S. HRG. 108–209

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

Printed for the use of the Joint Economic Committee

U.S. GOVERNMENT PRINTING OFFICE
90–494 PDF WASHINGTON : 2003

For sale by the Superintendent of Documents, U.S. Government Printing Office
Internet: bookstore.gpo.gov Phone: toll free (866) 512–1800; DC area (202) 512–1800
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C O N T E N T S

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 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 develop 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 (I0M), 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.

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[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

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[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.

[4] Mahadevia PJ, Fleisher LA, Frick KD, Eng J, Goodman SN, Powe NR. Lung cancer screening with helical computed tomography in older adult smokers: a decision and cost-effectiveness analysis. *Journal of the American Medical Association* 2003; 289:313-22.

[5] Danese MD, Powe NR, Sawin CT, Ladenson PW. Screening for Mild Thyroid Gland Failure at the Periodic Health Examination. A Decision and Cost-Effectiveness Analysis. *Journal of the American Medical Association* 1996; 276:285-292.

[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.

[8] Cruz-Correa M, Gross CP, Canto MI, Cabana M, Sampliner RE, Waring JP, McNeilSolis C, Powe NR. The Impact of Practice Guidelines in the Management of Barrett's Esophagus: A national prospective cohort study of physicians. *Archives of Internal Medicine* 2001; 161:2588-2595.

[9] Gross CP, Steiner CA, Bass EB, Powe NR. The Relation Between Pre-publication Release of Clinical Trials Results and the Diffusion of Carotid Endarterectomy. *Journal of the American Medical Association* 2000; 284(22):2886-2893.

[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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[11] Powe NR. Prescription Drugs in Medicare and the ESRD Program. *Seminars in Nephrology* 2000; 20(6):535-5.

[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.

AdvaMed
Advanced Medical Technology Association

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:

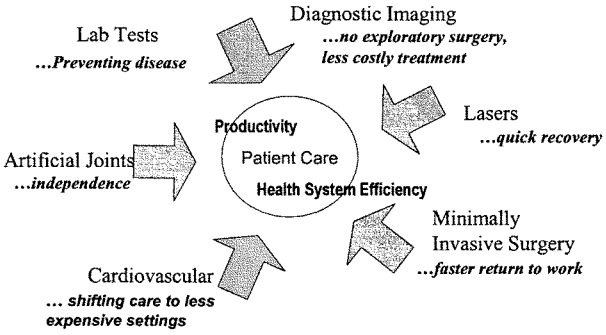
AdvaMed is pleased to provide this testimony on behalf of our member companies and the patients and health care systems we serve around the world. AdvaMed is the largest medical technology trade association in the world, representing more than 1,100 medical device, diagnostic products, and health information 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.

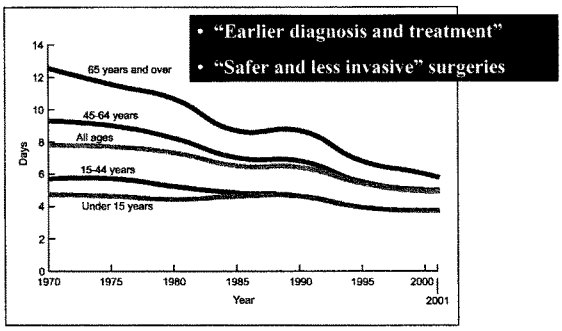
Medicare policies also directly affect the success of new medical technologies. The Center for Medicare and Medicaid Services' (CMS) policies can delay diffusion of new innovations by 15 months to more than 5 years. This can literally mean life or death for patients awaiting new treatments and breakthroughs 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.

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.



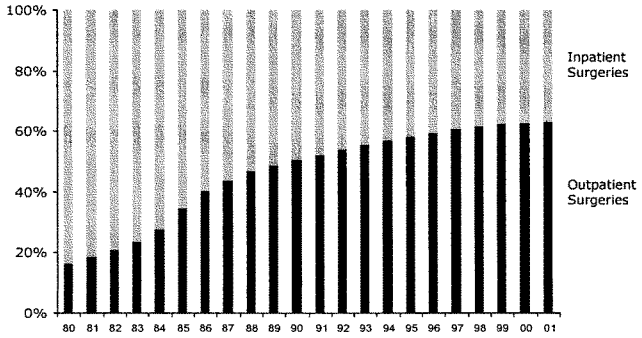
Diagnostic lab tests and imaging technology, such as CT and PET scans, are enabling earlier and more accurate detection of diseases without exploratory surgery. Artificial hip and knee joints are providing aging Americans mobility that is helping to keep patients fit and out of nursing homes. Minimally 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.



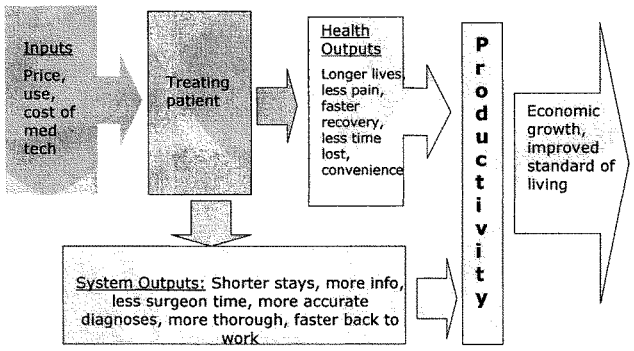
Average length of stay in days by age: United States, selected years 1970–2001

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.

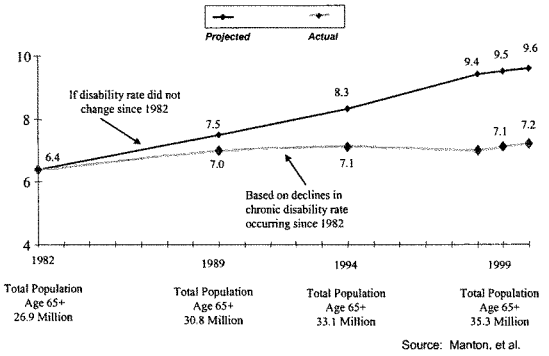


One of these studies was conducted by Yale University economist William D. Nordhaus. Nordhous calculated that society received up to $2 of benefits for every $1 it spent on health care in the 1980s – the last decade for which he has complete data.

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.

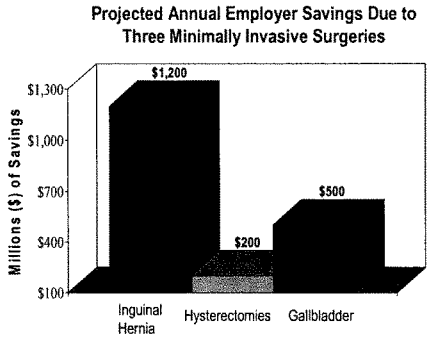
Professors Cutler and Mark McClellan (now FDA Commissioner) analyzed the economic value of increased spending in health care, focusing on added technological expenses. In four of the technologies studied—low birthweight infants, depression, heart attacks, and cataracts—the value of technological change 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