology itself. But, in fact, most experts agree on the basic tenants. Instead, the opposition more likely relates to the hardened American distaste for explicit rationing.

This is understandable, perhaps, but still, how do we get good value in face of this opposition?

I would offer five observations as we look ahead.

First, cost-effectiveness analysis should not be used rigidly. Leaders in the field have always warned against using cost-effectiveness analysis mechanically, but experiences teach us that rigid use of cost-effectiveness analysis will be resisted.

Expectations for cost-effectiveness analysis should be more modest. Cost-effectiveness analysis should inform decisions, not dictate them.

Second, cost-effectiveness analysis will probably not save money. Cost-effectiveness analysis should not be conceptualized or promoted as a cost-containment tool, but rather, as a technique for obtaining better value.

Paradoxically, using cost-effectiveness analysis may actually increase health spending because it often reveals under- rather than over-treatment.

Third, how you say it probably matters.

Research shows that physicians understand that resources are limited, but they are not willing to admit to rationing.

Similarly, health plan managers deny that they ration care, but admit that their budgets are constrained. These responses are instructive. It suggests that the term "cost-effectiveness," may be part of the problem. We might instead use terms such as "value analysis" or "comparability," rather than "cost-effectiveness analysis" and "rationing."

Context also matters.

Cost-effectiveness analysis may be acceptable to guide choices on how frequently to screen for certain diseases. It may not be acceptable to guide choices for those in need of life-saving treatments.

Fourth, incentives matter.

Debates about the use of cost-effectiveness analysis cannot be separated from debates about the underlying health system and the incentives it embodies.

Cost-effectiveness analysis is sometimes opposed because it is used centrally by a single decisionmaker. How to reconfigure incentives in the system is a related but somewhat separate and still critical challenge.

Fifth, the final message involves the importance of thinking expansively about applications of cost-effectiveness information.

Cost-effectiveness analysis should not simply focus on medical interventions; but more broadly, on interventions to improve health by reducing environmental exposures, injuries at home and in the workplace, and motor vehicle accidents.

In closing, let me emphasize that whether medical technology offers good value is a question that can be best informed by careful analysis.

I would encourage the judicious use of cost-effectiveness analysis in the years ahead.

Thank you very much, Mr. Chairman, again for your invitation and I'd be pleased to answer any questions you have.

[The prepared statement of Dr. Peter Neumann appears in the Submissions for the Record on page 53.]

Senator Bennett. Thank you very much.

Now am I pronouncing your name correctly, sir?

Dr. Powe. "Po."

Senator Bennett. "Po." Very good. Thank you for being with us and we'd appreciate hearing your testimony.

OPENING STATEMENT OF DR. NEIL R. POWE, DIRECTOR, THE WELCH CENTER FOR PREVENTION, EPIDEMIOLOGY, AND CLINICAL RESEARCH, THE JOHNS HOPKINS MEDICAL INSTITUTION

Dr. Powe. Good morning, Senator Bennett. I'm a general internist, a clinical epidemiologist, and a health services researcher. My research has assessed the clinical and economic impacts of biomedical innovation in medicine.

It examines the impact of new and established technologies on patients' longevity, functioning, quality of life and, of course, cost. I've conducted cost-effectiveness studies of technologies in several areas of medicine and I've attempted to do so with equipoise.

I've also studied physician decisionmaking and other determinants of the use of medical technology, including payers' decisions about insurance coverage for new medical technologies and the impact of financial incentives on the use of technology.

New medical technologies include drugs, devices, procedures and the systems in which we, as medical professionals, deliver them. They include so-called "little-ticket" technologies which cost relatively little individually, but when used at high frequency, can become expensive. One such emerging "little-ticket" technology is the C-reactive protein laboratory test for detecting inflammation now being debated as a useful technology for detection of heart attack risks. "Big-ticket" technologies such as body scans and organ transplantation have high individual price tags and can generate high costs, even when used relatively infrequently. In theory, a new medical technology can increase costs, have similar costs or decrease costs relative to an existing standard technology. Evidence to date suggests that much of new biomedical innovation increases cost to the health care system, especially in the short-term. "Little-ticket" or "big-ticket" technology should not be judged based simply on costs. The more important question that I'd like to address is what is the technology's value?

Value is commonly seen as the benefit that's derived relative to the cost. In theory, a technology can produce benefit relative to the existing standard if patient outcomes are better. On the other hand, it can produce no benefit if outcomes are similar or even produce harm if patient outcomes are worse. High value occurs when substantial improvement in patient outcomes occurs at a reasonable cost.

Americans believe in the concept of value and understand it. For example, they're willing to pay more for many things—a particular type of clothing, food, service, house, automobile—because they believe that the utility that's derived from the purchase is worth the higher price. Cost is a relevant factor, but value is paramount, so much so that medical technology needs to be judged in the same way.

Twenty-five years ago, the science of assessing value in medicine was rudimentary and underdeveloped. Many of the tools that Dr. Neumann talked about for assessing value were first applied to health care in the late 1970s and early 1980s. These include patient outcomes research comprising clinical trials, evidence synthesis and cost-effectiveness.

These have undergone refinement by researchers at universities around the country. Much of the work has been catalyzed and funded by the Agency for Healthcare Research and Quality. These researchers have sought to create rigorous standards of high quality research for value science.

Despite the maturation of and demand for the science of values, its impact has been limited for three reasons.

First, there is an unprecedented number of new technologies now entering the healthcare marketplace. These include minimally invasive surgery, as you mentioned, the transplantation of hearts, lungs, livers, kidneys, biotechnology drugs, indistinguishable from natural hormones for patients with congenital or acquired deficiencies, dialysis therapy for end-stage kidney disease, automatic

implantable defibrillators and cardiac resynchronization devices to bring life to those with life-threatening arrhythmias and heart failure.

Knowledge of the structure and function of the genes and proteins is advancing rapidly and the future will yield even more promising technologies we never imagined for identifying, preventing, and treating acute and chronic illnesses.

However, the level of funding for high-quality and unbiased value assessment pales in comparison to the explosion of new biomedical innovations.

To the public, payers, and providers, the entry of new medical technologies into the practice of medicine now seems like a series of intermittent "surprise attacks" on the pursestrings of American health care. It has been suggested that less than a fifth of all practices in medicine are subjected to rigorous evaluation and still less receive an adequate assessment of the cost consequences in addition to the clinical consequences.

We are likely to witness a continuing salvo of surprise attacks in the coming years without adequate funding to do early, comprehensive, balanced and rapid assessments.

In a study with researchers at AHRQ, I found that medical directors making coverage decisions for new medical technologies at private health care plans across our country are impeded in their decisions because of the lack of timely effectiveness and cost-effectiveness information. There is considerable trepidation to decide against covering potentially useful technology without adequate evidence.

Likewise, there is a concern about making a coverage decision in favor of a technology that might later be shown to have minimal benefits at a large cost to society. The preference of those making decisions about coverage and payment for technology was for high-quality outcomes research funded by authoritative government entities.

Early assessments of clinical and economic outcomes could be accomplished with investment of a small fraction of annual health care expenditures on value assessments. The payoff would be substantial.

For example, contrary to relentless, direct-to-consumer advertising for body CT scans to detect occult disease, my colleagues and I recently found that screening smokers for lung cancer with helical CT scans is unlikely to be cost-effective unless certain conditions are met.

The high number of false positive lung nodules detected by the scans can potentially lead to more harm from invasive and costly surgical procedures.

Early assessments such as this, which include primary data collection, secondary data collection, data synthesis, and sometimes modeling and forecasting will secure information for the American public and its policymakers in a timely fashion needed to prevent premature dissemination of costly technology with little or no value.

The Agency for Healthcare Research and Quality, as well as the National Institutes of Health, could act as a focal point to bring the best team of value researchers in the country to attack these issues

by performing clinical effectiveness trials, observational studies, cost-effectiveness analyses, and meta-analyses.

If introduction of some new technologies does not decrease cost, at least through generation of better and more timely information, Americans can make sure that what they are purchasing provides good value for the dollars they spend.

Early assessments are particularly important given rising numbers and costs of pharmaceuticals, current consideration of a Medicare prescription drug benefit and use of tiered pricing arrangements in the private sector to control drug spending.

Tiered pricing is a mechanism to allow consumers choice in particular drug treatments when they believe one drug has value over another. However, they must pay more when choosing to use a more expensive medication.

Placement of a pharmaceutical into a particular tier and patient decisions to buy and use it are dependent on unbiased information about the benefits and the costs of the pharmaceutical relative to the benefits and costs of competing medications. That is, relative value.

Second, as a corollary, funding for career development of value scientists needs substantial bolstering to expand the cadre of people with the capability to perform such research.

Far too few physicians and other health care professionals and scientists have the necessary training to understand and produce value science that integrates clinical and economic issues.

Third, understanding how technologies affect cost and value involves an understanding of the barriers to decisionmaking for health care providers. Barriers to optimal decisionmaking can lead to technologies being overused, underused, or misused.

My colleagues and I performed a study of the factors affecting physician decisionmaking with regard to adherence to clinical practice guidelines. We found that there is a process that must take place for a new technology to become routine standard practice.

Physicians must be aware that a new technology exists, agree that it has value, be willing to try it—that is, adopt it—and then they must adhere to its use.

Lack of awareness leads to underuse. Underuse of an effective technology can lead to higher expenditures in the future.

For example, if physicians were not aware that in patients with diabetes, urine protein screening for detection of occult kidney disease and application of ACE inhibitors can delay or prevent expensive dialysis treatment at greater than $50,000 per patient per year for end-stage kidney failure, they might never employ the strategy in their practice.

Fortunately, methods of communicating new information to clinicians are improving through rapid summary publications, clinical practice guidelines by professional societies, and dissemination through electronic means. Ways for helping them acquire and assimilate new information are needed.

If aware of a technology, physicians must agree with the evidence that a technology is effective or safe. If high-quality evidence on representative patient populations is not available, physicians may disagree on whether the technology provides benefit.

We studied how early assessments, released through brief clinical alerts that were not comprehensive, influenced the use of carotid endarterectomy. We found that clinicians may extrapolate research findings to populations without clear evidence and indications. Value science can provide clear evidence.

Awareness and agreement are necessary for appropriate use of technology, but insufficient. Even being aware and with strong evidence of effectiveness, physicians may not adopt innovations if there are administrative barriers to its use or the lack of self-efficacy.

They may also adopt technologies with little benefit if payment policies that we talked about and heard before prematurely promote a technology's use.

Financial incentives in payment policy influence both adoption of and adherence to use of technologies.

Thus, proper use of new technologies means that the physicians who apply them and the systems into which they are placed are adequately configured and incentivized to make optimal use of the technology.

To this end, there's a need for more behavioral and systems research that studies how biomedical innovation from laboratories is optimally and rapidly translated into interventions to improve the health of patients treated at hospitals and physicians' offices.

In conclusion, biomedical innovation has brought the United States new, unprecedented medical advances that save and improve the quality of patients' lives. We need to continue to encourage biomedical innovation. But we must recognize that for many health conditions, technologies will bring higher rather than lower absolute cost.

Cost is relevant, but value is far more important.

We need to protect biomedical innovation and America's purse by furthering the science of assessing value in medicine.

Strengthening our nation's capacity to perform value science will help private and public payers in this regard and provide information that physicians and consumers of medical technologies need to make decisions about their care.

The American people cannot afford to have technology used unwisely. A fraction of health care expenditures in the U.S. should be targeted to the value science of medical care.

Thank you for the opportunity to address you today and I would be happy to entertain any questions you have.

[The prepared statement of Dr. Powe appears in the Submissions for the Record on page 56.]

Senator Bennett. Thank you very much, both of you, for your thoughtful presentations.

You listened to the first panel. Were either of you anxious to break in with something that you really wanted to say and straighten out any of the conversation that we had in the first panel?

Dr. Powe. Well, I'd like to comment on your experience with the esophageal spasm, which I thought was interesting. Your question about whether there might be some innovation in the future, a test in the future that might have prevented the sequence of events

that you went through. And in fact, I think that there are likely to be technologies that do that.

One of the problems is that there may be 50 technologies that are tried out before we get it right. And what that means is that as we experiment and use those technologies, we don't know what effect each one of them is going to have on the system.

Senator Bennett. That means high cost at the front end, but, presumably, you end up with one that means low cost at the back end.

Dr. Powe. Right.

Senator Bennett. And we're not seeing the low cost yet. We're still getting all of the high-cost front-end stuff.

Dr. Powe. Right. And while we're trying them out, the typical situation is not that one technology will supplant another technology, but that it will add on in the process as we learn how to use it. Then maybe, in fact, later on, it may supplant another, our existing technologies.

Senator Bennett. Yes. Did you have anything?

Dr. Neumann. I just wanted to add one——

Senator Bennett. Don't worry about my spasm because it's fine.

[Laughter.]

Dr. Neumann. OK.

Senator Bennett. But the conversation, generally.

Dr. Neumann. Yes, and I'm very glad to hear that.

Senator Bennett. Yes.

[Laughter.]

Dr. Neumann. I agree with much of what was said earlier today.

One issue that perhaps was alluded to, but I would just amplify on, and I think it's an important policy lever, is funding for value research, cost-effectiveness research.

We spend a lot of money, and a lot of it is well spent, on biomedical research. We spend really, as Dr. Powe said, very little on health services research and value research.

Senator Bennett. Maybe part of our problem as we address this as policymakers, coming through in your testimony and in the first panel, is that we're looking down a stovepipe.

Let me give you another example out of real life.

Merrill-Lynch hired a doctor to come lecture to all of their brokers. That's a pretty good contract to have if you're the doctor. You get to train every Merrill-Lynch broker.

They did that. Every new broker hired at Merrill-Lynch had a session with this doctor. They said, "We decided to pay that cost, an increased training cost, because we suddenly realized how many of our brokers were dropping dead from stress, having heart attacks and literally dropping dead. We figured out how much it cost us to replace them in terms of training, experience, et cetera."

A manager of a large Merrill-Lynch office told me—now this was before the days of online trading and all the rest of this, this was at a time when everything was done in a particular office—"If we have a branch manager drop dead from a heart attack, that's hundreds of thousands of dollars that we have invested in him"—and it's usually a him. "And if, with tens of thousands——

[Pause.]

Senator Bennett. [Continuing.] Excuse me. The spasm may be fine, but my cold is still here.

"If with tens of thousands of dollars training people on diet, stress management, et cetera, up front, we can save the hundreds of thousands that would come from having these people die, it's worth it."

Now, we are focusing entirely in public policy discussions on the cost of health care premiums, the cost of Medicare. And I think the government is dealing with the cost of Medicare in exactly the wrong way by simply saying that we will arbitrarily pay only X-percentage of this.

But that's another debate and I said at the outset, we're not going to get into that debate here.

But I think when we're talking about value and costs, we're saying the country as a whole and the economy as a whole is better off, even if we're seeing an increase of 15 percent per year in cost, because of the increase in productivity, the increase in contribution, et cetera, of the lives that are saved. And we don't figure that into the conversation.

Now it does get figured in, wearing your economist's hat for just a minute—you both say you're not economists, but the Commissioner was.

Let's look at health care cost as a percentage of GDP, and say if the health care cost does not grow more rapidly than the GDP grows, we're fine, because we're getting the benefit of increased GDP.

Now, as soon as you do that, you're at 3 percent. And nobody's going to bring health care costs down to 3 percent. But if we could find some calculation that says the contribution to GDP is 12 percent per year by virtue of what we get, then we could say, society as a whole can justify this kind of an increase every year.

The problem for the employer is, the individual employer, he's getting hit with that 15 percent compound every year and he does not see the benefit in his employee pool because most of the benefit is coming for the retired. And he says, I can't sustain this any longer.

Just react to that and give me what you think the real value to society is from—to pick a number for sake of conversation, a 15-percent per year compounded increase in health care costs, which is enormous in terms of the burden that it puts on employers—and taxpayers.

Dr. Neumann. Right. Well, you raise many very good points.

I guess I would say a few things.

One, I think we in the academic community, maybe society at large, feel frustrated because we see increases in health care spending. We see the 15 percent. We see the 14 percent of GDP. And there's a feeling that perhaps we're not getting the benefits, the health gains we should be getting, or perhaps we don't have the tools to measure it very well.

I think some research that Dr. McClellan referred to by economists in recent years have begun to document better, that in fact, the additional spending on health is resulting in measurable gains

that are worth paying for, gains in terms of increased life expectancy, gains in terms of decreased disability rates, and so forth.

Now, even if we can get ourselves there, there's still the other problem you referred to, which is employers now feeling that they are getting those gains, that the gains are coming to retirees later in life and so forth.

I think that's a real problem and challenge.

Part of it may be a measurement issue, that in fact, productivity is growing and the employers genuinely are getting returns and we just haven't been able to measure them very well.

But part of it may be kind of a structural issue, that they are being asked to pay for health gains that occur later in life.

And that's a challenge.

Dr. Powe. I would agree that some of the benefits or value is coming in terms of longevity and improved quality of life. And at least for the working population in terms of increased productivity—and they've been measured in many types of the studies that we've talked about.

The issue of the pressure from retiree health expenditures, I think, is a vivid illustration of what Dr. McClellan was talking about, about incentives not being aligned correctly within our society with regards to health care.

So I think that's going to take an alignment of incentives in order to have everything work in concert to address that issue.

Senator Bennett. Do either of you have an opinion as to whether or not Federal laws and regulations distort the creation or the use of new technologies and innovations in health care? Or do they encourage?

Dr. Neumann. I guess I would say two things.

One, they probably do both and there are probably certain incentives in the system that encourage and some that discourage.

One issue that I've been doing some thinking and writing about is Medicare and cost-effectiveness. Medicare hasn't formally incorporated cost-effectiveness analysis into its decisionmaking process, despite attempts to do so, and even attempts to offer proposed regulations that would allow it to do so.

It doesn't seem to be a statutory issue. That is to say, Medicare's statute says that it will pay for reasonable and necessary services in some categories.

That seems to allow it to use cost-effectiveness analysis. It has never been able to get there because of larger issues, fear of rationing and so forth.

That may have to change with legislation eventually.

Dr. Powe. I think that our regulations and laws actually strike an appropriate balance, checks and balances within the system.

In some sense, we have patent regulation that promotes biomedical innovation because it provides a period of time where competitors cannot come in and sell particular products.

So I think that that promotes biomedical innovation and it's probably a necessary thing that we have.

But, on the other hand, then we have an approval process for drugs that the Food and Drug Administration on the back end says that you have to show efficacy and safety.

So that there's checks and balances there.

On the coverage side, whether things are paid for, I think that things are a little bit more helter skelter, both in regards to public and private coverage of new medical technologies.

And we don't really have a uniform system of criteria for doing that. I think that some of the points that we're trying to make is the use of value science to actually help in that process to develop the kinds of criteria that should be used to cover technologies.

Senator Bennett. Getting back to one of the questions that probably I should have asked the first panel, but you have just as much expertise in here.

One of the statements that is made is that once a provider invests in new equipment—say he buys an MRI machine—he then feels he has to use it, even if, medically and diagnostically, it isn't necessary because he has to get his money back by running as many tests as possible through it and charging.

Then another provider decides he has to buy an MRI machine if he's going to compete and you have overcapacity and then, ultimately, overuse.

Again, let me describe a brief experience that I had when I was on the campaign trail the first time and visiting a hospital. I'm a businessman by background. I innocently asked these people if they had an MRI machine. This is when MRIs were relatively new.

And they looked at me like I was an idiot—which I was—and they said, "Well, of course. We have to have an MRI machine." And I said, "What's your usage?" And they said, "30 percent of its capacity."

And, being a businessman, I said to them, "Well, the marketplace is trying to tell you something. It's trying to tell you that you don't need an MRI machine. Maybe we ought to do something at the Federal level to change the anti-trust laws in such a way that you could make a deal with the hospital down the street. If you're only using their MRI machine at 30 percent, then you could contract that you'd send your stuff there."

Again, they looked at me like I was a bigger idiot and said, "The marketplace demands that we have an MRI machine." And I said, "No. If the marketplace was demanding that you have an MRI machine, you'd be getting 100-percent utilization."

We talked past each other on this issue until the light suddenly went on in my mind, that when they were talking about the marketplace and their customers, they were talking about insurance companies. When I was talking about the marketplace, I was talking about customers—that is, patients.

Insurance companies told them, "We will not approve patients being sent to your hospital if you don't have an MRI machine." So they really didn't care whether it was utilized ever, as long as it was on the premises so they could certify, we have an MRI machine.

When I was talking about the marketplace, selling things to customers, I was talking about the number of customers walking through the door. The patients walking through the door weren't their customers. The insurance company paying the bills was their customer.

Now, do we have, in fact, an overcapacity built in by virtue of the third-party payer system and then a sense of we have to get

our money back by running tests through this machine that is part of the escalating health care situation created by technology?

Dr. Powe. Well, that's a tough question to debate.

Senator Bennett. That's why the staff came up with it.

[Laughter.]

Dr. Powe. I guess one solution would be to do away with insurance companies and have patients pay. But I think that that would cause even greater problems by having many people pay out of pocket.

There are safeguards that insurance companies do on the other hand in terms of making sure that the populations they serve receive the very best care and can do that because they have large purchasing power and can actually influence the quality of care that providers provide.

So I'm not sure that we ought to go to a system in which patients would pay directly out of pocket like we do in other areas, other sectors of the economy.

Dr. Neumann. I would agree with Dr. Powe, especially with the notion that that's a very tough question.

But I guess I would say two things.

One, in some sense it's an evidence question, it seems to me, and Dr. Clancy talked about this. As we move as a culture, as medical establishment toward evidence-based medicine, one hopes that tests that are ordered will be tied to studies that shows that they're appropriate, that they work for the patients they're being given to.

And part of the problem that you identified might be addressed with better evidence.

But another issue, and perhaps more important issue, is the structure of the marketplace and the incentives that it embodies.

Why the situation exists in the first place, that the hospital felt the need to buy the MRI in this case. And that's a very complicated question.

We create insurance because it solves a problem. But it also creates some other problems.

We can talk about establishing the structure of the marketplace and the incentives, changing incentives, but that's a very large debate.

Senator Bennett. Yes, and it's a debate I'll have in another forum at another time.

But, Dr. Powe, I'd be happy to talk to you about this. I think getting rid of the third-party payer for routine activity would actually be beneficial.

I think insurance ought to be for catastrophic events. Health is the only place where insurance pays for routine activities. If I have car insurance, it doesn't pay me for changing the oil. It only pays me when I'm in a wreck.

And I think health insurance should only pay me when I have a serious health problem. I should not necessarily have to file an insurance claim for a routine kind of test. But that's another debate for another day.

Dr. Powe. In fact, I think we're evolving to a system in that way. I think most people when they see a physician have to pay something out of pocket today in terms of coinsurance and deductibles.

Senator Bennett. Yes.

Dr. Powe. So the cost is not entirely free for non-catastrophic services today.

Senator Bennett. Do either of you know the extent to which Medicare or the veterans health program, as well as private insurers, are already using some kind of cost-benefit analyses to make judgment calls?

And if so, how do they do it? Or is this a brand new idea that still hasn't caught on?

Dr. Neumann. Well, for the most part, Medicare has not. There are a couple of exceptions over the years. They've added some preventive services that were informed by cost-effectiveness analysis. But they haven't formally incorporated into their coverage process.

Despite some attempts to do so, they haven't been able to for various reasons that probably have more to do with politics and fears of rationing than they do with statutory limitations.

My sense is that the VA does use it on occasion to inform decisions about which drugs go on formulary, which drugs go on first-line treatment, second-line treatment, and so forth.

But, again, my sense is it's limited there as well.

Senator Bennett. What about private insurers?

Dr. Neumann. Well, that's I think a difficult question to answer in the sense that surveys—and Dr. Powe has done some of these—surveys of health plan managers, medical directors, that ask them, "Do you use cost-effectiveness analysis?", often yield a response, "No, we don't use it."

We look up clinical evidence and base our decisions on clinical evidence.

I think if you drill down a bit, though, it becomes clearer that cost-effectiveness evidence and other economic information does inform decision.

And in some sense, perhaps they're not willing to admit it because they're afraid of admitting to the rationing. And in some sense, I think it's almost an indirect piece of evidence that they use because they've read a journal article or they adhere to a clinical guideline that has, in fact, used cost-effectiveness evidence.

Senator Bennett. Dr. Powe.

Dr. Powe. I would concur with Dr. Neumann. The entities that you mentioned are making value judgments. They may not formally be using cost-effectiveness analysis in the formal sense that researchers might, but they are making value judgments and using the components and the logic of the science of value in making those judgments.

They may not call it cost-effectiveness analysis as such.

Senator Bennett. Well, ultimately, who should decide whether the additional cost of a new drug or a new medical device is worth it? The provider? The drug company? The government? NIH?

Dr. Powe. I think we all should.

Senator Bennett. When everybody decides, then nobody decides.

Dr. Powe. Right. But I think individuals have to decide when they cost-share in medical care, so they have to know the value of the treatments that they might pay for.

I think that the Medicare program needs to know the value of the treatments that they're paying for. I think private insurers need to know the value.

So I think we all are in this together. We do it for different things. But what will help us all is better information on what value technology has.

Senator Bennett. A vote has just started, and we've been going for 2 hours. I would love to continue this dialog, but I think we probably will close.

Let me thank you both again for your being here and your willingness to share your expertise, and invite you, if either of you come across anything that you think would help inform the issue that we're addressing here, to send it on in to the Committee.

Again, thank you all.

Dr. Neumann. Thank you.

Dr. Powe. Thank you.

Senator Bennett. The hearing is adjourned.

[Whereupon, at 11:30 a.m., the hearing was adjourned.]

Submissions for the Record

PREPARED STATEMENT OF SENATOR ROBERT F. BENNETT, CHAIRMAN

Good morning and welcome to today's hearing on how technology and innovation affect health care costs.

The United States has a health care financing problem that goes well beyond the budget challenges posed by Medicare. For many years, our health care spending has grown at a significantly faster rate than the economy, and projections indicate that this will continue. Any financial arrangement where expenses grow significantly faster than income is truly on very shaky ground.

In other sectors, new technologies usually lead to greater efficiencies and lower costs, yet it is unclear whether the same is true for health care. What's different about health care? Is it the technology or the way we pay for it?

How can we strike the right balance—providing access to the latest breakthrough technologies, while limiting an open-ended raid on the public and private treasuries that fund our health care?

During this hearing, we will explore these issues, bringing together some of the best minds from the public and private sectors to help shed some light on this situation.

We should first question whether technology and innovation have truly added to health care costs, as some claim, or have reduced health care costs through enhanced efficiency.

Secondly, we should examine whether new technologies are disseminated in an efficient and effective manner, and if there are areas where they are being overused or underused. For example, some have expressed concern that advanced imaging technologies may be overused, in part because of poor incentives in the payment formulas used by Medicare and other insurers. At the same time, an article in this week's *Health Affairs* highlights how new technologies may be underused in treating people who lack health insurance.

We need to find the right balance. We need to judge the cost-effectiveness of new technologies, so that we properly fund this critical work, without overpaying and adding additional upward pressure on health care spending.

Unlike most of the recent congressional debate on health care, this hearing is not about Medicare or its coverage of prescription drugs. However, this issue is crucial to Medicare and every other health care purchaser that faces the dilemma of how to add innovative new benefits without setting off an explosion of health care costs.

On our first panel, we are privileged to welcome Dr. Mark McClellan, the Commissioner of the Food and Drug Administration, and Dr. Carolyn M. Clancy, the Director of the Agency for Healthcare Research and Quality (AHRQ).

Our second panel will provide further insights on health care innovation. We are privileged to have Dr. Peter Neumann, Associate Professor of Policy and Decision Sciences atHarvard School of Public Health, and Dr. Neil Powe, Director of the Welch Center for Prevention, Epidemiology, and Clinical Research at Johns Hopkins Medical Institution.

We welcome each witness's thoughts on the challenges facing health care today. I want to thank Ranking Member Stark for his interest and help in organizing this hearing and in bringing these distinguished experts before the Committee. I ask all of you to join me in a bipartisan spirit as we engage in this important task.

PREPARED STATEMENT OF REPRESENTATIVE PETE STARK,
RANKING MINORITY MEMBER

Thank you, Chairman Bennett. I would like to commend you for holding this hearing on "Technology, Innovation, and Health Care Costs." It's an important topic that requires serious inquiry.

Finding the right balance between cost consciousness and allowing access to new, potentially life-saving, innovations is crucial. Progress and technology often extend and improve lives, such as an MRI that provides early detection of a tumor or new surgical techniques for cataract treatment. Yet in too many cases, the latest technology simply becomes a profit center for hospitals when other, less costly, treatments would serve patients equally as well.

Smart utilization can spread the benefits of new technology without substantially increasing health care costs. I believe that providing the highest quality health services should be our goal—a goal that cannot be compromised. As we've seen with HMOs, it is too easy to deny patients access to appropriate care in the name of cost cutting. Analysis of cost-effectiveness must be mindful of the needs and interests of the patient.

New drugs and medical devices are not the only advances we need. Better use of information technology would not only improve care, it could save lives. An estimated 44,000 to 98,000 Americans die each year because of medical errors, according to an institute of Medicine study. This is unacceptable and unconscionable. Many medical errors are attributed to poor handwriting and other sloppy mistakes. Storing medical records on IT systems would prevent many of these mistakes—and deaths—as well as allow for the easy transfer of records when a patient switches doctors or visits a specialist. The technology is available, but it is not being fully used.

Cutting-edge medical technology may as well be science fiction for the 41 million Americans without health care—people without the means to utilize innovative, and often, preventative treatments available to those with insurance. Among the uninsured, illnesses and deaths that may have been avoided if they had access to new technologies for the treatment of just three conditions—heart attacks, cataracts, and depression—cost our society more than $1 billion a year. The inequity in access to health care prevents health outcomes from being as universally successful as they could be.

Thank you Mr. Chairman and I look forward to the testimony of our witnesses.

PREPARED STATEMENT OF MARK B. MCCLELLAN, M.D., COMMISSIONER OF FOOD AND DRUGS, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Good morning Mr. Chairman and Members of the Committee. I am Dr. Mark B. McClellan, Commissioner of Food and Drugs, and I welcome this opportunity to testify before the Committee today. As we enter the 21st century, America leads the world in developing and commercializing new medical innovations and technologies. From information technology to biotechnology to materials science, United States (U.S.) scientists and high technology workers are making new discoveries and developing new products every day that are steadily improving the quality of our lives. This progress is critical to our health and our economic prosperity.

Innovations resulting from breakthroughs in science and technology fuel economic growth. According to the Department of Commerce, the information technology sector accounts for just seven percent of all businesses in the U.S. economy, yet between 1996 and 2000, it drove 28 percent of the overall U.S. real economic growth and created jobs at twice the pace of other sectors. These jobs paid twice as much on average as well. Many leading economists now believe that new discoveries in information technology led to investments over the last couple of decades that helped account for the historic surge in economy-wide productivity growth in the 1990s.

BACKGROUND

While all economists appreciate the contribution of such economic growth to the well-being of the U.S., there is often less appreciation of the contribution of innovations in biomedical technology. A primary reason is that technological change in medicine brings benefits in addition to direct economic gains, including increased longevity, improved quality of life, and less time absent from work. These benefits are not taken into account in standard measures of aggregate economic output. If a country had real gains in its overall health, but not in its material well being (most often measured by per-capita income) the national income accounts would not change, even though those accounts are often thought to measure the well being of a population.[1] In addition, the direct economic and public health benefits of developing important new medicines often takes considerable time to be realized. If a

[1] "Measuring the Health of the United States Population", Brookings Papers on Economic Activity, *Microeconomics,* 1997, 217-272 (with Elizabeth Richardson).

high-technology firm invents a better memory chip, the time to get that innovation into products sold in the U.S. could potentially be as short as a matter of weeks or months. Regardless of how promising a drug or other new treatment appears in the laboratory or even in animals, it must undergo extensive clinical trials before it can be approved as safe and effective for market introduction.

In recent years, economists have tried to quantify the value of biomedical innovation to society. Some economists actually estimate that the value of the longer and better lives that have resulted from translating new biomedical knowledge into steps to prevent and slow diseases is worth literally many trillions of dollars in better health. In particular, the value of biomedical innovation to the U.S. equals the value of innovation in all other sectors of the American economy combined.[2] Even with the benefits of new medical technology, the fact remains that technological innovation is a major source of increase in real per-capita medical spending in the U.S. Innovations in medicine can reduce spending on medical care. For example, treatments ranging from effective care for depression to laser eye surgery are much less expensive than in years past. But many new technologies result in increased costs, and in some instances the net effect of overall technological change has been to raise health care expenditures. First, when a treatment becomes less expensive and safer (fewer complications), more patients may decide that a treatment is worth the risks and unpleasantness. In the early 1980s, relatively few seniors had cataracts removed because the procedure required an unpleasant hospital stay, often had complications, and yielded imperfect results. Today, thanks to improvements in technology, millions more seniors with more modest visual impairment find that modern cataract surgery improves their lives. Second, many treatments exist that do things that simply were not possible before, such as allowing many patients to survive previously fatal or impairing diseases. Americans spend much more on transportation today than they did a century ago because of innovations in transportation ranging from automobiles to airplanes, allow people to go places they simply could not before. Similarly, patients with heart disease, cerebrovascular disease, cancer, arthritis, AIDS, and countless other conditions are living longer and better lives because of medical innovations that transformed fatal illnesses or illnesses that could only be treated with comfort measures into manageable conditions.

The increased spending on health care does not necessarily reflect negatively on technological change. While many studies attribute a large share of the age- and price-adjusted growth in per capita medical spending in recent decades to technological innovation, a key issue is whether the benefits of innovation are rising faster or slower than the costs.

This important question is difficult to answer. It depends on our ability to determine the value of output from the health services sector, and putting a value on a longer life or a higher quality of life is hard to appraise. Nonetheless, a limited number of studies have attempted to aggregate the medical value of new innovations across the whole health care economy in general and the drug industry in particular. Even with these studies, it can be difficult to sort out whether the observed improvements in health are from medical technology, or from other factors that may influence health outcomes, such as higher incomes, improved public health measures, or changes in behavior as a result of greater biomedical knowledge. To try to identify the net value of medical technology itself, several studies have attempted to measure the value of specific kinds of innovations. A number of studies have examined outcomes for specific illnesses, such as heart attacks and depression, where the impact of specific changes in technology can be examined more closely. While none of these studies are completely convincing in themselves, they generally show that medical innovation has greatly increased value, that is, the value of the improved health is far larger than the increase in spending.[3]

The reasons are quite intuitive. Individuals are living longer and better lives, because our nation is making real progress in the quality of medical care for many conditions. While the achievements of health improvements in past decades have been impressive, recent progress in genomics, proteomics, nanotechnology, informa-

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[2] Cutler, David M. and Mark McClellan. "Is technological change in medicine worth it?" *Health Affairs*; September/October 2001: 11-29. Grabowski, H., J. Vernon, J.A. DiMasi. "Returns on research and development for 1990s new drug introductions." In "The Cost and Value of New Medicines in An Era of Change." *PharmacoEconomics* 2002; 20 (Suppl. 3):11-29.

[3] Lichtenberg, Frank R. "Are the Benefits of Newer Drugs Worth Their Cost? Evidence From the 1996 MEPS," reprinted from *Health Affairs*, Vol. 20, No. 5, September/October 2001. Kleinke, J.D. "The Price of Progress: Prescription Drugs in the Health Care Market," reprinted from *Health Affairs*, Vol. 20, No. 5, September/October 2001. Lichtenberg, Frank R. "The Effect of New Drugs on Mortality from Rare Diseases and HIV." NBER Working Paper W8677, December 2001.

tion technology, and many other fields promise even greater improvements in our lives in the years ahead.

We achieved the improvements of the last few decades without a sophisticated science of genomics—the human genome was sequenced in just the last few years. Genomically-based drugs, and gene and tissue therapies based on genomic sciences, are making up a growing number of the new drugs entering clinical trials. We also achieved our recent progress without the new science of proteomics, and an increasingly sophisticated understanding of how gene and protein expression interact to cause disease in individual patients. We also did it without a new generation of increasingly powerful biomedical tools based on the latest information technology that can enable sophisticated systems for supporting effective medical decision-making. These additional tools increase the future potential for more effective, more targeted, even individualized medical treatments that can cure or at least slow or halt disease progression.

IMPACT ON HEALTH CARE COSTS

As health care costs have gone up, it is increasingly important to make sure we are realizing the full value of the new medical technologies that we create. Maximizing our public health gains and our economic gains from new medical technology also requires that we encourage high value innovations and also realize more value from the products that we use. This is important for the future, because while the cost of new medical technologies may continue to rise, the potential benefits of new treatments could grow even more dramatically.

We must find better ways to increase value, to keep modern care affordable, while still encouraging medical innovation. With these unprecedented technological achievements have also come unprecedented concerns about the total spending on healthcare and, in particular, about the rising spending on these new medical technologies. Many worry that, even if these new technologies come along, they will not benefit because they will not be able to afford the high cost. While we need to take new steps to address the problem of health care affordability, we need to do it carefully. We must address this issue in a way that will not risk the tremendous potential for public health and economic benefits from continuing medical innovation by putting significant new limits on the payments or the intellectual property protections of innovative treatments that have made it through an increasingly long and costly development process.

In particular, there is concern about the threats to innovation because the process of medical innovation—of turning sound ideas from insights in the biomedical laboratory sciences into safe and effective products for treatments—has steadily become more costly. Getting a product into general use is an increasingly lengthy and costly business and fraught with significant risk.[4] Some estimates put the total cost of developing a novel drug at more than $800 million, and by all estimates it has increased substantially in the past decade.[5] Too often, the process is unpredictable, and may take years of hard work with high costs for product testing and developing reliable production lines.[6]

Many people involved in the development of new medical technology believe the slowdown in drug approvals is likely to be only temporary. Currently, the National Institutes of Health (NIH) is completing a five-year doubling of its budget, to more than $27 billion. Less well known is that spending on research and development by pharmaceutical companies worldwide has also doubled since 1995 and now is estimated to be more than $54 billion. R&D spending by biotech and medical device companies is also rising. The impact of these investments in research is already becoming evident in the form of more investigational new drugs (INDs) under development than ever.

But if the impact of information technology on the economy is any guide, it may require a decade or more of increased investments in order to have a real impact on productivity—on how much output we get as a result of these inputs. And it could take much longer, because of the unusual length and uncertainty of the product development process in health care. At this point in genomics, for example, sci-

[4] DiMasi, J.A. "Uncertainty in drug development: approval success rates for new drugs" Chapter 20 in *Clinical Trials and Tribulations,* 2d Edition, revised and expanded. Cato AE Sutton L Cato A III, editors. New York: Marcel Dekker, 2002:361-77.

[5] DiMasi, J.A., Hansen, R.W., Grabowski, H.G. "The Price of Innovation: New Estimates of Drug Development Costs." *Journal of Health Economics,* 2003.Mar; 22(2):151-85. Kaitin KI, Ed. "Post-approval R&D raises total drug development costs to $897 million." Tufts Center for the Study of Drug Development Impact Report 2003 May/Jun;5(3).

[6] Horrobin, David F. "Modern Biomedical Research: An Internally Self-Consistent Universe with Little Contact with Medical Reality?" *Nature Drug Discovery*; February 2003:151-154.

entists are still primarily gathering information, sorting out patterns, and only starting to understand what the turning on or off of hundreds of genes by a new drug means for whether it is safe and effective in patients. The increase in the time and cost of product development has already been associated with a decline in the number of truly new drugs and biological treatments being approved by FDA. Last year, FDA approved 21 new molecular entities (the truly new drugs) down from 44 such entities in 1996. And FDA approved 12 new biological license applications (BLAB), down from 27 BLAB in 1998. The decline in products approved is not the result of FDA rejecting more applications; it is directly related to a decline in the number of new applications for drugs and biologics coming in to the Agency, and it is a worldwide phenomenon.[7]

TRADITIONAL APPROACHES VERSUS NEW TECHNOLOGIES

While there are and no doubt will continue to be traditional "blockbuster"-type drugs in development that may bring important public health benefits to many millions of patients, breakthroughs in genomics, proteomics, and other new fields of molecular biology also hold great promise for truly individualized drug therapy in which diagnostic tests and novel drug delivery mechanisms guide the use of medications, turning heterogeneous diseases like cancer and heart disease into distinct types of pathologies that appropriately require distinct therapeutic approaches. Other new technologies are breaking down the traditional barriers between drugs, tissues, and devices, including products in development that are combinations.

Translating the new biomedical sciences into these new kinds of treatments for patients requires major new investments, and it seems plausible that such investments may take many years to reach fruition. It should not be surprising that we haven't yet seen the huge increase in biomedical investment of the past decade, and especially the last few years, turn into more and more valuable medical products for patients. But the fact remains that developers of biomedical products are not producing drugs particularly faster than they were before all these innovations came along. From a public health standpoint, with millions of Americans suffering from diseases that may be curable or at least manageable in the not too distant future, we cannot afford to wait many more years for all these investments to become valuable products.

On the research and development side, it's possible that the costs and uncertainty of developing new treatments could keep rising. It's easy to see how this could happen: there are not many more obvious drug targets left to exploit, and developing genomics- and proteomics-based therapies remains very costly. So far, genomics has mainly added steps at the front end of the development process, through microarray testing of gene responses, and has not reduced the costs of clinical research significantly. On the policy side, there is intense pressure to make health care more affordable, and so policymakers may focus only on reducing medical costs in the short run—which, if not done properly, could reduce the incentive to incur these high and rising development costs. This combination of rising costs of product development and pressures to control costs rather than increase value is not a good one for keeping the United States at the forefront of biomedical innovation, and more importantly it's not a good combination for affordable and high-quality, innovative health care for our population. Instead, a more effective approach would involve bringing costs down by reducing the high cost and uncertainty of developing new medical treatments, and taking more steps to help patients and doctors use them effectively after they are approved by FDA.

POTENTIAL POLICY SOLUTIONS

We can take steps today to improve the development and use of medical technologies, and find creative policy solutions that both support innovation and make healthcare more affordable, particularly for those with limited means and great needs. There are many ways to do this, but above all, we need to increase value in the process of developing and using new medical technologies. To these ends, a key element of FDA's new strategic action plan is efficient risk management. In all of FDA's major policies and regulations, the Agency is seeking to use the best biomedical science, the best risk management science, and the best economic science to achieve its health policy goals as efficiently as possible.

The enormous growth in research investment has required the Agency to deal with more complex and innovative products in development than ever before. As discoveries made in the laboratory are flowing into the medical products consumers are

[7] CDER 2002 Report to the Nation: "Improving Public Health through Human Drugs." May 13, 2003.

using, it means that the Agency is challenged to upgrade its own science to keep pace with this new innovation and the growing sophistication of manufactures. As part of a new FDA initiative on improving medical innovation announced in January 2003, the FDA is taking specific steps to help foster more efficient innovation, especially in emerging areas or those of great medical need. The initiative has several elements that are described below.

Need for Performance Measures

One element of this plan is the development of "quality systems" for the Agency's review procedures. The idea is to build on FDA's professional staff expertise to identify and apply best management practices internally to the review processes. This includes using peer review programs coupled with more empirical data for drug and device reviewers to exchange ideas and use each other's experience to learn about best practices. A key part of this effort is developing performance measures that the Agency's experts believe are related to the goal of approving safe and effective treatments as efficiently as possible.

FDA is also working to dèvelop new guidance documents that can bring more predictability to regulatory process. These are in a tradition of FDA documents that serve as roadmaps for drug and device developers, offering guidance on how to structure studies to prove that new treatments work. These new documents represent an enhanced effort to combine internal expertise with input from outside experts to make sure that are regulatory methods are up to date in important areas of technology development. Some of the guidance will focus specifically on diabetes, obesity, and cancer. Despite all the innovation that has already occurred, these are therapeutic areas that remain underserved by effective treatments and that have promising technologies under development today.

Developing New Guidance for New Areas

The Agency is also developing guidance in new areas of technology development, including pharmacogenomics, novel drug delivery systems, and cell and gene therapy. In each of these cases, the Agency expects to learn something from outside experts in the open process of developing them. For example, FDA is setting up a "research exemption" program for product developers as well as academic experts to share data on pharmacogenomic results, such as microarray studies, that may be useful for predicting clinical benefits and risks and thus reducing the costs of demonstrating safety and effectiveness. This kind of information can also be used to increase the value of a new medicine by allowing doctors to target drugs to patients most likely to derive a clinical benefit or least likely to suffer a rare side effect. The goal in all of these endeavors is to use the new regulatory standards to reduce the time and cost of product development and to ensure that the Agency's regulatory procedures are current at the same time. We hope this will lead to earlier and broader access to new treatments.

Rapid Access to Generic Drugs

Supporting the development of safe and effective new treatments is one of the most important ways that FDA can promote the public health. But when appropriate patents have expired, we need to facilitate broader access through lower-cost generic drug alternatives. Generic drug manufacturers produce medications that are just as safe and effective as their brand counterparts. Yet the prices of generics are generally much lower. A generic version of a $72 average brand-name prescription costs about $17. With more brand-name medications coming off patent—more than 200 of them in the next few years—and with ever-improving scientific knowledge and public awareness about the benefits of generic drugs, the health and economic benefits of using generic drugs are constantly growing.

Encouraging rapid and fair access to more affordable generic medications is one of FDA's major priorities. FDA is proposing new resources to enable us to implement major reforms in its generic drug programs to reduce the time it takes to get a generic drug approved. Right now, it takes well over a year and a half on average to approve a new generic medication and we think we can significantly improve. In addition, the Agency recently finalized a generic drug final rule that would expedite and increase access to more affordable generic drugs by limiting the ability of innovator drug companies to receive multiple extensions that delay entry of generic competition. This final rule is projected to save American consumers $35 billion dollars over the next 10 years. Furthermore, this rule makes changes to the patent listing process that are also designed to improve generic competition.

Revised Good Manufacturing Practices

Another application of the principle of efficient risk management to reduce medical costs and improved outcomes is in improving the way that medical products are

manufactured. These guidelines are referred to as good manufacturing practices (GMPs), and these GMP regulations for drugs have not been updated in 25 years. Meanwhile, best practices in manufacturing technologies and methods have undergone significant progress over that time, particularly in other high-tech industries. For example, the semiconductor industry also has a very low tolerance for impurities and inaccuracies in production. When its production processes were lagging because of high costs and too many errors that industry helped invent the "six sigma" production methods. Through continuous quality improvement, those methods achieved enormous improvements in production cost and quality, and they have since been widely adopted in manufacturing industries.

But continuous quality improvement in manufacturing hasn't been the subject of as much attention in the pharmaceutical industry, even though many experts on manufacturing processes believe that large savings in production costs could be realized while maintaining very high standards for purity and accuracy. FDA wants to make sure that regulations are encouraging such progress, not standing in the way. The Agency is working on a program for developing new GMPs based on the latest science of risk management and quality assurance. The new standards would be designed to encourage cost-reducing and precision-enhancing innovation in manufacturing and technology, and to ensure that all three FDA medical centers use consistent and up-to-date methods, including inspectors specializing in particular types of production methods.

In addition to substantial savings in the development and manufacturing of safe and effective medical products, there are many more opportunities to increase the value of the medical products FDA regulates after they are approved and maximize their public health benefits. By making better information available to patients and doctors about the benefits and side effects of new medical technologies, and by taking other steps to help doctors and patients avoid errors and adverse events, people can realize more value from these products by making better decisions about when to utilize them for maximum advantage.

Prevention of Medical Errors

Approved medical products, while safe and effective when used as intended, can be involved in costly and potentially preventable adverse events, including medical errors. A November 1999 report of the Institute of Medicine (IOM), entitled "To Err Is Human: Building a Safer Health System," focused a great deal of attention on the issue of medical errors and patient safety. The report indicated that as many as 44,000 to 98,000 people die in hospitals each year as the result of medical errors. About 7,000 people per year are estimated to die from medication errors alone—about 16 percent more deaths than the number attributable to work-related injuries.[8] Preventable errors and complications involving prescription drugs alone are also responsible for billions of dollars in additional health care costs each year, in addition to all of the unnecessary suffering. The IOM report estimates that medical errors cost the Nation about $37.6 billion each year; about $17 billion of those costs are associated with preventable errors. About half of the expenditures for preventable medical errors are for direct health care costs. That's too much money that would be better spent on proper care.

FDA has a role in helping to avoid these costly errors by supporting the development and use of safer health care systems; systems that help health professionals avoid errors and deliver higher quality care. The majority of medical errors do not result from individual recklessness, the report says, but from basic flaws in the way the health system is organized. Stocking patient-care units in hospitals, for example, with certain full-strength drugs (even though they are toxic unless diluted) has resulted in deadly mistakes. And illegible writing in medical records has resulted in administration of a drug for which the patient has a known allergy.

To help mitigate these risks, earlier this year FDA proposed a universal bar coding system for prescription medications and blood products. Coupled with barcode readers and electronic medical records, bar codes on drugs are expected to reduce the rate of medication errors that occur at the stage of dispensing and administering medications by half or more. Bar codes can help make sure that the right patient gets the right medication in the right dose at the right time, and soon a standardized system of codes will be built in to all drug packaging. Based on the published relationships between hospital admissions and adverse drug events, FDA has estimated that of 372,000 preventable adverse drug events per year in hospitals, bar code identifiers on drug products could be expected to avoid about 22 percent of these events. Over 20 years, FDA expects more than 413,000 fewer adverse drug events because of bar coded products. The average annual benefit of avoiding these

[8] To Err Is Human: Building a Safer Health System. *Institute of Medicine Press*, 2000.

events is $3.9 billion dollars in patient pain and suffering and direct treatment costs.[9] FDA's work on standards has another benefit. According to the hospital industry and many health care purchasers, standard bar codes will speed the adoption of electronic health information systems by hospitals and other healthcare organizations, because the standardized codes increase the payoff from having electronic systems.

Even with the best available data, drugs are sometimes found to have adverse effects that could not have been predicted or uncovered in any feasible clinical trial. Most of these subtle or rare problems, such as liver toxicities, that occur in a small number of people and most become apparent only after drugs have been used in real-world patient populations for some period of time. The Agency must have effective systems in place to detect such problems, so that preventable adverse events are identified, and better ways can be found to prevent these events.

As part of this effort, the Agency is working on developing information technology tools that will allow it to link into the electronic; medical records of large healthcare institutions and organizations, and automatically scan medical records for combinations of new drugs and clinical endpoints such as blood test results that might contain harbingers of trouble. The idea is to use modern information technology to acquire information on associations between adverse events and use of a medical product that might warrant focused further investigation. FDA wants to have systems in place that allow us to be proactive in collecting this clinical information, rather than continuing to rely primarily on vigilant doctors and FDA's voluntary adverse event reporting systems.

Safety and Efficacy Studies for Approved Medical Products

More studies of the safety and effectiveness of medical products after they are approved can be very helpful for learning more about the risks and benefits of medications in special populations and can help guide more informed medical decisions. For example for a new cancer drug that recently gained accelerated approval, the National Cancer Institute is funding so-called "Phase 4" studies to confirm clinical benefits and help assess longer-term risks. These efforts to use modern information systems and post-approval studies can add substantially to the body of knowledge about which patients are most and least likely to benefit from an approved treatment, in turn leading to higher-value treatment decisions.

Better Informed Consumers

FDA is also working to encourage more effective, high-value use of medical treatments by helping patients and health professionals get access to the latest and best information on risks and benefits. For all that improving medical technology can do, it is much less than people can do through their own choices to improve their health. From encouraging better guidance to patients in pharmacy labels, to clearer guidance on communicating risk and benefit information in direct to consumer advertising, to new enforcement initiatives against dietary supplement manufacturers who make health claims without scientific foundation, to food labeling that better discloses diet-disease information, FDA is undertaking new efforts to help consumers make better-informed decisions about how to use their health care dollars. In one recent example, FDA is working on a DailyMed program for physicians, so that a redesigned electronic product label that can be updated daily to include the most current information about a drug after they are already on the market. Only by facilitating access to complete, timely, and easily used information available to consumers and health professionals can FDA help to make sure that people are making the best decisions about their health based on the best available information.

CONCLUSION

Medical innovation is a difficult and complex process, but one that can bring great value to patients. This long and difficult process is also a delicate one that requires the right mix of incentives, safeguards, and effective regulation to make sure people can derive the maximum benefit from safe and effective new medical technologies.

[9] Bates, D.W., D.J. Cullen, N Laird, L.A. Peterson, S.D. Small, D Servi, et al. "Incidence of Adverse Drug Events and Potential Adverse Drug Events: Implications for Prevention." *The Journal of the American Medical Association*. July 5, 1995. Classen, D.C., S.L. Pestonik, R.S. Evans, J.F. Floyd, and J.P. Burke. 1997. "Adverse Drug Events in Hospitalized Patients: Excess Length of Stay, Extra Costs, and Attributable Mortality." *The Journal of the American Medical Association*. January 22/29. Jha, A.K., G.J. Kuperman, J.M. Teich, L Leape, B Shea, E Rittenberg, et al. 1998. "Identifying Adverse Drug Events." *The Journal of the American Medical Association*. May.

Only by adopting policies that protect the incentives to develop new drugs and medical devices, and reward cost-effective medical practice and the most high value use of new technology, will we continue to realize the full benefits of these innovations. As described in this testimony, at FDA, as Commissioner of Food and Drugs, I am working to implement numerous policies, initiatives, and regulatory improvements that reflect these critical needs in order to promote increased access to high quality, high value, safe and effective medical products, including drugs, biologics, devices and combinations of all three.

I appreciate the opportunity to provide this testimony and I would be pleased to respond to any questions.

PREPARED STATEMENT OF CAROLYN CLANCY, M.D., DIRECTOR, AGENCY FOR HEALTHCARE RESEARCH AND QUALITY

Good morning, Mr. Chairman and Members of the Committee. I am very pleased to be here today to discuss the important issues of how we can facilitate, sustain, and promote health care innovation while we ensure that we have a health care system that is affordable. As my testimony will indicate, I believe that the work of the Agency for Healthcare Research and Quality (AHRQ) is critical to achieving these goals and complements the important work of the National Institutes of Health (NIH) and the Food and Drug Administration (FDA) and supports decision-making by the Centers for Medicare and Medicaid Services (CMS).

AHRQ'S ROLE

Let me begin with a few words about where AHRQ fits within the Department of Health and Human Services. The basic and biomedical research supported by the NIH serves as the foundation for many of the advances in the prevention, diagnosis, and management of disease and impairment. Its work greatly expands the realm of possible public health and clinical interventions. While the Centers for Disease Control and Prevention (CDC) takes the lead on public health, community-based interventions often led by state and local health departments or public service media campaigns to improve health, AHRQ focuses on the role of clinical care and the health care delivery system.

AHRQ's mission is to improve the effectiveness, quality, safety, and efficiency of healthcare services that patients receive. What is unique about our mission is that it encompasses both the evaluation of the effectiveness and quality of clinical services and the most effective and efficient ways to organize, manage, and safely deliver those services. As the Institute of Medicine report *To Err Is Human* made clear, this dual focus—on services and systems—is critical to improving health care.

AHRQ contributes to efforts to speed the diffusion of effective medical breakthroughs. Our research can extend the findings of biomedical research to populations not included in clinical trials, evaluate the effectiveness and cost-effectiveness of interventions to determine which populations benefit most, and develop effective strategies to facilitate their rapid adoption. We also facilitate adoption of new knowledge by putting into perspective the available scientific evidence so that clinicians can better assess the importance of recent breakthroughs.

In the area of drugs and devices that have received FDA approval, AHRQ focuses on their effectiveness (especially in comparison to existing options) and cost-effectiveness. We complement FDA's focus on the safety of drugs, biologics, and devices, with our focus on their safe use in daily practice. In the context of this hearing, this role is especially important. The harm that can result from inappropriate use of otherwise safe drugs, biologics, and devices is not only a tragedy for the patients involved but adds to health care inflation through the costs involved in attempting to repair the damage and related increases in medical liability expenditures. As a result, I am delighted to report that Dr. McClellan and I are developing an increasingly strong partnership between FDA and AHRQ in these areas.

However, innovations in health care are not limited to drugs and devices but may also include new surgical procedures, new applications of existing technology, information technology or communications advances. Moreover, while some of these innovations offer unprecedented breakthroughs for some patients they may also result in unintended harm if not used appropriately. AHRQ's role, then, is to provide the best evidence regarding how to match specific services to patients' needs and preferences to promote the best possible outcomes.

Finally, we serve as a science partner for efforts by the Centers for Medicare and Medicaid Services to improve the effectiveness, quality, and safety of services they support and improve the ability of beneficiaries to make more informed health care choices. Prior to our 1999 reauthorization, we were required by law to make rec-

ommendations to CMS on coverage decisions. Today, upon request, we undertake technology assessments and other research activities to objectively synthesize all existing evidence on the effectiveness of medical interventions under consideration for coverage by CMS. We do not make recommendations.

HEALTH CARE INNOVATION AND HEALTH CARE COSTS

Mr. Chairman, America has a track record for health care innovation that is the envy of the world. The Administration and Congress in partnership have done much to accelerate and sustain that record through their commitment to biomedical and health care research. As a result, the pace of innovation has accelerated, the number of scientific journals and published research studies is exploding, and reports of scientific breakthroughs appear almost daily.

Many of these developments offer the potential for greatly improving the quality of life for patients; in other cases the improvements are marginal at best. In some cases, innovation leads to the same or even higher quality of care at significantly lower costs while other innovation is cost increasing. The underlying challenge, therefore, is to effectively sort through the increasing array of clinical care options to develop objective scientific information so that those who make decisions—policymakers, systems managers, insurers, purchasers, clinicians, or patients—can make informed choices. The ultimate goal is to ensure that they can get real value for their health care dollar. Each of us may make different decisions as we weigh the evidence. My Agency's role is not to make those judgments. It is to develop and synthesize the evidence regarding health care interventions so that, whether you favor the current insurance-based system or favor a more consumer-driven model of health care decisionmaking, objective credible scientific information—on effectiveness, cost-effectiveness, and benefits (including downstream cost savings)—is available to inform those decisions.

The need for such information has never been more compelling. Moreover, the resurgence of health care cost inflation at a time of increasingly constrained resources, both in the public and private sector, will only accelerate the demand for proof that we are getting real value for the health care dollars that we spend. Because our research focuses on both the effectiveness and cost-effectiveness of health care services as well as ways to improve the effectiveness, efficiency, and safety of the ways we deliver and use health care services, AHRQ is uniquely positioned to develop this type of scientific evidence.

HOW AHRQ CAN HELP

Let me suggest five broad areas in which AHRQ can assist in sorting through the array of new health care innovation and help to speed the adoption of effective interventions.

First, AHRQ research identifies what is effective and cost-effective in daily practice. Experience suggests that new drugs, technologies, and medical or surgical interventions are seldom equally effective for all types of patients. Will a breakthrough for the treatment of arthritis, tested in clinical trials with patients who only have that affliction, work as well in patients who not only have arthritis but are also taking medications for diabetes, congestive heart failure, and hypertension? Or how well does it work in patients whose racial, ethnic, and demographic characteristics differ from those in the clinical trial? Consider two examples from our research, one demonstrating the value of using the low-cost option; the other demonstrating the value of investing in much more expensive pharmaceuticals.

The first example, treatment of otitis media (middle ear infection), is the most frequent reason for administering antibiotics to children. Over-prescribing increases the chance for adverse reactions, leads to the development of bacterial resistance, and increases expenditures. AHRQ supported researchers found that the use of the less expensive generic antibiotics resulted in the same or lower failure rates. They concluded conservatively that substituting low cost antibiotics for only half of the expensive antibiotic prescriptions would have saved Medicaid nearly $400,000. This research has led to the development of guidelines by the American Academy of Pediatrics recommending less-expensive antibiotics and to a metric used to accredit health plans.

By contrast, in some cases, costly new interventions can reduce the long-term use of other health care resources. AHRQ research demonstrated that new, more costly anti-retroviral therapy for treating AIDS patients is both effective and cost-effective. The increased expenditures for those drugs are much less than the savings in inpatient, outpatient, and emergency room costs. Overall annual costs per patient were reduced from $20,300 to $18,300. If extrapolated to the approximately 335,000

adults receiving care for HIV infection in 1996, over $500 million will be saved in HIV related healthcare.

Second, AHRQ research identifies strategies for overcoming barriers to the use of effective services. Great opportunities for improving health, developed through biomedical research, are easily lost if physicians and patients are unable to make the best use of the knowledge in everyday care. These wasted opportunities are apparent daily in the under use of effective interventions and continued reliance upon outmoded approaches to patient care, which in turn contributes to the ever-increasing cost of care and avoidable loss of lives. By conducting and supporting research that focuses on their effective use, and working with clinicians and health care organizations to assure that this information is accessible when decisions are made, AHRQ ensures that Americans reap the full rewards of basic research and medical innovation.

For example, NIH-supported research identified the potential of warfarin, a blood thinner, to reduce the risk of stroke in patients with atrial fibrillation. But physicians seldom prescribed warfarin for their patients. AHRQ-supported researchers concluded that warfarin was effective in daily practice, identified the reasons that physicians were reluctant to use warfarin, and developed a program of providing warfarin that would have an expected annual net savings of $1.45 million per 100,000 people aged 65 years or older, of whom 6,000 would be expected to have atrial fibrillation. Using this knowledge, Medicare Peer Review Organizations implemented projects to increase anticoagulation, and 28 projects in 20 states had a 58-71% increase, with a projection of 1,285 strokes prevented. The findings of this AHRQ funded study were influential in the development of guidelines by the American College of Physicians, American Heart Association, American College of Chest Physicians, and the Joint Council of Vascular Surgeons. Based on this work, United HealthCare has included use of anticoagulation therapy for patients with atrial fibrillation in the profiling of its 262,000 physicians.

Third, AHRQ facilitates the use of Evidence Based Medicine. In recent years AHRQ has focused increased attention on the development of technology and tools to facilitate the use of evidence-based medicine. For example, each year tens of thousands of patients who go to an emergency department worried that their chest pain is being caused by a heart attack, are inappropriately sent home, inappropriately hospitalized, or suffer because of delay in treatment due to an inconclusive electrocardiogram (EKG). These delayed or missed diagnoses have serious implications for patient survival or impairment rates, hospital costs and subsequent malpractice lawsuits. An increasing number of EKGs are now equipped with special software developed by AHRQ research that improves diagnosis by predicting the likelihood of whether chest pain is the result of a heart attack. The software could prevent 200,000 unnecessary hospitalizations and more than 100,000 coronary care unit admissions a year and save roughly $728 million a year in hospital costs if implemented in half of the hospitals nationally. Soon-to-be-published research estimates that improved accuracy of diagnosis that results from use of this predictive tool could reduce malpractice costs nationally by $1.2 billion per year.

Approximately 600,000, or 15 percent, of the 4 million Americans who develop pneumonia each year are hospitalized. Because of the lack of evidence-based admission criteria and the tendency to overestimate the risk of death, many low-risk patients who could be safely treated outside the hospital are admitted for inpatient care. An easy-to-use method developed by AHRQ-supported researchers accurately predicts which pneumonia patients can be safely treated at home, which costs 10 to 15 times less than hospital care for pneumonia. The findings from this study also suggest that hospitals could reduce pneumonia hospital stays in many cases by 1 day without adversely affecting patient health. Criteria were developed to assist physicians with determining when patients could be discharged safely.

Fourth, AHRQ research assesses the effectiveness of cost containment and management strategies. With Medicaid pharmaceutical costs increasing 20% per year, States are considering and implementing a variety of cost containment strategies. An example of how our past research can be helpful to today's decisionmakers involves a study of an initiative by a New England legislature to limit Medicaid reimbursement to three prescriptions per month. AHRQ concluded that the strategy backfired. Increases in utilization costs were 17 times greater than the savings in drug expenditures. The result was that the state abolished the prescription cap, and another 9 states have also changed their policies based on this research.

AHRQ research has also demonstrated that 85% of women with pelvic inflammatory disease, the leading cause of infertility, can be safely and effectively treated as outpatients, and developed an evidence-based approach to identify which nursing home patients require hospitalization for possible pneumonia and which can be treated at the nursing home This approach not only saves the cost of a hospitaliza-

tion but also helps frail, elderly patients avoid the risks of experiencing additional hospital complications.

Fifth, AHRQ's role in speeding the pace of evaluation of health care innovation. AHRQ's 1999 reauthorization directed us to serve as a science partner for public and private sector efforts to improve quality and urged us to continue our efforts, begun in the mid-1990s, to speed the pace of the evaluation of health care innovations.

One of the critical roadblocks to coverage of innovative interventions is the lack of solid scientific evidence regarding their effectiveness, especially in comparison with existing interventions. While the FDA determines that a drug, biologic, or device is safe and that it has an impact when compared to placebo, those making coverage decisions, including clinicians and patients, still need more information regarding its relative effectiveness and relative costs. Similarly, promising biomedical research breakthroughs face a similar test. This is often frustrating for those whose creativity leads to the development of promising new technologies as they come to realize that passing FDA scrutiny is only part of the journey toward seeing their innovation in widespread use.

While these constraints are not of AHRQ's making—and are certainly not unique to the public sector; the private sector takes technology assessment seriously as well—we have begun, and will continue, our efforts to facilitate the speed of this process. For example, when Medicare asked us to evaluate the effectiveness of lung-volume reduction surgery, we concluded that there was insufficient evidence to reach a determination at that time. But we pointed out to Medicare the potential for developing the evidence through an innovative process of conditional coverage—in which Medicare would pay for the procedure in selected institutions, provided the surgeons and patients agreed to the collection of outcomes data. This resulted in a partnership between Medicare, the National Heart Lung and Blood Institute, and AHRQ to assess the procedure. As a result of this study, we now know which patients are likely to benefit, and very importantly, a subgroup of patients who experienced increased mortality as a result of the procedure were identified so that avoidable and unintended deaths can be reduced.

Similarly, AHRQ has revamped its ability to provide Medicare with much more timely scientific advice, in as little as two weeks for brief assessments of the volume of available evidence to full-scale technology assessments that might take a year. These time frames reflect as significant improvement in our ability to serve Medicare more effectively.

There are at least two other ways in which we can serve as a science partner for private sector innovation. First, most technology assessments conclude that there is a lack of credible scientific studies from which to judge whether a technology is effective or ineffective. We are prepared to work with industry trade associations to assist their members, who have products moving to the end of the FDA review process, to better understand the types of studies that will be needed to assess the effectiveness of their products. This simple step would make a significant contribution to facilitating timely assessment of health care innovation.

Second, in future years, as existing patient safety grants end, we will want to expand our focus on human factors research. As one wag commented, human factors research helps us to "idiot proof our technology." More accurately, this research helps us to develop controls for our technologies so that they remain easy to program even by a harried, stressed, distracted, sleep-deprived health care professional. One example is the infusion pumps, used to administer fluids to patients through their veins, that are often involved in patient safety adverse events. Human factors research would help us to understand approaches for reducing inadvertent errors in programming these pumps. As we expand our support for human factors research within our patient safety portfolio we will want to work with industry to ensure that we are targeting the critical questions that will improve the safety and quality of the products they design in the future. By ensuring that this type of critical information in the public domain, we can be a science partner for their efforts to develop even more effective and safe health care technologies.

AHRQ'S NEW DIRECTION

Mr. Chairman, before concluding, I would like to say just a few words about the future direction of AHRQ. As you know, I have been serving as Acting Director since March, 2002 and Director now for five months. During that time, our senior staff and I have undertaken a top to bottom review of our procedures and processes to determine how we can better fulfill the mandate of our 1999 reauthorization legislation to serve as a science partner for public and private sector efforts to improve quality.

We are determined to make AHRQ a "problem solving" agency. This entails a greater focus on "implementation research" that is designed to develop strategies for overcoming barriers to the adoption of clinical interventions that are both effective and cost-effective. We need to be more pro-active in closing the gap between what we know is, effective and cost-effective in health care and what is done in daily practice.

We have developed closer linkages, at every stage of the research process, between the ultimate customers of our work and researchers, to ensure that we are addressing their highest priority challenges. In the public sector, we are beginning to work more closely than ever before with Medicare, Medicaid, the Community Health Centers, the Federal Employee Health Benefit Program, and the Departments of Defense and Veterans Affairs.

We also will be giving greater priority to identifying strategies for eliminating waste, assuring that evidence-based information is current, bringing our health care infrastructure, especially information technology, into the 21st century, redesigning workflow so that health care professionals can work more efficiently and effectively, and evaluating our financial and other incentives to ensure that we encourage safe, high quality care.

CONCLUSION

Mr. Chairman, in conclusion, let me note that one study demonstrated that the time frame from the approval of a research grant that ultimately yields useful findings to the widespread diffusion and adoption of those results was at least 17 years. That time frame is unacceptable. AHRQ is committed to playing its role in developing the scientific evidence for identifying effective interventions sooner and increasing the pace of their diffusion.

This concludes my formal testimony. I will be happy to respond to any questions.

ESTIMATES OF THE IMPACT OF SELECTED HEALTH INFORMATION TECHNOLOGIES ON QUALITY AND COSTS IN INPATIENT AND OUTPATIENT SETTINGS

EXECUTIVE SUMMARY:

Healthcare Information Technology has the potential to improve the quality, safety and efficiency of healthcare by helping health care professionals make the best decisions and by assuring that those decisions are implemented as intended. This potential value will be realized in better adherence to clinical protocols, utilization of clinical decision support, reduction in medical errors, cost reductions and improved access to healthcare information.

In order to estimate and put in context the relative value of these high-impact HIT functions AHRQ compiled the following analysis. The relative impact on quality, cost and net savings for selected in/outpatient HIT functions is outlined below:

HIT Function	Impact on Quality	Impact on Cost/Net Savings
Computerized Physician Order Entry (inpatient).	Decrease rate of serious med error by 55%; decrease rate of potential adverse drug events by 84%.	Total annual savings range from $7 to $14 billion (nationally)
Clinical Decision Support Technologies	Decrease ordering of drugs that pt. is allergic to; decrease in orders for wrong (ineffective) meds.	Decrease antibiotic cost by -$200 per hospitalization; lower cost of hospital care ($26,315 v $35,283) and shorter hospital stays (10 v 12.9 days)
Automated Medication Dispensing Systems (inpatient).	Significantly fewer missed doses of drugs (-16.9%).	One hospital realized savings of $1.28 million over 5 yrs.
Bar Coding Technologies	75% decease in errors caused by administration of wrong meds; 93% reduction in errors from wrong med to wrong pt..	Annual national savings of $15.3 billion.
E-Prescribing in Physician Practices	Decreased medication errors; Improved physician efficiency.	One study demonstrated reduced pharmacy costs of $1.15 PMPM; 30% decrease in physician to pharmacy phone calls.

HIT Function	Impact on Quality	Impact on Cost/Net Savings
Computerized Physician Order Entry (outpatient).	Eliminate 2 million adverse drug events; Avoid 1.3 million office visits and 190,000 hospitalizations.	$27 billion savings in medication expenses (nationally)
Electronic Medical Records (Primary Care Settings).	34% reduction in adverse drug events; 15% decrease in drug utilization; 9% decrease in unnecessary lab utilization.	Reduced Spending by $44 billion per year: Savings of $86,400 per provider over a five yr. period.

ESTIMATED NET SAVINGS:

Our analysis demonstrates potential savings ranging in the tens to hundreds of billions for these few high value functions.

COMPUTERIZED PHYSICIAN ORDER ENTRY IN INPATIENT SETTINGS

• **Description.** Computerized physician order entry (CPOE) systems allow physicians to submit orders for medications and laboratory tests using an online system. The technology includes algorithms that prompt physicians about possible drug-drug interactions, drug allergies, and the need to order certain laboratory tests to measure whether a medication is effective. A study by Bates et al., conducted at Massachusetts General Hospital and Brigham and Women's Hospital in Boston, Massachusetts, compared the rates of adverse drug events before and after implementation of CPOE.

• **Impact on Quality.** The study showed that use of CPOE in those hospitals reduced the rate of serious medication errors resulting in patient injuries by 55 percent, from 10.7 events per 1000 patient-days to 4.86 events. The rate of potential adverse drug events—that is, errors that did not result in an injury—decreased by 84 percent. The study found that the rate of errors in ordering of medications fell by 19 percent, the rate of errors in transcription of orders fell by 84 percent, the rate of errors in dispensing of medications fell by 68 percent, and the rate of errors in administration of medications fell by 59 percent.

• Another study by Teich et al. (2000) examined the CPOE system at Brigham and Women's Hospital and Massachusetts General Hospital as well. The study compared physician prescribing practices before and after implementation of the CPOE system. It found that use of CPOE occurred contemporaneously with an increase in adherence with certain clinical guidelines that were programmed into the CPOE system. Use of computerized guidelines was associated with an increase in the use of a recommended drug, while use of a dose selection menu was associated with a decrease in variation in drug dosages among similar patients. The proportion of doses that exceeded the recommended maximum dosage decreased from 2.1 percent to 0.6 percent, while the display of a guideline for administration of a particular drug increased the proportion of orders that complied with the guideline. Each of those results was statistically significant.

• **Impact on Cost.** An earlier study by Bates and colleagues found that the annual cost of preventable adverse drug events at Brigham and Women's Hospital was $2.8 million. A 17 percent reduction in preventable adverse drug events was observed in this study, which would equate to annual savings of $480,000 for that hospital.

Estimated Net Savings. Implementing computerized patient order entry in all hospitals in the U.S. could reduce the rate of preventable adverse drug events by 17 percent, avoiding 656,800 preventable adverse drug events per year.

The additional cost of treating a preventable adverse drug event has been estimated at $5,857. Thus, the savings from averted preventable adverse drug events could total $654 million per year.

A study of the implementation of CPOE in a hospital with 726 beds found that annual savings for that hospital were between $5 and $10 million. If this savings can be extrapolated to the over 1 million hospital beds in the U.S., total annual savings would range from $7 to $14 billion.

The first year cost of implementing a CPOE system in an individual hospital ranges from $2,480 to $15,000 per bed, while the ongoing cost of maintaining the system ranges from $870 to $1500 per bed. Amortizing the initial costs over 20 years at 7 percent interest, the national costs of implementing CPOE systems in each of the 1 million hospitals in the U.S. could range from $1.1 to $2.9 billion. (Amortizing those costs over 5 years would equate to annual costs of $1.5 to $5.1 billion,

while amortizing those costs over 10 years would equate to annual costs of $1.2 to $3.6 billion.)

CLINICAL DECISION SUPPORT TECHNOLOGIES

• **Description.** LDS Hospital in Salt Lake City, Utah, implemented a clinical decision support system that assists clinicians in choosing a course of antibiotic and anti-infective therapy for patients in the intensive care unit. The decision support system uses information about the patient's diagnosis, white-cell count, body temperature, and information from pathology and microbiology reports to recommend a course of anti-infective therapy for identified and potential pathogens. The system also considers information about drug allergies, drug-drug interactions, and costs in choosing a recommended course of therapy. A study of the system was reported by Evans et al., 1998.

• **Impact on Quality.** The study found that the system was associated with a significant reduction in orders for drugs to which patients had reported allergies (from 146 to 35 during the previous two-year period), reduced excess drug dosages (from 405 to 87), and reduced antibiotic-susceptibility mismatches (from 206 to 12). The average number of days of excessive drug dosage was significantly reduced (from 5.9 to 2.7), as was the number of adverse events caused by anti-infective agents (from 28 to 4.) Each of those results was statistically significant.

• **Impact on Costs.** The study found that patients who received the recommended anti-infectives had lower costs of anti-infective agents ($102 vs. $340 for those in the preintervention period), lower costs of hospital care ($26,315 vs. $35,283 for those in the pre-intervention period), and shorter hospital stays (10 days vs. 12.9 days for those in the pre-intervention period.)

AUTOMATED MEDICATION DISPENSING SYSTEMS IN THE INPATIENT SETTING

• **Description.** Automated medication dispensing systems replace the existing manual systems used in many hospitals to dispense a 24-hour supply of each patient's drugs to nurses on the floor. The automated system is connected to the pharmacy computer system, so that orders for new prescriptions are transferred electronically to the automated dispenser. The automated system stores and dispenses most of the medications that nurses administer to patients, while automatically billing for the drugs used. A study of the use of an automated dispensing system at the University of California, San Francisco Hospital was reported by Schwarz et al., 1995.

Another study of an automated dispensing technology in a 600-bed teaching hospital in Dallas, Texas, was conducted by Borel and Rascati (1995).

• **Impact on Quality.** The University of California study found that after implementation of the automated dispensing system, there were significantly fewer missed doses of drugs. The number of reported medication errors decreased for the surgical unit, but increased for the coronary intensive care unit.

The Texas study found that before implementation of the automated dispensing system, the medication error rate was 16.9 percent, while after implementation of the system, the error rate dropped to 10.4 percent. (Most errors consisted of administering a drug at the wrong time.)

• **Impact on Costs.** The authors estimate that the automated dispensing system could save the hospital $1 million over five years if all personnel time savings could be translated into reductions in staffing. The cost of the automated dispensing system for 330 acute care beds and 48 critical care beds was $1.28 million over five years. The savings of $2.08 million over 5 years was attributable to decreased labor costs for pharmacists, pharmacy technicians, pharmacy billers, and nurses.

BAR CODING TECHNOLOGIES

• **Description.** Bar code technologies replace traditional data entry. Bar codes similar to those utilized in many other industrial sectors allow the quick accurate linkages between component parts of a complex process. For example, a patient's ID bracelet with a bar code is scanned and compared against a similar code in a medication dispensing unit prior to medication delivery. Another example is the usage of bar codes to conduct inventory in a hospital pharmacy. Both these examples allow for faster entry of information with fewer errors.

• **Impact on Quality.** A review of the use of bar code technologies was conducted by Bridge Medical, Inc. The Colmery-O'Neil Veterans Affairs Medical Center, a division of the Eastern Kansas Health Care System, developed proprietary Bar Code Medication Administration software. In 2001, the health system reported a medication error rate of 3.0 incidents per 100,000 units dispensed, compared with 21.7 incidents per 100,000 units in 1993, the last year in which a manual medication system

was used. The health system experienced a 75 percent decrease in errors caused by administration of the wrong medication; a 62 percent decrease in errors caused by incorrect dosing, a 193 percent improvement in errors related to giving drugs to the wrong patient, and an 87 percent decrease in errors related to administering drugs to patients at the wrong time.

- **Impact on Cost.** FDA expects their proposed bar coding rule, once fully implemented, to lead to 12.8 fewer adverse drug events per hospital, a national reduction of 84,200 (23% less).

Full implementation of this rule would lead to annual net savings of about $190 million in hospital treatment costs, roughly $29,000 per hospital. This considers an average additional treatment cost of $2,257 per adverse drug event associated with errors occurring at bedside. The average start up costs for a hospital is $369,000, and, after installation, the average annual operating costs are predicted to be $312,000 per hospital.

The annual societal benefit from avoiding medication errors is about $2.3 million per hospital, an estimated benefit of $15.3 billion nationally. Approximately 2,400 mortalities and 1,600 permanent disabilities would be avoided each year.

When both treatment and societal savings are combined, annual reductions per hospital would be $2,329,000. Considering start up costs (amortized over 20 years at 7%) and annual operating costs, the net annual benefit is likely to be $1,983,000 per hospital.

E-PRESCRIBING IN PHYSICIAN PRACTICES

- **Description.** E-prescribing technologies allow physicians to submit prescriptions to pharmacies electronically. The technologies eliminate problems associated with hand-written prescriptions and incomplete orders, and also allow physicians to check potential drug interactions at the time the prescription is ordered. Advocates of e-prescribing believe it is capable of improving patient safety, improving adherence to formularies, and increasing online access to patient information and decision support resources. Quantum, Inc., a physician practice management company in San Antonio, Texas, implemented an e-prescribing system sold by Allscripts, Inc., in 1998. Another example includes the Tufts Health Plan and AdvancePCS implementation of an e-prescribing technology called PocketScript. The technology which can be used remotely on Personal Digital Assistants or even Blackberries was introduced to 100 physicians' offices in Massachusetts. Finally, in another study Gandhi and colleagues (2002) compared rates of medication errors and adverse drug events in two physician practices that used electronic prescribing technologies with two practices that used traditional hand-written prescribing over a six-week period.
- **Impact on Quality.** The Cap Gemini Ernst and Young studied the Quantum/Allscripts implementation and found the system improved the practices' efficiency and increased use of generic drugs by about 4 percent. In survey conducted following the Pocketscript implementation, 35 percent of physicians reported patient care benefits due to the ability to check drug interactions and prescription accuracy. The Gandhi study found that the practices that used electronic prescribing had fewer violations of prescribing rules and fewer medication errors, but the rates of preventable and non-preventable adverse drug events were not significantly different. The main types of errors were related to identifying medication-related symptoms and inappropriate drug choice. Computerized ordering checks would have prevented only one-third of the preventable adverse drug events that occurred.
- **Impact on Cost.** One of the Quantum physician practices in which the technology was used experienced savings of $1.15 per member per month in pharmacy costs, for a total of $69,000. Increased operational efficiency contributed to an additional $12,000 in savings for that practice. Pocketscript technology improved operational efficiency for the practices. It reduced phone calls between physician practices and pharmacists by 30 percent, and saved nearly one hour per pharmacist in a typical day.

AMBULATORY COMPUTERIZED PHYSICIAN ORDER ENTRY

- **Description.** Computerized Physician Order Entry (CPOE) systems in the ambulatory (or outpatient) setting allow physicians to submit orders for medications, immunizations, lab tests, radiology studies, nursing interventions, and referrals. A key component of CPOE in the ambulatory setting is clinical decision support, which gives physicians tools for diagnosing and treating patients while avoiding medical errors. Clinical decision support, one of the most important attributes of CPOE, essentially gives the physician access to a bank of medical knowledge at the point and time of care. A review of CPOE in ambulatory settings was conducted by the Center

for Information Technology Leadership. It included a literature review, interviews of vendors, and an expert panel meeting.

- **Impact on Quality.** The review found that nationwide adoption of advanced CPOE systems in the ambulatory setting would eliminate more than 2 million adverse drug events, and over 130,000 life-threatening adverse drug events. In addition, nationwide use of CPOE would avoid nearly 1.3 million physician office visits per year, and more than 190,000 hospitalizations per year.
- **Impact on Cost:** The study estimates that nationwide use of CPOE in the ambulatory setting could save nearly $27 billion in medication expenses each year. Those savings include switches from brand to generic drugs, switches from more expensive to less expensive drugs within the same therapeutic class and more appropriate drug utilization. Of that total, savings of more than $2 billion would be achieved through averted hospitalizations from prevented adverse drug events, while $10 billion of savings would come from reduced radiology costs and nearly $5 billion in reduced laboratory costs.
- **Estimated Net Savings:** The Center for Information Technology Leadership estimates that implementing advanced CPOE systems in the outpatient setting would eliminate over 2 million adverse drug events per year, and would avoid nearly 1.3 million physician visits, 190,000 hospital admissions, and over 130,000 lifethreatening adverse drug events per year.

Nationwide adoption of advanced CPOE systems in the outpatient setting would avoid about $44 billion per year in health care spending. That savings would consist of savings on medications (60%), radiology services (24%), laboratory services (11%) and avoided adverse drug events (5%).

The cost of adopting advanced CPOE systems that include ambulatory electronic medical record systems is over $29,000 per provider in the first year, and about $4000 per provider in subsequent years. If those costs were applied to each of the over 473,000 office-based physicians in the U.S. and amortized over 20 years at 7 percent interest, the annual cost of implementing an advanced CPOE system across the U.S. would be $2.2 billion. (Amortizing those costs over 5 years would equate to annual costs of $2.7 billion, while amortizing those costs over 10 years would equate to annual costs of $2.4 billion.)

ELECTRONIC MEDICAL RECORDS IN PRIMARY CARE SETTINGS

- **Description.** Partners Healthcare System in Boston, Massachusetts, internally developed an electronic medical record that replaces paper medical charts. The system aggregates a patient's complete medical record—including physician notes, lab test, radiology results, immunization records and a host of other data elements—into an electronic version. The record, up to date and secure, is then available to providers either at the patient's primary point of care (physician office) or via secure linkage, at other sites of care (ER, specialist, etc . . .). A cost-benefit analysis of the electronic medical record was conducted by Wang et al., 2003.
- **Impact on Quality:** The authors estimated that the electronic medical record was associated with a 34 percent reduction in adverse drug events, a 15 percent decrease in drug utilization, a 9 percent decrease in laboratory utilization, and a 14 percent reduction in radiology utilization.
- **Impact on Cost.** The study found that the electronic medical record had net financial benefits of $86,400 per provider over a five-year period. Savings in drug expenditures made up one-third of that amount, with the remainder of savings attributable to decreased radiology utilization, decreased billing errors, and improved charge capture.

PREPARED STATEMENT OF PETER NEUMANN, SC.D., ASSOCIATE PROFESSOR OF POLICY & DECISION SCIENCES, HARVARD SCHOOL OF PUBLIC HEALTH

Thank you very much Mr. Chairman for your invitation to speak before this committee on the topic of technology, innovation, and their effects on cost growth in health care.

I would like to speak today about how we can better understand the value or cost-effectiveness of medical technology.

Broadly speaking, medical technology contributes to growth in health care expenditures.

But this research says nothing by itself about the benefit side of the equation. As we consider medical technology, it is important to address not just how much medical technology contributes to health costs, but whether the investments in medical technology are worth the health benefits produced.

We all would like to get good value for our money when we pay for new drugs, devices, and procedures. How do we get there? What tools do we have to use, and what policy options are available? Formal economic evaluation can help us answer these questions.

The field of economic evaluation of health and medical interventions has been an active area of research in recent years. It includes cost-effectiveness analysis, which shows the relationship between the total resources used (costs) and the health benefits achieved (effects) for an intervention compared to an alternative strategy. Often a standard metric such as life-expectancy or quality adjusted life-expectancy is used as the measure of health benefits.

In part with funding from the Agency for Health Care Research and Quality, my colleagues and I have compiled a list of over 1500 cost-effectiveness ratios, covering a wide variety of medical technologies and public health strategies in many disease areas. More information is available on our website *www.lispb.harvard.edu/cearegistry*.

These data underscore several important points about the cost-effectiveness of medical technology. First, a great deal of information on the topic has become available to policymakers in recent years. Unlike many unsupported assertions made about the "cost-effectiveness" of drugs and other medical technology, these studies quantify costs and health effects using data and a standard, well-accepted methodological technique.

Second, according to peer-reviewed articles, many technologies are indeed cost-effective. Examples include warfarin therapy to prevent stroke in those with atrial fibrillation, immunosuppressive drugs for those with kidney transplants, and treatment with mood-altering drugs for those suffering from depression. These interventions provide good value in the sense that they produce health benefits for relatively little cost, or may actually save money for the health care system.

Third, cost-effectiveness does not mean cost-savings. Over the years, people have sometimes confused these terms. But restricting the term cost-effective to cost-saving interventions (where equal or better health outcomes is implied) would exclude many widely accepted interventions, which do not save money but are "cost-effective" in the sense that their additional benefit are worth their additional cost.

A related point is that a critical aspect of any medical technology's cost-effectiveness involves the manner in which the question is framed. A technology is not intrinsically cost-effective or cost-ineffective. It is only meaningful to say that a technology is cost-effective compared to something else. A drug prescribed to lower an individual's blood pressure may in fact be cost-effective compared to the option of no treatment, but not necessarily when compared to an alternative intervention, such as an intensive program of diet and exercise, or another medication. Similarly, claims of cost-effectiveness often depend on the population under investigation. For example, statin drugs used to lower an individual's cholesterol have been found to be relatively cost-effective as secondary prevention in persons with existing heart disease, but considerably less cost-effective as primary prevention.

Does anyone actually use CEA? Logically, cost effectiveness analysis should be used by private insurers and state and federal policy makers. However, many payers, including Medicare, have shied away from using CEA in coverage and reimbursement decisions.

But why? Cost-effectiveness analysis promises to inform decisions and enhance population health in an explicit, quantitative and systematic manner. Medical journals, including the most prestigious ones, routinely publish CEAs. Furthermore, many other countries have incorporated CEA into their policy decisions.

How do we explain this paradox? Studies point to a couple of explanations. Some of them fault the methodology itself. But in fact, most experts agree on the basic tenets. Instead, the opposition more likely relates to the hardened American distaste for explicit rationing. This is understandable, perhaps. But still, how do we get good value in face of this opposition?

I would offer five observations as we look ahead.

CEA should not be used rigidly. Leaders in the field have always warned against using CEA mechanically, but experiences teaches that rigid use of CEA will be resisted. Expectations for CEA should be modest. CEA should inform decisions not dictate them.

CEA will not save money. CEA should not be conceptualized or promoted as a cost containment tool, but rather as a technique for obtaining better value. Paradoxically, using CEA may actually increase health spending, because it often reveals under—than over treatment.

How you say it matters. Research shows that physicians understand that resources are limited but they are not willing to admit to rationing. Similarly, health plan managers deny that they ration care but admit that their budgets are con-

strained. These responses are instructive. It suggests that the term "cost-effectiveness" may be part of the problem. We might instead use terms such as "value analysis" and comparability, rather than cost-effectiveness analysis and rationing.

Incentives first. Debates about the use of cost-effectiveness cannot be separated from debates about the underlying health system and the incentives they embody. The technique is sometimes opposed if used centrally. But reconfiguring the incentives facing providers and patients is challenging and critical.

Think broadly across sectors. A final message involves the importance of thinking expansively about applications of CE information. CEAs should not simply focus on medical interventions but more broadly on interventions to improve health by reducing environmental exposures, injuries at home and in the workplace, and motor vehicle accidents.

In closing let me emphasize that whether medical technology offers good value is a question that can only be informed by careful analysis. I would encourage the judicious use of cost-effectiveness analysis in the years ahead.

Thank you very much.

Table 1: Selected Cost-Effectiveness Ratios

Interventions	Cost per QALY ratio (US $2002)
Onetime colonoscopic screening for colorectal cancer at 60-64 yrs old vs. no screening in women over 40 years old	Cost-saving.
Cost-saving Chemoprevention with tamoxifen vs. surveillance in 40-year-old women with high-risk breast cancer 1/2 mutations	$1,800
Drug treatment vs. no treatment in stage I hypertensive patients: men, age 80	$4,800
High-dose palliative radiotherapy vs. best supportive care in patients with advanced non-small-cell lung cancer	$13,000
Combined outreach for the pneumococcal and influenza vaccines vs. no new outreach program in persons aged 65 years old and older never vaccinated with pneumococcal vaccine and/or not vaccinated for influenza in the last year	$13,000
Screening for diabetes mellitus vs. no systematic diabetes mellitus screening in all ndividuals age 35-44	$22,000
Driver side air bag vs. no air bags in driving population (and passengers)	$30,000
Bypass surgery vs. medical management + aspirin over 5 years in ischaemic heart disease patients	$35,000
Automated external defibrillators on large-capacity aircraft, selective training vs. no automated external defibrillators, attendants with basic life support training in patients experiencing cardiac arrest onboard US commercial aircraft during a 12 month period	$36,000
Coronary artery bypass graft surgery vs. percutaneous transluminal coronary angioplasty (PTCA) in 55-yr. old men with 3-vessel coronary artery disease and type A lesions with severe angina and normal ventricular function	$99,000
Intensive school-based tobacco prevention program vs. status quo (Current average national tobacco educational practices) in every 7th and 8th grade in the U.S.	$5,300-650,000
MRI + dynamic susceptibility contrast-enhanced (DSC) magnetic resonance imaging (MRI) vs. head computed tomography (CT) scan only in patients presenting for the first time to an Alzheimer's Disease center/clinic	$530,000
Triple therapy with zidovudine, lamivudine, and indinavir for all exposures vs. the current United States Public Health Services (USPHS) post-exposure prophylaxis guidelines in health care workers dosed to known HIV+ blood	$850,000
Surgical strategy vs. Medical strategy in 45 year old men with severe esophagitis	$1,900,000

Source: Harvard School of Public Health Cost-Effectiveness Registry, 2003. www.hsph.harvard.edu.cearegistry.

Cost-Effectiveness of Underutilized Interventions in the Medicare Population

Health Intervention	Cost-Effectiveness ($/QALY)	Percent Implementation in Medicare Population
Influenza vaccine	Cost saving	40-70
Pneumococcal vaccine	Under $10K/QALY	55-60
Beta blocker treatment after myocardial infarction	Under $10K/QALY	85
Mammogram	Under $20K/QALY	75 (depending on age)
Colon cancer screening	Under $20K/QALY	20-40 (depending on age)
Osteoporosis screening	Under $20K/QALY	35
Antidepressant medication management	Under $25K/QALY	40-55
Hypertension control	Under $50K/QALY	35

Source: Harvard School of Public Health, 2003.

QALY=quality-adjusted life year.
Note: The estimates in this table are intended to provide a rough guide to cost-effectiveness and implementation. However, study methodology for estimated cost-effectiveness often varies across analyses. Moreover, cost-effectiveness may depend on factors such as the age and gender of the population, and the particular screening and technologies used.

Prepared Statement of Neil R. Powe, M.D., MPH, MBA, Professor of Medicine, Epidemiology and Health Policy & Management, Johns Hopkins University

Good morning Mr. Chairman, Senators and Representatives. I am Neil R. Powe, MD, MPH, MBA, Professor of Medicine, Epidemiology and Health Policy & Management at Johns Hopkins University in Baltimore, Maryland. I direct the Welch Center for Prevention, Epidemiology and Clinical Research, an interdisciplinary research center of the Johns Hopkins School of Medicine and Bloomberg School of Public Health. I am a general internist, clinical epidemiologist and health services researcher. My research has assessed the clinical and economic impacts of biomedical innovation in medicine. It examines the impact of new and established technologies on patients' longevity, functioning, quality of life and costs. I have conducted cost-effectiveness studies of technologies in several areas of medicine and have attempted to do this with equipoise. Among the technologies I have studied are kidney replacement therapies such as dialysis and transplantation, biotechnology medications such as recombinant human erythropoietin, cardiac revascularization procedures, imaging tests for lung and heart disease, laboratory testing for periodic screening, laser therapies, vascular procedures to prevent stroke and minimally invasive surgery. I have also studied physician decision making and other determinants of use of medical technology including payers' decisions about insurance coverage for new medical technologies and the impact of financial incentives on the use of technology.

New medical technologies include drugs, devices, procedures and the systems of care in which we, as medical professionals, deliver them. These include so called "little ticket" technologies which cost relatively little individually, but when used at high frequency, can become expensive. One such emerging "little ticket" technology is the C-reactive protein (CRP) laboratory test for detecting inflammation now being debated as a useful technology for detection of heart attack risk. "Big ticket" technologies such as "body scans" and organ transplantation have high individual price tags and can generate high cost even when used relatively infrequently. In theory, a new medical technology can increase costs, have similar costs or decrease costs relative to the existing standard. Evidence to date suggests that much of new biomedical innovation increases cost to the health system, especially in the short run. "Little ticket" or "big ticket", technology should not be judged based simply on costs. The more important question that I would like to address is "what is a technology's value".

Value is commonly seen as the benefit that is derived relative to the cost. In theory, a technology can produce benefit relative to the existing standard if patient outcomes (effectiveness and/or safety) are better; on the other hand it can produce no benefit if outcomes are similar, or even produce harm if patient outcomes are worse. High value occurs when substantial improvement in patient outcomes occurs at a reasonable cost. Americans believe in the concept of value and understand it. For example, they are willing to pay more for many things—a particular type of clothing, food, service, house or automobile—because they believe that the utility (happiness, satisfaction, health, well-being) that is derived from the purchase is worth the higher price. Cost is a relevant factor, but value is paramount. So much so, that medical technology needs to be judged in the same way.

Twenty-five years ago, the science of assessing value in medicine was rudimentary and underdeveloped. Many of the tools for assessing value were first applied to health care in the late 1970s and early 1980s. These include patient outcomes research comprising clinical trials, evidence synthesis (including meta-analysis) and cost effectiveness analysis. At that time it was uncertain how these tools would fare in assessing health care. They have undergone refinement by researchers at universities across the country. Much of this work has been catalyzed and funded by the Agency Healthcare Research and Quality. These researchers have sought to create rigorous standards of high quality research for value science. Teams of clinicians, epidemiologists, health services researchers, health economists and others are involved in assessing value. Despite the maturation of and demand for the science of value, its impact has been limited for three reasons.

First, there is an unprecedented number of new technologies now entering into the healthcare marketplace. These technologies earn the admiration of the world and are made possible from continual progress in biomedical science. They include minimally invasive surgery, transplantation of hearts, lungs, kidneys and livers, biotechnology drugs indistinguishable from natural hormones for patients with congenital or acquired deficiencies, dialysis therapy for end stage kidney disease, automatic implantable defibrillators and cardiac resynchronization to bring life to those with life threatening arrhythmias and heart failure. Knowledge of the structure and function of genes and proteins is advancing rapidly and the future will yield promising technologies we never imagined for identifying, preventing and treating acute and chronic diseases in an aging population. For example, genetic tests are now in the making for early detection of breast cancer, Huntington's disease and Alzheimer's disease. However, the level of funding for high quality and unbiased value assessments pales in comparison to the explosion of new biomedical innovations.

To the public, payers and providers, the entry of new medical technologies into the practice of medicine now seems like a series of intermittent "surprise attacks" on the pursestrings of American health care. It has been suggested that less than a fifth of all practices in medicine are subjected to rigorous evaluation and still less receive an adequate assessment of the cost consequences in addition to the clinical consequences. We are likely to witness a salvo of "surprise attacks" in the coming years without adequate funding to do early, comprehensive, balanced and rapid assessments. In a study with researchers at the AHRQ, I found that medical directors making coverage decisions for new medical technologies at private healthcare plans across our country were impeded in their decisions because of lack of timely effectiveness and cost-effectiveness information.[1] There is considerable trepidation to decide against covering potentially useful technology without adequate evidence. Likewise there is concern about making a coverage decision in favor of a technology that might later be shown to have minimal benefits at a large cost to society.[2] The preference of those making decisions about coverage and payment for technology was for high quality outcomes research funded by authoritative government entities.[3]

Early assessments of clinical and economic outcomes could be accomplished with investment of a small fraction of annual healthcare expenditures on value assessments. The payoff would be substantial. For example, contrary to relentless, direct-to-consumer advertising for body scans to detect occult disease, my colleagues and I recently found that screening smokers for lung cancer with helical CT scans is unlikely to be cost-effective unless certain conditions are met.[4] The high number of false positive lung nodules detected by the scans can potentially lead to more harm from invasive and costly surgical procedures. We have performed similar cost-effectiveness studies to guide decision making for detection of mild thyroid gland failure using thyroid stimulating hormone (TSH) laboratory tests and use of cardiac ultrasound devices in patients with stroke showing what tests have substantial value.[5,6] Early assessments such as these, which include primary data collection, secondary data collection, data synthesis, modeling and forecasting would secure information for the American public and its policymakers in the timely fashion needed to prevent premature dissemination of costly technology with no or little value. The Agency for Healthcare Research and Quality as well as the National Institutes of Health could act as the focal point to bring the best teams of "value researchers" in the country to attack these issues, by performing clinical effectiveness trials, observational studies, cost-effectiveness analyses and meta-analyses. If introduction of some new technologies does not decrease costs, at least through generation of better

[1] Steiner CA, Powe NR, Anderson GF, Das A. Technology coverage decisions by health care plans and considerations by medical directors. *Medical Care.* 1997; 35:472-89.

[2] Boren SD. I had a tough day today, Hillary. *New Engl. Jour. of Med.* 1994; 330:500-2.

[3] Steiner CA, Powe N, Anderson GF, Das A. The Review Process and Information Used by Health Care Plans in the United States to Evaluate New Medical Technology. *Journal of General Internal Medicine* 1996; 11:294-302.

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[6] McNamara R L, Lima JAC, Whelton PK, Powe NR. Echocardiographic Identification of Cardiovascular Sources of Emboli to Guide Clinical Management of Stroke: A Cost-effectiveness Analysis. *Annals of Internal Medicine* 1997; 127:775-787.

[7] Cabana MD, Rand CS, Powe NR, Wu AW, Wilson MH, Abboud PA, Rubin HR. Why Don't Physicians Follow Clinical Practice Guidelines? A Framework for Improvement. *Journal of the American Medical Association,* 1999; 282(15):1458-1465.

and more timely information, Americans can make sure that what they are purchasing provides good value for the dollars they spend.

Early assessments are particularly important given rising numbers and costs of pharmaceuticals, current consideration of a Medicare prescription drug benefit and use of tiered pricing arrangements in the private sector to control drug spending. Tiered pricing is a mechanism to allow consumers choice in particular drug treatments when they believe one drug has value over another. However, they must pay more when choosing to use a more expensive medication. Placement of a pharmaceutical into a particular tier and patient decisions to buy and use it are dependent on unbiased information about the benefits and costs of the pharmaceutical relative to the benefits and costs of competing medications, i.e. relative value.

Second, as a corollary, funding for career development of "value scientists" needs substantial bolstering to expand the cadre of people with the capability to perform such research. The AHRQ and the NIH could amplify training programs focused on preparing and assuring experienced value scientists to perform this function, just as the AHRQ and NIH have support training of biomedical scientists who innovate. Far too few physicians and other health care professionals and scientists have the necessary training to understand and produce value science that integrates clinical and economic issues.

Third, understanding how technologies affect cost and value involves an understanding of the barriers to decision making for health care providers. Barriers to optimal decision making can lead to technologies being overused, underused or misused. Physicians are responsible for most of the decisions in medicine and therefore the use of medical technologies. My colleagues and I performed a study of the factors affecting physician decision making with regard to adherence to clinical practice guidelines.[7] We found there is a process that must take place for a new technology to become routine, standard practice. Physicians must be aware that a new technology exists, agree that it has value, be willing to try it (adopt) and then, they must adhere to its use. Lack of awareness leads to underuse. Underuse of an effective technology can lead to higher expenditures in the future. For example, if physicians were not aware that in patients with diabetes, urine protein screening for detection of occult kidney disease and application of angiotensin converting enzyme inhibitors can delay or prevent expensive ($>50,000 per year) dialysis treatment for endstage kidney failure, they might never employ this strategy in their practice. Fortunately, methods of communicating new information to clinicians are improving through rapid summary publications (Up To Date, ACP journal club), clinical practice guideline production by professional societies and dissemination through electronic means. The continued proliferation of technology will be even more challenging for physicians to keep abreast of new technology. Ways for helping them acquire and assimilate new information are needed.

If aware of a technology, physicians must agree with the evidence that a technology is more effective or safe. If high quality evidence on representative patient populations is not available, physicians may disagree on whether the technology provides benefit.[8] We studied how early assessments, released through brief clinical alerts that were not comprehensive influenced the use of carotid endarterectomy.[9] We found that clinicians may extrapolate research findings to populations without clear evidence and indications. Value science can provide clear evidence.

Awareness and agreement are necessary for appropriate use of technology but insufficient. Even being aware and with strong evidence of effectiveness, physicians may not adopt innovations if there are administrative barriers to its use or lack of self-efficacy (i.e. belief in their ability to use the technology to improve outcomes). They may also adopt technologies with little benefit if payment policies prematurely promote a technology's use. Financial incentives in payment policy influence both adoption of and adherence to use of technologies. We found that providers responded to financial incentives in payment policy for a biotechnology product (recombinant erythropoietin) used to treat the profound anemia associated with kidney dis-

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[7] Cabana MD, Rand CS, Powe NR, Wu AW, Wilson MH, Abboud PA, Rubin HR. Why Don't Physicians Follow Clinical Practice Guidelines? A Framework for Improvement. *Journal of the American Medical Association*, 1999; 282(15):1458-1465.

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[10] Powe NR, Griffiths RI, Anderson GF, de Lissovoy GV, Watson AJ, Greer JW, Herbert RJ, Whelton PK. Medicare Payment Policy and Recombinant Erythropoietin Prescribing for Dialysis Patients. *American Journal of Kidney Diseases* 1993; 22:557-567.

ease.[10, 11] Under a fixed, per case payment system, administered doses of this medication were less than optimal to achieve the maximal benefit. Changes in payment policies by the Centers for Medicare and Medicaid Studies were necessary to assure that Medicare spending was leading to maximal value for recombinant erythropoietin. Thus, proper use of new technologies means that the physicians who apply them and the systems into which they are placed are adequately configured and incentivized to make optimal use of the technology. To this end, there is a need for more behavioral and systems research that studies how biomedical innovation from laboratories is optimally and rapidly translated into interventions to improve the health of patients treated at hospitals and physicians offices. The AHRQ can play a role in this regard.

A final issue affecting cost and value is whether new technologies supplant older ones and whether technology induces more demand. New tests do not always replace older ones.[12] For example, CRP testing is a new test that could be routinely adopted for assessing heart attack risk. But it is unlikely to substitute for other tests such as cholesterol and diabetes testing. Similarly, ambulatory blood pressure monitors are unlikely to substitute for traditional office-based blood pressure monitoring. Minimally invasive surgery is an example of a technology that may induce persons who would otherwise not have a surgical procedure to undergo an operation. Although these technologies may not substitute for older traditional tests and may induce further expenditures through wider use, they may provide health value.

In conclusion, biomedical innovation has brought the United States new, unprecedented, medical advances that save and improve the quality of patients' lives. We need to continue to encourage biomedical innovation. But we must recognize that for many health conditions, technologies will bring higher rather than lower absolute costs. Cost is relevant, but value is far more important. We need to protect biomedical innovation and the America's purse by furthering the science of assessing value in medicine. Strengthening our nations' capacity to perform value science will help private and public payers in this regard and provide information that physicians and consumers of medical technologies need to make decisions about their care. The American people cannot afford to have technology used unwisely. A fraction of health care expenditures in the U.S. should be targeted to the value science of medical care.

Thank you for the opportunity to address you today. I would be happy to entertain any questions you may have.

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[12] Eisenberg JM, Schwartz JS, McCaslin FC, Kaufman R, Glick H, Kroch E. Substituting diagnostic services. New tests only partly replace older ones. *Journal of the American Medical Association* 1989; 262:1196-200.

[1] Steiner CA, Powe NR, Anderson GF, Das A. Technology coverage decisions by health care plans and considerations by medical directors. *Medical Care.* 1997; 35:472-89.

July 9, 2003

Honorable Robert F. Bennett
Chairman
Joint Economic Committee
United States Congress
G-01 Dirksen Senate Office Building
Washington, D.C. 20510

Dear Chairman Bennett:

AdvaMed is pleased to provide this testimony on behalf of our member companies and the patients and health care systems we serve around the world. AdvaMed is the largest medical technology trade association in the world, representing more than 1,100 medical device, diagnostic products, and health information systems manufacturers of all sizes. AdvaMed member firms provide nearly 90 percent of the $71 billion of health care technology products purchased annually in the U.S. and nearly 50 percent of the $169 billion purchased annually around the world.

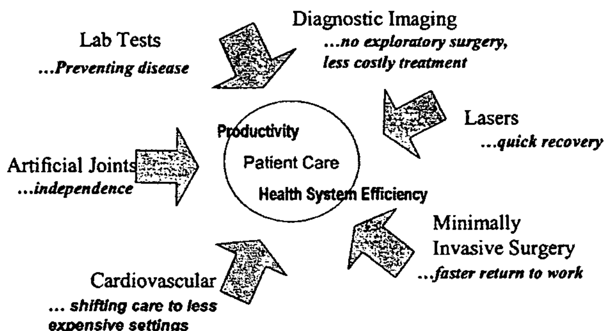
AdvaMed would like to thank Chairman Bennett for his leadership of the Committee, and for focusing attention on the role medical technology can play in improving the return on our health care investment.

The Federal Government plays an integral role in influencing the development and success of medical technology innovations. The Food and Drug Administration (FDA) oversees the clearance and approval of all new medical technologies. This initial regulatory hurdle is essential to the success of any new technology and the speed of that progress directly impacts patient access to these innovations.

Medicare policies also directly affect the success of new medical technologies. The Center for Medicare and Medicaid Services' (CMS) policies can delay diffusion of new innovations by 15 months to more than 5 years. This can literally mean life or death for patients awaiting new treatments and breakthroughs it also can have a significant impact on the success or failure of many medical technology companies, 90 percent of which have 100 or fewer employees.

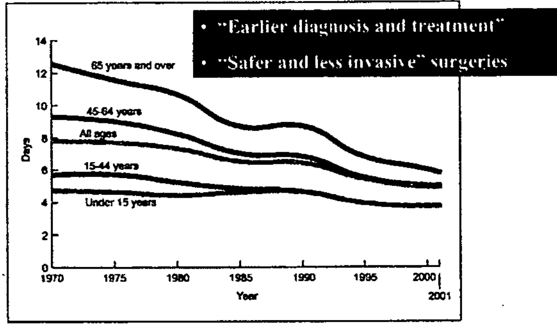
Honorable Robert F. Bennett July 9, 2003

Medical technology is one of the key reasons health care in the U.S. is the best in the world. In his State of the Union Address in January, 2003, the President described our health care system as the model of skill and innovation for the world. The President noted that the pace of discovery in advanced health care and preventive care in our country is "adding good years to our lives" and "transforming" health care. Medical technology is transforming health care in a variety of ways, and the results are measurable and impressive. In addition to the benefits to patients, these innovations improve productivity and health system efficiency.



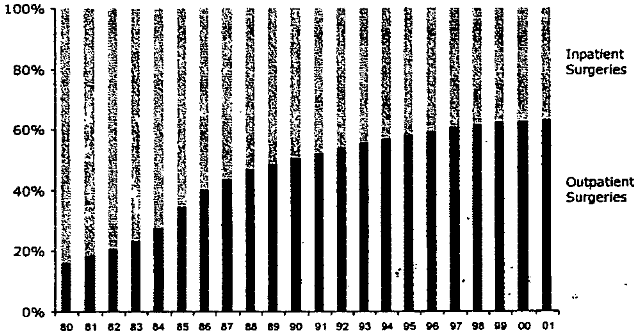
Diagnostic lab tests and imaging technology, such as CT and PET scans, are enabling earlier and more accurate detection of diseases without exploratory surgery. Artificial hip and knee joints are providing aging Americans mobility that is helping to keep patients fit and out of nursing homes. Minimally invasive inguinal hernia, gallbladder, and hysterectomy surgeries are reducing recovery times and getting patients back to active life and work faster, and with fewer complications. Minimally invasive surgeries are also shifting sites of care from inpatient to outpatient settings and cutting hospital stays dramatically. Finally, advances in cardiovascular care, such as stents, cardio resynchronization therapy, and implantable cardiac defibrillators, are leading to a steady decline in heart attack and stroke deaths and enabling more patients to benefit from this advanced care.

These transformative advances have lead to a dramatic decline in hospital stays (as depicted in the following chart) from 7.8 days to 4.9 days in the last 30 years. Seniors have experienced the most dramatic decreases in lengths of stays—half those of 30 years ago. Today, seniors stay an average of 5.8 days in the hospital, compared to 12.6 days in 1970.



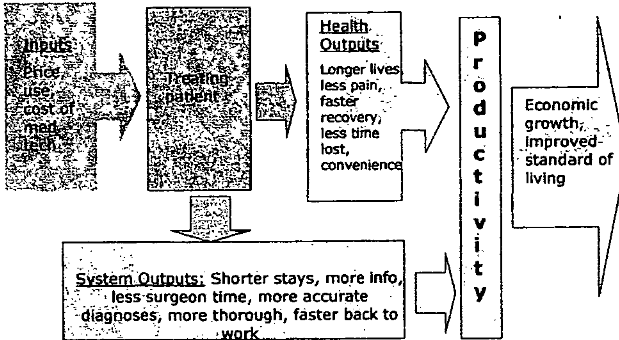
Average length of stay in days by age: United States, selected years 1970–2001

These advances have also revolutionized the way care is delivered—moving it from the more expensive inpatient setting to the less expensive outpatient setting and, increasingly, to home care settings. This shifting care translates into more care being delivered for less money to more patients. The following chart shows the percentage distribution of inpatient versus outpatient surgeries from 1980 – 2001.



Source: The Lewin Group analysis of American Hospital Association Survey data 1980 - 2001

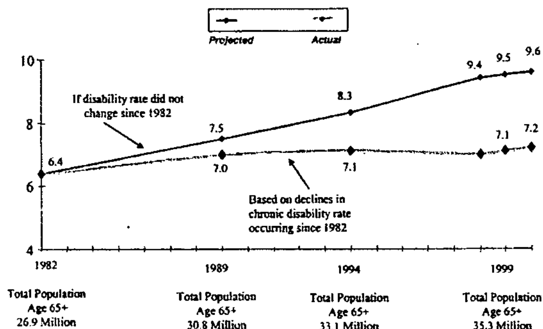
Historically, the cost inputs for medical technology were measured through the increases in health care spending. In recent years, however, researchers are measuring the benefits of the health and economic outputs from these expenditures. These studies have examined the economic value of increased life and productivity, and the results have been striking. The following chart illustrates the changes that medical technology innovation means for patients and the health care system.



One of these studies was conducted by Yale University economist William D. Nordhaus. Nordhous calculated that society received up to $2 of benefits for every $1 it spent on health care in the 1980s – the last decade for which he has complete data.

Another study by Ken Manton of Duke University found the innovation contributed substantially to reduced nursing home stays and declining disability. The study found that medical technology is helping fuel dramatic declines in disability, which improves quality of life, increases productivity, and dramatically reduces health care costs. The number of disabled seniors in 1999 was 2.2 million less than was projected in 1982, saving Medicare $19 billion in 1999 alone, which is depicted in this chart.

Projected Versus Actual Disabled Elderly
Number of Chronically Disabled Americans Age 65 and Over (in millions)



Source: Manton, et al.

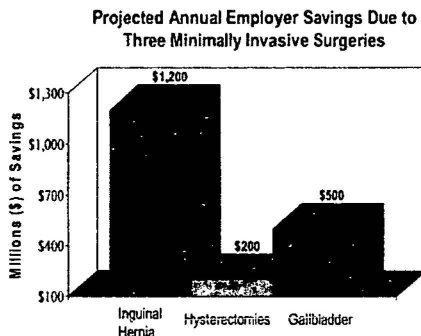
Professors Cutler and Mark McClellan (now FDA Commissioner) analyzed the economic value of increased spending in health care, focusing on added technological expenses. In four of the technologies studied—low birthweight infants, depression, heart attacks, and cataracts—the value of technological change is estimated to be much greater than the cost. In breast cancer (the fifth condition analyzed) costs and benefits are roughly equivalent. The authors defined benefits as better health (primarily longer life) and increased productivity that results when a person is able to work. They used the widely accepted figure of $100,000 as the value for every year of life without disease.

Condition	Net Benefit of Technology per patient
Heart Attack (1984 – '94)	$60,000
Low birthweight infants (1984 – '94)	$200,000; 6 to 1 return
Depression (1991 – '96)	Quality of life 6 times cost
Cataracts (1969 – '98)	$95,000 over 5 years
Breast cancer (1985 – '96)	4 month increase in life; dollar value and cost about equal

Cutler, McClellan, Health Affairs, Sept/Oct 2001

Cutler and McClellan concluded that, "The benefits from lower infant mortality and better treatment of heart attacks have been sufficiently great that they alone are about equal to the entire cost increase for medical care over time."

As these studies and facts show, the transformation in health care is benefiting patients, the health care system, and our economy. It is also directly benefiting employers by helping patients return to work sooner and be more productive on the job. This chart illustrates this fact by showing the results of one study that shows that employers are saving over $2 billion annually from improved productivity resulting from three minimally invasive procedures:



Source: The Importance of Indirect Benefits When Evaluating New Medical Technologies: A Case Study, by DRI-McGraw Hill for the Health Care Technology Institute, February 1995

Policy Issues Impeding Medical Technology Innovation

As outlined above, medical technology holds the potential to help the United States and the world cope with increasing health care demands by patients and an aging population. Innovation is enabling patients to live longer and healthier lives, require less medical care and enable our health care system to get more for every dollar spent. More Americans are receiving higher quality care than ever before. The result is increasing life expectancy, reduced disability, and increased national productivity.

Yet, our current system does not acknowledge or adequately recognize the benefits of this innovation. Specifically,

- The current system fails to take into consideration the long term savings and increased productivity arising from innovations. Our system fixates on health insurance costs and missed the bigger and more important picture – how society and patients overall are benefiting from medical technology innovation. Sometimes medical technologies have high up front costs but deliver enormous long term benefits.

- New technology is often confused with higher costs. In fact, the opposite is true. As noted above, medical technologies reduce costs over time by shifting the site of care to less expensive settings, cutting procedure time, reducing direct insurance costs, and shortening hospital stays. Costs are increasing because volume is increasing. This means more patients are benefiting from this innovation. More, better care is good for patients and our economy. A recent study, in fact, found that patients are still only receiving a little over half of the recommended care for the diseases investigated.

- Delays at FDA and CMS create barriers to new technologies, which slows innovation overall. Medicare can take months or years to correctly cover, code and pay for a new medical technology. Imagine if a new computer or cell phone had to go through the same process.

In fact, medical technology innovators indicate that government policy impedes innovation. A recent survey of medical technology innovators found that the industry is encountering significant FDA regulatory hurdles in getting these advances approved. Some 73% of the companies with premarket approval (PMA) technologies indicated that the average elapsed development time for their technologies has increased over the last five years. Moreover, 76% of the companies get their technologies to market faster in Europe (versus 5% that get their technologies to the market faster in the United States).

The survey also indicated delays in Medicare coverage and payment are also major factors affecting patient access to those innovations. More than one-third of the companies indicated that they learn frequently of patients who cannot afford access to technologies due to inadequate coverage and reimbursement. The survey also documents that these reimbursement policies are increasing the cost of innovation.

A copy of the survey findings are attached to this statement.

Important FDA Reforms Passed Last Year:
Congress Must Fulfill Its Obligation to Provide Its Part of the Funding Bargain

AdvaMed applauds Congress' steps to enact the Medical Devices User Fees and Modernization Act (MDUFMA). This is important legislation that will help assure faster reviews of innovative medical technology. The additional funds to the agency through the user fees will help assure the agency has the resources necessary to minimize delays in FDA reviews. AdvaMed calls on Congress to provide the needed appropriations required by MDUFMA to fully fund the program. AdvaMed also applauds the steps taken by the new Commissioner to streamline the agency and improve the review process.

Congressional Efforts to Improve Medicare Beneficiary Access to Technology

AdvaMed applauds Congress for the steps it took in the Balanced Budget Refinement Act of 1999 (BBRA) and the Benefits Improvement and Protection Act (BIPA) of 2000 to begin to make the Medicare coverage, coding and payment systems more effective and efficient. In addition, the Centers for Medicare and Medicaid Services (CMS) has recently made some changes to modernize its coverage and payment systems. Despite these efforts, however, current policies still fail to keep up with the pace of new medical technology. Serious delays continue to plague Medicare in its efforts to make new medical technologies and procedures available to beneficiaries in all treatment settings.

As demonstrated by a Lewin Group report provided by AdvaMed to the Congress in 2000, Medicare delays can total from 15 months to five years or more because of the program's complex, bureaucratic procedures for adopting new technologies. Keep in mind that all this is after the two to six years it takes to develop a product and the year or more it takes to go through the Food and Drug Administration (FDA) review. In addition, the impact of the delays is even more pronounced when you consider that the average life cycle of a new technology can be as short as 18 months.

These delays stem from the fact that for a new technology to become fully available to Medicare patients, it must go through three separate review processes to obtain coverage and receive a billing code and payment level. Serious delays in all three of these areas create significant barriers to patient access. AdvaMed supports reforming the Medicare system to promote greater competition and innovation within the program so seniors and people with disabilities can choose a benefits package that best suits their needs. AdvaMed supports increased private health plan participation within Medicare and the use of market-based pricing, rather than reliance on fee-schedules. A more market-oriented system will also promote more timely adoption of technologies that improve patient outcomes and improve the efficiency of health care delivery.

AdvaMed is pleased by the inclusion of important provisions in the House and Senate Medicare reform bills now proceeding to conference. We encourage Congress to adopt the provisions in these bills.

Specifically, both House and Senate versions of the legislation (H.R. 1 and S. 1) contained important provisions of the bipartisan *Medicare Innovation Responsiveness Act of 2003* (H.R. 941; S. 823), which was introduced by Reps. Jim Ramstad (R-MN), Anna Eshoo (D-CA) and Joseph Pitts (R-PA), as well as Senators Rick Santorum (R-PA) and Blanche Lincoln (D-AR).

Provisions of the bill include:

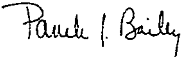
- Reforms to provide increased access to breakthrough technologies in the inpatient setting by setting reasonable thresholds for special add-on payments for new technologies;
- Coverage of routine patient care costs for breakthrough medical technology trials;
- National coverage and coding decision deadlines of 9 and 12 months depending on whether a decision is referred to the Medicare Coverage Advisory Committee or for an outside technology assessment;
- Establishment of a Council for Technology and Innovation to better coordinate coverage, coding and payment decisions and serve as a single point of contact for small medical technology innovators; and
- Allowing the Secretary of HHS to adopt ICD-10 as a new coding standard to facilitate better classification and payment for emerging technologies.

Both bills also adopted provisions of the *Medicare Patient Access to Preventive and Diagnostic Test Act* (H.R. 569), introduced by Reps. Jennifer Dunn (R-WA), Jim McDermott (D-WA), Mike Ferguson (R-NJ) and Peter Deutsch (D-FL) to improve access to new diagnostic tests that can detect diseases earlier and more accurately by establishing a transparent, predictable process for setting Medicare reimbursement rates for these technologies.

Conclusion

AdvaMed thanks the Committee members again for their collaborative efforts to focus attention on the value of medical technology innovation and the steps needed to assure patients benefit from these new technologies. We look forward to working with this Committee, the Congress and the Administration on advancing policies like those mentioned above so as to improve the quality of care available to patients here and abroad.

Sincerely,



Pamela G. Bailey
President