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HEARING ON STRATEGIES TO INCREASE INFORMATION ON COMPARATIVE CLINICAL EFFECTIVENESS

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON WAYS AND MEANS
U.S. HOUSE OF REPRESENTATIVES

ONE HUNDRED TENTH CONGRESS

FIRST SESSION

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HEARING ON MEDICARE PAYMENT ADVISORY COMMISSION'S ANNUAL MARCH REPORT

TUESDAY, JUNE 12, 2007

U.S. HOUSE OF REPRESENTATIVES,
COMMITTEE ON WAYS AND MEANS,
SUBCOMMITTEE ON HEALTH,
Washington, DC.

The Subcommittee met, pursuant to notice, at 10:05 a.m., in Room 1102, Longworth House Office Building, The Honorable Fortney Pete Stark (Chairman of the Subcommittee) presiding.

[The advisory announcing the hearing follows:]

ADVISORY

FROM THE COMMITTEE ON WAYS AND MEANS

SUBCOMMITTEE ON HEALTH

FOR IMMEDIATE RELEASE
June 12, 2007
HL–13

CONTACT: (202) 225–3943

Stark Announces a Hearing on Strategies to Increase Information on Comparative Clinical Effectiveness

House Ways and Means Health Subcommittee Chairman Pete Stark (D–CA) announced today that the Subcommittee on Health will hold a hearing on strategies to increase research and information on comparative clinical effectiveness. **The hearing will take place at 10:00 a.m. on Tuesday, June 12, 2007, in room 1100, Longworth House Office Building.**

In view of the limited time available to hear witnesses, oral testimony at this hearing will be from the invited witness only. However, any individual or organization not scheduled for an oral appearance may submit a written statement for consideration by the Committee and for inclusion in the printed record of the hearing.

BACKGROUND:

Rising health care costs and a lack of evidence justifying extreme variations in the provision of medical services have led many to call for a Federal effort to substantially increase information on the relative effectiveness of health care services. Health policy experts across the political spectrum advocate that such information is a sorely needed public good, and that greater investment in comparative effectiveness research is critical to assuring high-quality care and reducing unnecessary spending.

Various authorities both within and outside government have called for national investment in comparative effectiveness information, and have identified issues and options to help Congress determine optimal financing and governance for this activity. Providing Medicare with better information about the relative strengths and weaknesses of various products, procedures and services will help public and private payers equitably and efficiently manage rising health care costs.

On announcing this hearing, Chairman Stark said: **"As Medicare's steward, Congress needs to ensure that Medicare resources are being used effectively to provide high quality care and achieve the best possible patient outcomes. Getting reliable, unbiased comparative information is our best shot at reducing health spending while improving care and preserving access. This hearing will identify ways we can get the information we need to achieve this important goal."**

FOCUS OF THE HEARING:

The hearing will review the benefits of comparative effectiveness research, and opportunities for the Federal Government to expand the availability and value of such research.

DETAILS FOR SUBMISSION OF WRITTEN COMMENTS:

Please Note: Any person(s) and/or organization(s) wishing to submit for the hearing record must follow the appropriate link on the hearing page of the Committee website and complete the informational forms. From the Committee homepage, *http://waysandmeans.house.gov*, select "*110th Congress*" from the menu entitled, "*Committee Hearings*" (*http://waysandmeans.house.gov/Hearings.asp?congress=18*). Select the hearing for which you would like to submit, and click on the link entitled, "*Click here to provide a submission for the record*." Once you have followed the online instructions, completing all informational forms and clicking "submit" on the final page, an email will be sent to the address which you supply confirming your interest in providing a submission for the record. You ***MUST REPLY*** to the email and ***ATTACH*** your submission as a Word or WordPerfect document, in compliance with the formatting requirements listed below, by close of business **June 26, 2007**. **Finally**, please note that due to the change in House mail policy, the U.S. Capitol Police will refuse sealed-package deliveries to all House Office Buildings. For questions, or if you encounter technical problems, please call (202) 225–1721.

FORMATTING REQUIREMENTS:

The Committee relies on electronic submissions for printing the official hearing record. As always, submissions will be included in the record according to the discretion of the Committee. The Committee will not alter the content of your submission, but we reserve the right to format it according to our guidelines. Any submission provided to the Committee by a witness, any supplementary materials submitted for the printed record, and any written comments in response to a request for written comments must conform to the guidelines listed below. Any submission or supplementary item not in compliance with these guidelines will not be printed, but will be maintained in the Committee files for review and use by the Committee.

1. All submissions and supplementary materials must be provided in Word or WordPerfect format and MUST NOT exceed a total of 10 pages, including attachments. Witnesses and submitters are advised that the Committee relies on electronic submissions for printing the official hearing record.

2. Copies of whole documents submitted as exhibit material will not be accepted for printing. Instead, exhibit material should be referenced and quoted or paraphrased. All exhibit material not meeting these specifications will be maintained in the Committee files for review and use by the Committee.

3. All submissions must include a list of all clients, persons, and/or organizations on whose behalf the witness appears. A supplemental sheet must accompany each submission listing the name, company, address, and telephone and fax numbers of each witness.

Note: All Committee advisories and news releases are available on the World Wide Web at *http://waysandmeans.house.gov*.

The Committee seeks to make its facilities accessible to persons with disabilities. If you are in need of special accommodations, please call 202–225–1721 or 202–226–3411 TTD/TTY in advance of the event (four business days notice is requested). Questions with regard to special accommodation needs in general (including availability of Committee materials in alternative formats) may be directed to the Committee as noted above.

Chairman STARK. The Subcommittee will begin. Today is another in our series of hearings on how to improve Medicare, and we'll focus on long-term solutions to increase and assure the value of health care expenditures. This we hope to deal with the issue of comparative clinical effectiveness. That means comparing the relative value of different clinical treatments, drugs, devices, tests, procedures, bandages, pills, anything else you want to take, and trying to get a comparative ranking.

Too often, physicians and patients have trouble understanding when a new product or test or procedure will be most helpful and

how to choose among existing courses of treatment. Given the absence of information on comparative effectiveness, it's hardly surprising that GAO and MedPAC find dramatic variation in the use of medical services across regions, from different providers, by different specialties. Even worse, researchers find that the areas with the highest use of some services aren't necessarily linked to higher quality or better outcomes. To the contrary, beneficiaries may be put at greater risk when they're subjected to more and more complicated tests and treatments.

As Medicare's Board of Directors, Congress should ensure that Medicare resources are used effectively and efficiently to provide high-quality care and achieve the best possible outcomes. Getting reliable, unbiased comparative information is our best chance at controlling health care spending while improving care and access. Even if Mr. Orszag won't give us savings immediately for our efforts, we can identify ways that we can get the information we need to achieve this goal and lay the groundwork for a more efficient and effective system.

Health policy experts across the political spectrum advocate that comparative information is sorely needed for the public good. They argue that greater investment in comparative effectiveness research is critical to assuring high-quality care and reducing unnecessary expenditures. Better information about the relative strengths and weaknesses of various products, procedures and services will help physicians and patients make wise decisions and will help public service and private payers equitably manage rising health care costs.

Many countries have already made major investments to provide this information to physicians, patients, policymakers, and it's high time we do the same. Many of my colleagues urge that we should pay for performance. We already do that. The providers perform and we pay. It's just that we pay the same whether the service is done on the right people at the right time or the wrong people at the wrong time. We really have to know what the effective and appropriate services are before we can know how to reward the care that achieves the best outcomes.

Various authorities both within and outside government have called for a substantial national investment in comparative effectiveness information and have identified issues and options to help us determine the optimal financing and governance for this activity. My personal preference is to move toward a system that's accountable yet independent and free from both industry and political influence. I want to repeat that. Free from both the industry and political influence. Both clinicians and patients need to be confident that the work that will be done is in the best interests of the patient. To me, that points to a government-led effort.We are fortunate to have with us today some of the leading experts as well as representatives of the prominent stakeholders. I am particularly pleased to welcome our first witness, but prior to that and prior to my introduction of him, I'd like to yield to Mr. Camp for any remarks he'd care to make.

Mr. CAMP. Well, thank you, Chairman Stark. The U.S. health care system lacks the kinds of comparative information that would allow consumers to make informed health care choices and pro-

viders to prescribe the best course of care. While we have agencies like the FDA to determine if drugs and devices are safe, we have very little information that compares the actual effectiveness of drug devices and medical procedures. Frequently, physicians lack the information that would allow them to compare what treatments work best for particular types of patients. This type of data could help health care providers identify best practices, ultimately leading to improved clinical outcomes.

Comparative effectiveness data will also be necessary if we are to ever more to a more consumer-focused model of delivering health care, where individuals are able to make more choices about the care they receive. This information also has the ability to help reduce expenditures under the major Federal health programs by helping to eliminate unnecessary procedures, leading to a significant savings for taxpayers.

At the same time, we cannot allow comparative effectiveness to become another hurdle that slows patients' access to new therapies. The current health care bureaucracies, especially those in the Medicare and Medicaid programs, are often unable to keep up with the dynamic and changing nature of health care. Government agencies should not be required to use or to rely solely on comparative effectiveness data to set reimbursements or make coverage decisions.

Comparative effectiveness can be a building block that leads to better health outcomes, but only if it's done in a transparent and timely way. This will require a process that encourages independent research, which also recognizes that not all therapeutic choices will be appropriate for all patients. Patient protections must be in place to make certain that unique patients are not harmed in the name of cost saving initiatives. Put simply, comparative effectiveness should be viewed as a tool to influence decisions. It should not, however, be used to limit patient access to the best course of treatment.

I look forward to hearing the testimony of the witnesses today, and hope that we can work together on legislation that will provide providers and patients with the information that can improve the quality of their health care.

Thank you, Mr. Chairman. I yield back the balance of my time.

Chairman STARK. You're welcome. Mr. Camp, I'd like to associate myself with your remarks. I think our, at least my interest in this effort, is to get us the information. I don't want to predetermine how we would use that information, but right nowand I've said this often to other people. We just went through an allergy season that was one of the worst, my pediatrician tells us, in 14 years. But you saw six or eight or ten antihistamines in every popular magazine, but nobody really had good records of which one was the best to use for your kids.

As I'd say to the people in the audience, when the men in the audience get prostate cancer, you won't know what is the best treatment. You'll know that you'll live through the initial treatment whether you do chemo or radiation or surgery. We just don't have figures that are reliable that will tell you what happens to you 10 years out. The same with the ladies in the audience who may unfortunately get breast cancer. You won't have the kinds of

statistics we need for you to predict with your physician what's the best course for you to follow. I hope that whatever comes out of the work we do on this Committee will help providers, beneficiaries, the taxpayers and everybody to understand that better.

To that end, I'm pleased to welcome our first witness, Congressman Tom Allen from Maine, who has been a leader in the House on the issue of comparative effectiveness and has recently submitted legislation to address this problem. The subsequent witnesses I'm sure will enlighten us on whatever their strategy is to improve health care in the United States, and I look forward to their testimony.

Tom, would you like to enlighten us in any manner you'd care to? If you have a prepared statement, it will appear in the record in its entirety without objection.

STATEMENT OF THE HONORABLE TOM ALLEN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MAINE

Mr. ALLEN. Thank you, Mr. Chairman. Thank you for holding this hearing, and I want to thank you and Ranking Member Camp for inviting me to testify today. I would ask my entire statement to be submitted.

Chairman STARK. Without objection.

Mr. ALLEN. I will talk from that statement. We have a huge gap in our health care system today: the absence of independent, evidence-based information about the comparative effectiveness of prescription drugs, medical devices and other treatments that deal with the same illness or condition.

Better information on how various treatments compare to one another will enable doctors and their patients to make informed decisions about whether new or high-priced drugs, devices and other medical treatments do or do not provide better clinical outcomes. The health care marketplace will be greatly enhanced by independent information more widely disseminated.

We've seen remarkable innovations in health care in recent years, but the aggregate health care costs have grown considerably faster than the overall economy. The United States spends more than any other nation on health care, but we rank 37th in the world in health outcomes. Nearly 47 million Americans are uninsured, and millions more are underinsured.

On May 7th of this year, I introduced H.R. 2184, the Enhanced Health Care Value for All Act, with Representative Jo Ann Emerson, who has been with me on this issue for the lastwell, this is the third Congress. The bill extends the success of the Agency for Healthcare Research and Quality's Effective Health Care Program and provides more funding for on the comparative effectiveness of health care services, including prescription drugs, medical devices, procedures, and other treatments, and can include clinical trials as well as surveys of existing literature.

Better clinical information on health care products and service is a public good. Therefore, the legislation creates a public-private funding mechanism to pool Federal resources with funds from health insurance plans and large employers with self-insured plans.

The investment in comparative effectiveness studies provides a sound, bipartisan approach to a fundamental challenge: how to ensure that we get the best value for our health care dollar. This initiative has gained the support of a very broad group of stakeholders representing patients, medical professionals, health services researchers and health care purchasers.

My bill expands on Section 1013 of the Medicare Prescription Drug Improvement and Modernization Act of 2003. That provision authorized AHRQ to carry out systematic reviews of existing research on the clinical comparative effectiveness and safety of prescription drugs and other treatments. Section 1013 was based on legislation that Representative Emerson and I introduced in the 108th Congress, and H.R. 2184, our current bill, expands on the small initial investment in comparative effectiveness, $15 million appropriated by Congress in the last two fiscal years.

Leaders at CMS, MedPAC, the Institute of Medicine and CBO have begun to explore this issue in greater detail. Economists Uwe Reinhardt, Stuart Altman and former CMS Administrator Gail Wilensky have put forth bold visions on where increased investment in comparative effectiveness could take us.

To have the best medical outcome, patients need the right care at the right time. Without good information on comparative effectiveness, we can't be confident that we are using products in the optimal way. The FDA approval process, as Mr. Camp indicated, does not give us this data, because it tests only for safety and for effectiveness compared to a placebo, not effectiveness compared to other drugs or devicesother drugs in that casethat treat the same illness or condition.

In closing, I want to make four critical points:

Number one. More effective treatments mean better health outcomes and reduce side effects.

Two. Overall comparative effectiveness data doesn't negate the need for individualized care. this is not, as some critics argue, a path to one-size-fits-all medicine.

Three. Broadening comparative effectiveness studies will provide better information about differential impacts on subpopulations and the interaction of various treatments in patients with multiple illnesses. In other words, broader information will be very helpful.

Fourth. High quality comparative effectiveness studies shouldn't threaten innovation. Instead, they will clarify the many reasons individuals can be exceptions to "average" outcomes and will facilitate transition to a system of affordable, personal health care.

I thank you very much for having me here today and look forward to working with you on this legislation.

[The prepared statement of Mr. Allen follows:]

Prepared Statement of The Honorable Thomas Allen, a Representative in Congress from the State of Maine

Mr. Chairman and Ranking Member Camp, thank you for inviting me to testify today.

We have a huge gap in our health care system: the absence of independent, evidence-based information about the comparative effectiveness of prescription drugs, medical devices, and other treatments that treat the same illness or condition.

Having better information on how various treatments compare to one another will enable doctors and their patients to make informed decisions about whether new or

high priced drugs, devices, and other medical treatments do or do not provide better clinical outcomes. The health care marketplace will be greatly enhanced by independent information more widely disseminated.

We have seen remarkable innovations in health care in recent years. New discoveries in medicine, medical devices and treatments have improved the quality of life and extended the average life expectancy of Americans.

Yet aggregate health care costs have grown considerably faster than the overall economy, contributing to double digit inflation for health care services. By 2016, U.S. health care spending is expected to almost double to $4.1 trillion and account for 20 percent of every dollar spent.

The U.S. spends the most per capita of any nation on health care, yet it ranks behind most industrialized nations on major health outcomes. Nearly 47 million Americans are uninsured, and millions more are underinsured.

On May 7, 2007 I introduced H.R. 2184, the Enhanced Health Care Value for All Act, with Representative Jo Ann Emerson. The bill builds on the success of the Agency for Health Care Research and Quality's "Effective Health Care Program" and provides increased funding to finance new research on the comparative effectiveness of health care services (including prescription drugs, medical devices, procedures, and other treatments), which may include clinical trials.

Recognizing that better clinical information on health care products and services is a public good, the legislation creates a public-private funding mechanism which will pool federal resources with funds from health insurance plans and large employers with self-insured plans.

Investment in comparative effectiveness studies provides a sound, bipartisan approach to a fundamental challenge: how to ensure that we get the best value for our health care dollar. This initiative has gained the support of a broad group of stakeholders representing patients, medical professionals, health services researchers and health care purchasers.

My bill expands on Section 1013 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. This provision provided authority for the Agency for Health Care Research and Quality to carry out systematic reviews of existing research on the clinical comparative effectiveness and safety of prescription drugs and other treatments. Sec. 1013 was based on legislation that Representative Emerson and I introduced in the 108th Congress (H.R. 2356) which gained broad bipartisan support.

The Enhanced Health Care Value for All Act expands on the small initial investment in this research of $15 million appropriated by Congress in Fiscal Years 2005, 2006 and 2007.

Leaders at the Centers for Medicare and Medicaid Services, Medicare Payment Advisory Commission, and Institute of Medicine have also begun to explore this issue in greater detail. Economists Uwe Reinhardt, Stuart Altman and former Health Care Financing Administration (now CMS) Administrator Gail Wilensky have put forth bold visions on where increased investment in comparative effectiveness could take us.

There is widespread agreement that to have the best medical outcome, patients need the right care at the right time. If we don't have good information on comparative effectiveness we can't have strong confidence we are using products in the optimal way. The FDA approval process does not give us this data. For example, it approves drugs after testing for safety and effectiveness compared to a placebo, not for comparative effectiveness at treating a particular illness.

In closing, I would like to make four critical points about comparative effectiveness studies:

1. More effective treatments mean better health outcomes and reduced side effects.
2. Overall comparative effectiveness data doesn't negate the need for individualized care. This is not, as some critics argue, a path to "one size fits all medicine."
3. Broadening comparative effectiveness studies will provide better information about differential impacts on sub-populations and the interaction of various treatments in patients with multiple illnesses.
4. High quality comparative effectiveness studies shouldn't threaten innovation; instead they will clarify the many reasons individuals can be exceptions to "average" outcomes, and will facilitate transition to a system of affordable, personalized health care.

Thank you for inviting me to testify today. I look forward to working with you to move toward a common goal: improving value in health care spending and ensuring that patients have access to the treatments that are right for them.

Chairman STARK. Tom, thank you. If I understand your bill correctly, the question of who gets to plead their product or service at this court of effectiveness, that the entry key would be an FDA approval, for example.

Mr. ALLEN. Yes.

Chairman STARK. So, first you'd have to go through the process of proving that it was safe and as opposed, say, to a placebo, it did something.

Mr. ALLEN. Right.

Chairman STARK. That you just weren't bringing a placebo to the table.

Mr. ALLEN. That's correct. I don't think it's right to slow down the process of getting approval at the FDA level, because I think that the AHRQ ought to be able to decide the appropriate time to conduct research on a particular group of drugs or a particular group of devices or treatments.

Chairman STARK. Would the stakeholders haveor the manufacturers, the providers, the physicians, the pharmaceutical companies, whomeverwould they have input into selecting theor setting the agenda for this panel? In other words, there's certainly going to be more people lined up wanting an effectiveness test, then there will be a time lag. Howhave you given any thought to how that would be fairly determined?

Mr. ALLEN. Well, what we've done is we create in this legislation, we expand the authority for the comparative effectiveness advisory board, and we want to make sure that the selection of the members of that board takes out people with financial interests in stakeholders, whether they be manufacturers of devices or manufacturers of prescription drugs.

Then for each individual study, there is a clinical advisory panel. We want the same transparency, the same process there to make sure that the people with a financial interest in the outcome of the study are not choosing the people who will oversee it.

Chairman STARK. So, to pick an example, MedPAC. Would that meet the standards that you have in mind? The way it's formulated and the panel is picked?

Mr. ALLEN. Yes. We're looking for panels that have some degree of political oversight, because all of this run ultimately through the Secretary of Health and Human Services, but is as independent as possible and as transparent, and fully transparent, so that conflicts of financial interests are weeded out. So, you'll really have the independent, evidence-based product at the end of the day that we need to do this research effectively.

Chairman STARK. Now I hesitate to bring this up, but I know you're talking about buy in effect an all payer system, which makes sense. But can you give us a ballpark idea of what we're talking about in costs? I know you have it coming out ofthe money coming out of the trust fund. The question, could we use appropriated

funds? I don't know. But what kind of agive me a, to the closest billion dollars or so what are we going to spend on this?

Mr. ALLEN. Well, as I understand it, ultimately, that's up to this Committee and the Congress as a whole. But the legislation, we think the appropriate scale of investment os $3 billion over 5 years, and that one-third of that, $1 billion, should be public money and should come from the Medicare trust fund, limited to a maximum of $200 million a year.

The other we have support from the insurers and from large employers with self-insured plans, and they have bought into the concept of funding the other two-thirds. Because, remember, this information is going to be of great help to insurers and to large companies with self-insured plans. They're going to use it their own way. What we're simply trying to do is get good, evidence-based information out there for the public.

Chairman STARK. So, what you're suggesting is that for the public, the beneficiaries at large, the public, the government should come up with that money out of revenues of one sort or another? The other two-thirds would be contributed by the providers and/or the manufacturers, people with a commercial interest at stake?

Mr. ALLEN. Well, by the insurance plans and by large employers. We are not suggesting that the pharmaceutical industry contribute to that fund. We are saying those who use the information in their own way. This kind of research is being done now by individual insurance companies, but because that information is not widely shared, it's notit doesn't have the impact that it could.

Chairman STARK. Thank you. Mr. Camp?

Mr. CAMP. Well, thank you, Mr. Chairman. Mr. Allen, thank you for your testimony. Obviously, we often lament the fact that we don't have good enough data or information even for policy decisions, much less so that individuals and physicians can make the appropriate decisions on the kind of care, as the Chairman mentioned earlier in this hearing.

But, obviously, I think there's a broad agreement that this kind of information, comparative effectiveness research, could help informed decision making in the health care area.

But as you look at other nations that do this, and they're further along than we are, there's a concern that insurance companies, maybe even CMS in America, could use this information to limit access to certain treatments, because someone may not fit the "average" stereotype. I realize there could be subgroups that might sort of mitigate that. But does your legislation have any specific safeguards to assure that access to patient-centered treatments is still available?

Mr. ALLEN. I would put it this way. The legislation is designed simply to deal with access to information and make that information available. We would obviously be open to suggestions along the lines that you are making here today. But the legislation itself is very clear. In your opening, you raised the concern about whether the information would inform decisions or drive decisions. It is not the intention of this legislation to drive decisions. But we're obviously open to suggestions to clarify the point that you're making today.

Mr. CAMP. Why did you choose the comptroller general and not have this be a part of AHRQ? Any particular reason?

Mr. ALLEN. In terms of selecting the panels?

Mr. CAMP. Yes. Sort of the authority or the chain of command of this group would report to the comptroller general. I just was wondering your thought process behind that choice and not some other model.

Mr. ALLEN. What we are trying to do is get a mix of some political oversight and some independence from politics. We are trying to get something like the MedPAC board. I mean, that's the goal. It's a bit of a difficult situation, because though we call for a study of completely independent funded centers, research centers, we think that probably, probably that leaves you never can be quite sure that you've got either the transparency and maybe the risk of being infiltrated by parties with interests in that kind of system.

We think we've got the right balance, but that's why we were doing it. Trying to get a balance with some control and the right mix of control and independence.

Mr. CAMP. All right. Thank you. Thank you, Mr. Chairman.

Chairman STARK. Mr. Doggett?

Mr. DOGGETT. Well, thank you very much for your testimony. I don't know of another Member of Congress who has given more thought than you have to different ways to improve our health care system, and I think this is one important aspect of that.

As far as the funding, Chairman Stark. explored that with you a little bit. I know that, for example, on NIH, that's all done through appropriated funds. Should we be considering an alternative that focuses on appropriated funds to pay for this important public purpose?

Mr. ALLEN. I would say that we believe, I believe, that an all payer system better reflects the sharing of the benefits. That you can try to pay for this entirely through appropriated funds, but then it becomes a heavier lift in terms of getting comparative effectiveness research on the scale that I believe it's needed.

In fact, you alreadywe already have buy-in from insurance plans and some large employers who believe and understand that it will help both improve the quality of their plans and their management of their plans, and drive down their costs. So, the benefits are both public and private. There are savings to the public systems and there are savings to the private systems, and that's why we argue an all payer plan makes the most sense.

Mr. DOGGETT. Thank you very much for your important recommendation.

Chairman STARK. Thank you. Mr. Ramstad, would you like to inquire?

Mr. RAMSTAD. Thank you, Mr. Chairman. Tom, good to see you as always.

Mr. ALLEN. Thank you.

Mr. RAMSTAD. I appreciate your kicking off this dialog. Like many concepts, I think comparative effectiveness sounds good in theory. Who can argue with comparison and effectiveness, comparative effectiveness? But I do have concerns about its implementation, just to follow up on Mr. Camp's line of questioning.

My question is this. With respect to your legislation, I'm concerned about the power that the single comparative effectiveness entity or authority might have to determine what's covered by insurance, again, to follow up on Mr. Camp's questioning.

Let me ask you specifically, would this advisory board, this comparative effectiveness advisory board, as provided in your legislation, make specific recommendations about which procedures, which devices, which drugs Medicare and private plans should cover or not cover?

Mr. ALLEN. My understanding of the legislation the way it's meant to work is the answer is no. The answer is, as I understand it, simply the studies will be done. They will be available on a public website for those who want the information to review, and to use in making their own decisions. This legislation does not try to drive the decisionmaking process of other bodies.

Mr. DOGGETT. So, it wouldn't preempt current law with respect to that decisionmaking process?

Mr. ALLEN. That is correct.

Mr. DOGGETT. It wouldn't say we recommend that Device A should be reimbursed and Device B should not?

Mr. ALLEN. That is correct.

Mr. DOGGETT. Okay. That's all I have. Thank you again, Tom. Mr. Chairman, I yield back.

Chairman STARK. Thank you. Mr. Camp, we have some full Committee Members who are not on the Subcommittee. Could they thank you. Then I'd call one of our distinguished Members who is here, Mr. Becerra. Would you like to inquire?

Mr. BECERRA. Mr. Chairman, I just wanted to acknowledge and welcome our colleague from Maine, Mr. Allen, for being here with us. I applaud him on his effort, but I will yield to my other colleagues.

Chairman STARK. Ms. Schwartz, would you like to?

Ms. SCHWARTZ. Thank you. I might hold my questions for the next panel, but I do think the interest in expanding our information about effectiveness and comparing that effectiveness is potentially very, very helpful to providers making that decision. I do share the concern I think of the other side. Mr. Camp mentioned about this information not being used in a way to limit access, particularly when it's a specific device or treatment is necessary for a particular person.

So, it's interesting information I think partly how we expand and how we get that information out there, but then how do we actually make sure it's used in the best way possible to help our providers provide the best care for the consumers in this country.

Chairman STARK. Mr. McDermott?

Mr. MCDERMOTT. Thank you, Mr. Chairman. Tom, in answer to your question, or Congressman Allen, in answer to your questions to Mr. Camp and Mr. Ramstad, this is basically a toothless tiger. It will gather up information and have information on a website but have no impact, no intended impact. Is that correct?

Mr. ALLEN. I think that sound, evidenced-based information on complicated topics that are widely available to providers and the public has an impact; that it drives decisions. I'll give you an example where it might have been effective in the past. Celebrex and

Vioxx, two drugs to treat osteoarthritis, were advertised at the level, you know, several hundred millions of dollars went into advertising those drugs. They were best used, according to the research, for those people who, when taking ibuprofen, had gastrointestinal troubles.

But they were marketed through Dorothy Hamill and others to a much broader to the entire population as if the entire population had something to gain. Simple comparative effectiveness studies on Celebrex, Vioxx and ibuprofen, to give just one example, might have driven a very different, number one, marketing strategy, but also a very different strategy by those who were prescribing those particular the two prescription drugs.

I would add, specifically in the case of those drugs, if we had had broader information, surveys of existing literature, ongoing comparative effectiveness studies that were independent, the problems with Vioxx, for example, might have been discovered considerably sooner. That's why I don't believe that there's a need at this moment. I think we need to create the system and provide the information, and that information will drive decisionmaking in a helpful way.

Mr. MCDERMOTT. The reason I asked the question is I guess if you've been here a while you sort of see stuff and you see it happen and you wonder about it. The quality control agency was a very effective agency in the past. Once they did a study on back surgery. They suggested that back surgery in many instances was not useful at all. They immediately were attacked by those folks who were the beneficiaries of that kind of surgery, not the patients, but the professionals involved in it. Their study was discredited, and there was a great big hooha because they were about to use this in Medicare in terms of making decisions about whether or not they were going to give it.

Now I wonder about why more information. I know insurance companies. I've dealt enough with them, when we did the effort with Mrs. Clinton back in 1993. Insurance companies have panels where they decide what they're going to put out and what they're going to pay for, what they're going to use stem cell transplants for, or what they're going to use bone marrow transplants for, or what illnesses they're going towhat are they going to use and pay for. They don't share that information at all. You can't find out from Blue Cross/Blue Shield who makes those technical decisions.

I guess I have some problem with creating another set of evidence-based medicine evidence, but not using it to drive decisionmaking in terms of how we control cost.

It seems to me that we're just saying let the market do whatever it wants to do, and anybody who can come up with a new device comes in and somehow gets it approved and away it goes, there has to be some way you look at the evidence as to whether this device is actually better than this device, or this medicine better than this medicine. Otherwise, there is no end of the cost in health care. That's what we've got today. That's why we've got the prices going out of sight.I don't did you just figure you didn't want to use it yet until you had the information gathered? Or do you think it's not a good idea to have the government in the position of trying to protect the patient's cost?

Mr. ALLEN. I would say that we believe that by itself, all by itself, bettera widerwider availability of better information, evidenced-based information that's generated by independent studies, not by the manufacturers of the device or the drug, and that serves everyone, that's available to everyone, it's available to the public and people running the public bodies. It's available to doctors and hospitals and other health care providers.

That information is going to, we believe, just by being out there and being of the kind of information of which there isn't enough now, we think that is going to drive better health care decisions both in terms of quality and in terms of cost.

Now, I mean this is, you know, my crystal ball only works some days and not today. But I think all by itself, having significantly more and better information on comparative effectiveness, is going to drive better decision making and save cost at the same time.

Mr. MCDERMOTT. I hope you're right.

Mr. ALLEN. I hope I am, too. Mr. Chairman?

Chairman STARK. Go ahead.

Mr. ALLEN. Can I just clarify one?

Chairman STARK. Sure.

Mr. ALLEN. When Mr. Camp was questioning me, I want to clarify some of the things I said right then. The comparative effectiveness advisory board reports ultimately to the Secretary of Health and Human Services and to Congress, not to the comptroller general. The comptroller general's only role is to oversee the advisory board's selection process, as it does for MedPAC. It's an attempt to get and you may have, I didn't say this, and you may have understood this. But it's the attempt to make that selection process of the advisory board independent of political considerations.

Chairman STARK. Thank you. I want to thank you for your efforts and your testimony and assure you that as soon as one of my colleagues plagiarizes your good bill and introduces it under their own name, it will probably scoot right through this Committee.

[Laughter.]

Chairman STARK. You'll be left out there wondering what happened.

Mr. ALLEN. Mr. Chairman, you can't be serious.

Chairman STARK. Oh, ho ho. But thank you very much, and we appreciate your contribution to our venture here in learning about this.

Mr. ALLEN. Thank you.

Chairman STARK. You're going to be followed by a panel of government experts in this case; Dr. Carolyn Clancy, who is the Director of the Agency for Healthcare Research and Quality, and Dr. Peter Orszag, who is the Director of the Congressional Budget Office.

Dr. Mark Miller, who advises us frequently and often and most helpfully on issues before us in the Medicare arena.

After you are seated, get a chance to get settled, we will have you proceed in the manner in which I called you.Without objection, your full prepared testimony will appear in the record and you can enlighten us in any manner in which you are comfortable.

Dr. Clancy, would you like to lead off?

STATEMENT OF CAROLYN M. CLANCY, M.D., DIRECTOR, AGENCY FOR HEALTHCARE RESEARCH AND QUALITY, ROCKVILLE, MARYLAND

Dr. CLANCY. Thank you. Good morning, Mr. Chairman and Members of the Subcommittee. I am very pleased to testify before you on the exciting issue of comparative effectiveness. I ask that my written testimony and samples of AHRQ's comparative effectiveness reports and other materials be made part of the record.

I am thrilled about the growing interest in and attention to enhancing the role of comparative effectiveness research in our health care system. I am particularly pleased to be able to tell you about the important work that my agency, the Agency for Healthcare Research and Quality, is doing in the area of comparative effectiveness.

AHRQ's mission is to improve the quality, safety, efficiency, and effectiveness of health care for all Americans. Effectiveness in our mission includes comparative effectiveness: What is the right innovation or treatment for the right patient at the right time?

Comparative effectiveness research is a means to an end. Our mission is fulfilled when health care decisionmakers, including patients, clinicians, purchasers, and policy-makers, use up-to-date evidence-based information about their treatment options to make informed health care decisions. Since they are making these decisions every day, we have a sense of urgency about this work.

As a doctor and as AHRQ's director, I am very pleased that Congress recognized the programs and infrastructure the AHRQ has established for providing the health care system with scientific evidence when it authorized us to do comparative effectiveness research. This infrastructure enabled AHRQ to establish our Effective Health Care program and begin work rapidly without having to reinvent the wheel or create a new bureaucracy.

In addition, our reputation as an unbiased and trusted source of information has moved the health care system to adopt and use the findings to improve the quality, safety, and effectiveness of health care.

An important hallmark of the Effective Health Care program is transparency in all aspects of the process. Priorities for the program are set after receiving broad public input through Federal Register notices, public listening sessions, and other means.

We have been very fortunate to have developed very cooperative relationships with a broad range of stakeholders, and we actively seek out comments and input from as many as possible.

The public and all interested stakeholders have the opportunity to comment on the initial research priorities, framing of the specific questions, and draft reports. We also extensively focus test and seek input from consumers on materials that we develop specifically for them based on our comparative effectiveness reports.

In addition to the open invitation to comment, manufacturers are notified when a study is begun that affects their products, and are invited to submit relevant studies and data. Input from manufacturers can raise questions and concerns. We have worked with our researchers to develop a process to minimize conflicts so we can create public/private partnerships with confidence.

As AHRQ has implemented the Effective Health Care program, we have five significant observations to share. First is priority-setting. It is important to set clear priorities that meet the needs of all the stakeholders in health care. Therefore, end users and stakeholders must continuously provide input through an open and transparent process.

Second is framing the research questions. Research must follow how clinicians and patients make health care decisions every day. After much deliberation, we decided that our research should focus on conditions rather than interventions. At the end of the day, that is how health care decisions are made. It is also very important to recognize the importance of updating findings frequently to incorporate new evidence that may change or modify the conclusions about what works best and for whom.

The third relates to balancing benefits and harms. Comparative effectiveness research, by definition, must provide information on benefits and harms of a particular medication or intervention. Evaluating the balance of harms and benefits is a critical component of informed decisionmaking.

Few interventions are risk-free, and for many chronic conditions the therapeutic goal is management of symptoms and disease state rather than cure. Oftentimes the decision comes with some assumption of harm by both patient and clinician, but with the understanding that the benefits are worth that risk.

Fourth, research is a means, not an end. The ultimate goal of our research efforts is to develop timely, relevant information for decisionmaking. This requires us to go well beyond the products of traditional research, namely, scholarly articles, and translate findings in language and formats that are appropriate for different audiences. Our goal is that valid, reliable, and useful information be there when and where people need it.

Fifth, trust is incredibly important. We view it as a process, not a structure. As Gail Wilensky has said, comparative effectiveness research can be risky business, and there may be winners and losers. While we have learned that there are often no clear winners and losers, but differing risks and benefits between different interventions, it is still important that there be a level playingfield among all stakeholders. For that reason, our program has adopted a policy of transparency and inclusion.

In addition, it is clear that the program's success to date is dependent on effective collaboration with scientists from industry as well as academia. We are working very carefully to minimize conflicts in the analysis and development of knowledge, while taking advantage of the collective knowledge of a variety of different researchers through peer review and methodological work.

The question of trust also extends to the integral role that patients plan in research. Although government and the private sector pay for research, patients assume the risks and benefits of enrolling in clinical trials and other studies. For that reason, it is critically important to recognize that these findings need to be carefully translated so that patients can receive the benefits of this knowledge in making their decisions.

We all need to learn from the knowledge gained in research. But for patients, it can be a matter of life and death. Mr. Chairman,

at some point we are all consumers of health care, so we can all recognize the importance of having unbiased, trustworthy information to inform our decisions.

AHRQ's Effective Health Care program is a model for how this vision can be achieved. It is a transparent, participatory approach that is driven by the needs of users and which encourages broad engagement of stakeholders to explore and mitigate any controversies, and to expand opportunities for the rapid diffusion of findings of this research.

In short, the Effective Health Care program represents a foundation on which a large investment in comparative effectiveness can be built. Thank you very much, and I would be pleased to answer any questions.

[The prepared statement of Dr. Clancy follows:]

Prepared Statement of Carolyn M. Clancy, M.D., Director, Agency for Healthcare Research and Quality, Rockville, Maryland

Good morning, Mr. Chairman and Members of the Subcommittee. I am Dr. Carolyn Clancy, the Director of the Agency for Healthcare Research and Quality (AHRQ), an agency of the U.S. Department of Health and Human Services (HHS). I am very pleased to testify before you on the exciting issue of comparative effectiveness. I am thrilled about the growing interest in, and attention to, enhancing the role of comparative effectiveness research in our health care system. And I am particularly pleased to be able to tell you about AHRQ's important efforts in this area of research.

This is a very interesting time in the history of health and medicine. Our investments in biomedical research have resulted in many new diagnostic and therapeutic options. Clinicians and patients can often now choose among an expanded array of choices for treating hypertension, heart failure, HIV, mental illness, and other chronic illnesses, and unprecedented innovations in diagnosis and prediction bring us closer to a vision of personalized health care than ever.

We also are beginning to reap the benefits from the advances in health information technology (health IT) that can bring this information immediately to clinicians, patients, and others when and where they need it. Health IT also is enhancing our research capacity and our ability to diffuse breakthroughs quickly and efficiently throughout the health care system. Health IT can make research a natural by-product of delivering health care.

While this brave new world of health care presents wonderful opportunities, it also creates challenges. Chief among them is how to evaluate these innovations and determine which represent added value, which offer minimal enhancements to current choices, which fail to reach their potential, and which work for some patients and not for others. The need to develop better evidence about the benefits and risks of alternative choices is imperative.

The mission of AHRQ is to improve the quality, safety, efficiency, and effectiveness of health care for all Americans. Effectiveness sits squarely in our mission—what is the right treatment for the right patient at the right time.

Comparative effectiveness research is a means to an end. Our mission is fulfilled when health care decision makers including patients, clinicians, purchasers, and policymakers—use up-to-date, evidence-based information about their treatment options to make informed health care decisions.This goal was the inspiration for the creation of AHRQ by those Members of Congress who grasped the power of information to improve the health care system and the health of Americans.

Effective Health Care Program

AHRQ was granted authority under Section 1013 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) to conduct and support evidence syntheses and research on topics of highest priority to Medicare, Medicaid, and the State Children's Health Insurance Program (SCHIP).

I would like to thank Congress for its recognition of the programs and infrastructure that AHRQ has established for providing the health care system with the scientific evidence that it needs to provide safe, high quality effective health care. AHRQ's Evidence-based Practice Centers (EPCs), Centers for Education and Re-

search on Therapeutics, and other research programs have become a trusted, unbiased national source of information on health care diagnostics and treatments

These programs are an integral part of the AHRQ's Effective Health Care program, which was created under the authority of Section 1013. AHRQ was able to establish the Effective Health Care program and begin work very quickly because of our solid, existing research enterprise.

The Secretary of HHS, Michael Leavitt, has established priorities for research conducted in the Effective Health Care Program by establishing high priority conditions that have a major impact for the Medicare, Medicaid, and SCHIP programs. To be effective, comparative effectiveness research must be relevant to its users. Decision makers are often faced with situations for which multiple different treatments are relevant at different times. For example, should a fifty-five-year-old woman with a scan showing greatly decreased bone density take drugs, increase Vitamin D and calcium intake, focus on weight-bearing exercise, or watchfully wait? We know that drugs are effective, but there is limited information on their long-term effects. Some women will develop kidney stones after increased calcium; current evidence does not allow precise formulation of an effective exercise prescription; and many women will never experience a fracture.

The key to success for this research is that it provides evidence that informs the choices confronting clinicians and patients and, where possible, should closely align with the sequence of decisions they face. As MMA Section 1013 directs, we also need to ensure that findings are frequently revisited, so they remain relevant and up-to-date. New evidence, such as a genetic test that identifies people at increased risk of untoward outcomes, affects comparative effectiveness and should be incorporated into these reviews at the appropriate times.

Under the statute, the Secretary of HHS is required to establish priorities, informed by a transparent priority-setting process that includes all stakeholders. Priorities for the Effective Health Care Program therefore are set after receiving broad public input through *Federal Register* notices, public listening sessions, and other means.

There was much discussion within HHS about how to approach these priorities. During our discussion of research on diseases or conditions, for example, we debated specific questions about treating diabetes and heart disease, and whether our research should center on particular medications and interventions, such as stents or proton pump inhibitors.

We decided to take a disease- and condition-based approach because, at the end of the day, that is how health care decisions are made. A patient comes to the health care system with a condition or disease, and all decisions, including how best to treat it, follow.

In December 2004, based on input from stakeholders, the Secretary of HHS identified 10 priority conditions—all of special significance to the Medicare program—to be the first addressed by the Effective Health Care Program. These conditions are:

- Arthritis and nontraumatic joint disorders
- Cancer
- Chronic obstructive pulmonary disease/asthma
- Dementia, including Alzheimer's disease
- Depression and other mood disorders
- Diabetes mellitus
- Ischemic heart disease
- Peptic ulcer/dyspepsia
- Pneumonia
- Stroke, including control of hypertension

AHRQ's Effective Health Care Program comprises three parts. The first capitalizes on effectiveness research conducted by AHRQ's existing 13 EPCs, which were created in 1997. The EPCs develop comparative effectiveness reviews which focus on treatments for the priority conditions. These reports synthesize currently available scientific evidence, including both published and unpublished studies, comparing treatments, including drugs, to determine relative benefits and risks, and wherever possible, measure these outcomes for subpopulation groups. In addition, the EPCs identify major gaps in the existing knowledge base.

To help fill these gaps, AHRQ established the second part of the Effective Health Care program, called the DEcIDE network (Developing Evidence to Inform Decisions about Effectiveness), which will focus on conducting rapid-cycle research to address specific issues that do not necessitate larger, more time-consuming randomized clinical trials. The DEcIDE network consists of 13 research centers that have

access to databases that contain clinical information for more than 50 million patients but do not identify them individually.

The third part of the Effective Health Care program is the John M. Eisenberg Clinical Decisions and Communications Science Center, based at the Oregon Health and Science University's Department of Medicine. The Eisenberg Center was established to ensure that the findings of our comparative effectiveness research are translated into formats that are understandable for all potential users. The center—named the John M. Eisenberg Center in honor of AHRQ's late director—assists in ensuring that effectiveness research leads to real-world quality improvements by translating complex scientific findings into understandable language for different audiences. The Center will help assure that reports are presented in formats that make them useful to a wide range of audiences and also will develop tools that encourage and empower consumers to make informed health care decisions.

An important hallmark of the Effective Health Care program is transparency in all aspects of the process. The transparency begins with the open process for setting research priorities, described earlier. The public and all interested stakeholders also have the opportunity to comment on the framing of specific research questions, as well as commenting on draft reports. In addition to the open invitation to comment, manufacturers are notified when a study is begun on one of their products and are invited to submit relevant studies and data.

Draft research questions and reports are posted on AHRQ's Effective Health Care Program Web site (www.effectivehealthcare.ahrq.gov), and the Web site has a listserv that automatically notifies interested parties when draft questions or draft reports are posted.

Comparative Effectiveness Reviews

To date, AHRQ has released seven comparative effectiveness reviews. These reviews can be found on the Effective Health Care Program Web site, discussed above. They are:

Gastroesophageal Reflux Disease (GERD)

For management of gastroesophageal reflux disease, medications called proton pump inhibitors can be as effective as surgery in relieving the symptoms and improving quality of life.

Breast Cancer Diagnosis

Among women who receive an abnormal mammography findings or physical exams, four common noninvasive tests (magnetic resonance imaging, ultrasonography, positron emission tomography scanning, and scintimammography) are not accurate enough to routinely replace biopsies.

Managing Anemia In Cancer Patients

Among cancer patients undergoing chemotherapy or radiation, there is no clinically significant difference between epoetin and darbepoetin in the management of anemia. The drugs show no clinically significant difference in improving hemoglobin concentration and reducing the need for transfusion.

Osteoarthritis Drugs

Non-steroidal anti-inflammatory drugs (NSAIDs) and COX–2 inhibitors present similar increased risks of heart attacks while offering about the same level of pain relief for patients with osteoarthritis. The exception is naproxen, which presents a lower risk of heart attack for some patients than other NSAIDs or COX–2 inhibitors.

Renal Artery Stenosis

Increasing numbers of patients with narrowed kidney arteries are undergoing vessel-widening angioplasty and placement of a tubular stent, but evidence does not show a clear advantage of that treatment over prescription drug therapy.

Off-Label Use Of Atypical Antipsychotics

Some newer antipsychotic medications approved to treat schizophrenia and bipolar disorder are being prescribed for depression, dementia, and other psychiatric disorders without strong evidence that such off-label uses are effective. Research is urgently needed for new treatments of dementia patients with severe agitation.

Second-Generation Antidepressants

Today's most commonly prescribed antidepressants are similarly effective to first-generation antidepressants and provide relief to about six in 10 patients, but current evidence is insufficient for clinicians to predict which medications will work best for individual patients. Six in 10 patients experience at least one side effect, ranging from nausea to sexual dysfunction.

In January 2007, AHRQ released the first summary guide for consumers and clinicians derived from a comparative effectiveness report by the Eisenberg Center. The consumer report, titled *Choosing Pain Medicine For Osteoarthriti* s, translates the information from the comparative effectiveness report on osteoarthritis drugs into language that will help consumers choose among their treatment options. The companion guide, *Choosing Non-Opioid Analgesics for Osteoarthritis,* further synthesizes the evidence into a resource that can help clinicians work with their patients to make informed decisions about treatments for osteoarthritis.

AHRQ has a series of upcoming reports that deal with critically important issues facing the health care system. They include:

- Medications for type 2 diabetes
- ACEIs (Angiotensin-converting enzyme Inhibitors) vs. ARBs (angiotensin II receptor antagonists) for high blood pressure
- Surgery vs. stents coronary artery disease
- Medications and other treatments (e.g., diet, exercise) for low bone density

Health Information Technology

I would like to mention briefly the role of health IT, which will make it easier for researchers to gather information for their research and for users of research findings to get information in real time when they need it. The health care system's growing investments in health IT provide us with an unprecedented opportunity for redefining the possibilities of observational studies, accelerating and targeting the uptake of relevant information, and providing feedback to the biomedical enterprise itself.

Health IT will make it possible for research to answer the pressing questions facing the health care system more quickly and efficiently. In the future, health IT will provide us with the vehicle for transforming our health services research enterprise so that we can evaluate the effectiveness of interventions and treatments in real time as a byproduct of providing care.

AHRQ's Fiscal Year 2008 budget request includes $15 million for a personalized health care initiative that will begin the infrastructure for a federated system of databases that can help answer critical comparative effectiveness questions. This system would enable researchers to match treatments and outcomes, and in that way learn from the nation's day-to-day medical practice and improve safety and effectiveness of medical treatments.

Health IT also will greatly improve the ability to diffuse evidence and information more quickly throughout the health care system. For example, clinical decision support tools will make it possible to deliver relevant information to clinicians and patients, at the point of decision making. Most commonly envisioned as a pop-up reminder on a screen, clinical decision support should include information communicated directly to patients and caregivers at home—by phone, computer, or by other means.

Conclusion

As AHRQ has implemented the Effective Health Care program, we have some significant observations:

Priority setting: It is important to set clear priorities that meet the needs of all of the stakeholders in the health care system. Therefore, end users and stakeholders must continuously provide input through an open and transparent process.

Framing the research questions: Research must track closely with how clinicians and patients make health care decisions every day. The Secretary's decision to use a disease- and condition-based approach to priorities embodies this perspective. It is also very important to recognize the importance of revising findings frequently to incorporate new evidence that may change the conclusions of what works best and for whom.

Balancing benefits and harms: Comparative effectiveness research must provide information on benefits and harms of a particular medication or intervention. Evaluating the balance of harms and benefits is a critical component of

informed decision making. Few interventions are risk free, and for many chronic conditions the therapeutic goal is management of symptoms and disease state rather than cure. Often times, the decision comes with some assumption of harm—by both patient and clinician—but with the understanding that the benefits are worth that risk.

Research is a means, not an end: The ultimate goal of our research efforts is the development of timely, relevant information for decision making. This requires us to go beyond the products of traditional research, namely scholarly articles, and translate findings into language and formats that are appropriate for different audiences. Creating evidence and information that is not useful and accessible, or that does not take advantage of the latest communication technologies and vehicles, is a missed opportunity.

Trust as a process, not a structure: As has been stated, comparative effectiveness research can be a risky business, and there are winners and losers. Therefore, it is important that there be a level playing field among stakeholders. AHRQ's Effective Health Care program has adopted a policy of transparency and inclusion. Manufacturers are notified when a study is begun, are invited to submit relevant studies and data, and have the opportunity—along with any other interested party—to comment on the framing of the specific research questions as well as draft reports. In addition, it is clear that the program's success is dependent on effective collaboration with scientists from industry as well as academia. At the same time, we ensure that the authors of the comparative effectiveness reports are free of conflict to make sure that the results are not perceived as being biased in any way.

The question of trust also extends to the integral role that patients play in research. Although government and the private sector pay for research, patients assume the risks and benefits of enrolling in clinical trials and other studies. A question that is the subject of debate is whether study findings can ethically be kept secret from other researchers and patients themselves. We all need to learn from the knowledge gained in research, but it can be a matter of life and death for patients. We must move to an atmosphere where it is unacceptable to hold back research findings that may have an impact on the care that patients receive.

In conclusion, the U.S. health care system is poised to take advantage of advances in science and health information and communications technology in ways that have previously only seemed like something out of science fiction.

The need for valid, reliable, and accessible information on the comparative benefits and potential harms of treatment options has gained an urgency due to recent policies to promote the adoption of interoperable health IT, continued expansion of diagnostic and treatment options, increased consumer interest in health and health care decisions, and broad interest in improving value.

AHRQ's Effective Health Care program is a model for how this vision can be achieved: A transparent, participatory approach that is driven by the needs of users and encourages broad engagement of stakeholders to mitigate any expected controversies and to expand opportunities for diffusion of findings of comparative effectiveness research. The Effective Health Care Program represents a foundation in which a larger investment in comparative effectiveness can be built.

Thank you very much and I would be pleased to answer any questions.

Chairman STARK. Thank you, Doctor.

Dr. Orszag?

STATEMENT OF PETER R. ORSZAG, Ph.D., DIRECTOR, CONGRESSIONAL BUDGET OFFICE

Mr. ORSZAG. Thank you, Mr. Chairman and Members of the Committee. My oral testimony this morning will make three basic points.

First, the central fiscal challenge facing the United States is the growth of health care costs, not aging, despite what many media portrayals would suggest. This chart illustrates the point. Over the past four decades, costs per beneficiary in Medicare and Medicaid have grown 2.5 percentage points faster than income per capita. If

that rate of growth continued, you wind up on the top line. Medicare and Medicaid would grow from 4½ percent of the economy to 20 percent of the economy by 2050.

The bottom dotted line shows you what happens if that excess cost differential were zero, and isolates the effect of aging on the programs. I think you can see that where you wind up on that bottom line is higher than where you start. So, there is some effect of aging, but that difference is much smaller than the difference between the bottom dotted line and the top line in 2050.

In other words, the central long-term fiscal challenge facing the United States is how rapidly health care costs grow compared to income per capita, not the aging of the population or the coming retirement of the baby boomers.

These rising health care costs, by the way, also represent a challenge not only for the Federal Government, but for private payors. Indeed, costs per beneficiary in the public programs have tracked costs per beneficiary in the rest of the health sector over long periods of time.

My second point is that a substantial opportunity exists to constrain health care costs, both in the public programs and in the rest of the health system, without adverse health consequences. Perhaps the most compelling evidence in favor of this observation is the substantial geographic variation in costs per beneficiary across parts of the United States that cannot be explained by the underlying riskiness of the patientand I present the chart here, with the darker areas being higher spending regionsand which do not translate into higher life expectancy or measured improvements in other health statistics in the higher spending regions.

Furthermore, hard evidence is often unavailable about which treatments work best for which patients or whether the added benefits of more expensive but more effective care are worth the cost. The variation in treatments across the United States is often greatest for those types of care for which evidence about relative effectiveness is lacking.

Various Federal efforts to conduct this kind of comparative effectiveness have been undertaken in the past and some continue today, but on a scale that is significantly smaller than most observers believe is warranted.

If policy-makers want to expand Federal efforts to study comparative effectiveness, the effort could be organized and funded in various different ways. My written testimony describes some of these options, and a forthcoming CBO report that has been requested by the Senate Finance and Senate Budget Committees will go into even more detailed analysis of them.

However the effort is organized, having more health records available in electronic form would facilitate the use of existing data for research, which could create new opportunities for examining what works and what doesn't in a rigorous way.

Finally, comparative effectiveness research holds the potential to reduce health care spending significantly over the long term without having adverse effects on health. To effect medical treatment and reduce health spending in this way, the results of comparative effectiveness research would have to be used in ways that changed the behavior of doctors, other professionals, and patients.

For example, the higher value care identified by comparative effectiveness research could be promoted in the health system through financial incentives, the payments that doctors receive, or the cost-sharing that patients face. Making substantial changes in payment policies or coverage under the Medicare program to reflect information about comparative effectiveness would almost certainly require legislation.

I must also note that getting to the point where additional research on comparative effectiveness could have a noticeable impact on health care spending would take time. In addition to the time required to get the new activities underway and up to scale, a lag would exist before the results were generated, particularly if they depended on new clinical trials.

As a result of these lags and other implementation lags, it is relatively unlikely that there would be any significant net reduction in costs over the next decade or so. But despite all these caveats, it is so rare as CBO director that I get to have the ability to say that anything holds the potential to reduce costs over the long term that I want to repeat that final observation and repeat my basic conclusions, which are:

The United States is on an unsustainable fiscal course largely because of projected health care costs. There is a substantial amount of variation in those costs that cannot be explained by the underlying riskiness of the patients and that does not translate into better health outcomes for the population. Additional research on comparative effectiveness, if combined with incentives to implement the results of that research, hold substantial potential to reduce health care costs over the long term without impairing, and perhaps even improving, the health of Americans.

Thank you very much, Mr. Chairman.

[The prepared statement of Mr. Orszag follows:]

CBO TESTIMONY

Statement of
Peter R. Orszag
Director

Research on the Comparative Effectiveness of Medical Treatments: Options for an Expanded Federal Role

before the
Subcommittee on Health
Committee on Ways and Means
U.S. House of Representatives

June 12, 2007

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CONGRESSIONAL BUDGET OFFICE
SECOND AND D STREETS, S.W.
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Chairman Stark and Members of the Committee, it is my pleasure to be here today to discuss an issue that could play an important role in helping to address the central fiscal challenge facing the nation: rising health care costs. Over the past four decades, Medicare's and Medicaid's costs per beneficiary have increased about 2.5 percentage points faster per year than has per capita gross domestic product (GDP).[1] If those costs continued growing at the same rate over the next four decades, federal spending on those two programs alone would rise from 4.5 percent of GDP today to roughly 20 percent by 2050. The rate at which health care costs grow relative to income is the most important determinant of the long-term fiscal balance; it exerts a significantly larger influence on the budget over the long term than other commonly cited factors, such as the aging of the population.

Rising health care costs represent a challenge not only for the federal government but also for private payers. Indeed, both trends largely reflect the same underlying forces, and cost growth per beneficiary in Medicare and Medicaid has tracked that in the rest of the health system over long periods of time. Total health care spending, which consumed about 8 percent of the U.S. economy in 1975, currently accounts for about 16 percent of GDP, and that share is projected to reach nearly 20 percent by 2016. About half of that spending is now publicly financed, and half is privately financed.

A variety of evidence suggests opportunities to constrain health care costs both in the public programs and in the rest of the health system without adverse health consequences. Perhaps the most compelling evidence of those opportunities involves the substantial geographic differences in spending on health care—both among countries and within the United States—which do not translate into higher life expectancy or measured improvements in other health statistics in the higher-spending regions. For example, Medicare's costs per beneficiary vary significantly in different regions of the United States. Research has shown that much of the variation cannot be explained by differences in the population and that the higher-spending regions do not generate better health outcomes than the lower-spending regions.[2]

Furthermore, hard evidence is often unavailable about which treatments work best for which patients or whether the added benefits of more-effective but more-expensive services are sufficient to warrant their added costs. In many cases, the

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1. That figure takes changes in the age and sex of enrollees into account for Medicare but not for Medicaid. See Congressional Budget Office, *The Long-Term Budget Outlook* (December 2005), pp. 6–7 and 31–32.

2. See John E. Wennberg, Elliot S. Fisher, and Jonathan S. Skinner, "Geography and the Debate Over Medicare Reform," *Health Affairs,* Web Exclusive (February 13, 2002), pp. w96–w114; and Elliot S. Fisher and others, "The Implications of Regional Variations in Medicare Spending, Part 1: The Content, Quality, and Accessibility of Care," *Annals of Internal Medicine*, vol. 38, no. 4 (February 18, 2003), pp. 273–287.

extent of the variation in treatments is greatest for those types of care for which evidence about relative effectiveness is lacking. Together, those findings suggest that better information about the costs and benefits of different treatment options, combined with new incentive structures reflecting the information, could eventually yield lower health care spending without having adverse effects on health—and that the potential reduction in spending below projected levels could be substantial. Moving the nation toward that possibility—which will inevitably be an iterative process in which policy steps are tried, evaluated, and reconsidered—is essential to putting the country on a sounder long-term fiscal path. But even if it did not bring about significant reductions in spending, more information about comparative effectiveness could yield better health outcomes from the resources devoted to health care.

In response to a request from the Senate Budget and Finance Committees, the Congressional Budget Office (CBO) will issue a report on comparative effectiveness in the near future. Although that report will analyze the issues surrounding federal research efforts in greater depth, CBO's preliminary work has identified several key questions. In that light, my testimony today makes five main points:

- Because any private-sector entity (such as a health plan) has only a limited incentive to produce information that could benefit many entities, an argument can be made to coordinate comparative effectiveness research in a more systematic way than is currently done. In addition, because federal health insurance programs play a large role in financing medical care and represent a significant expenditure, the federal government itself has an interest in evaluations of the effectiveness of different health care approaches.

- If policymakers want to expand federal efforts to study comparative effectiveness, the effort could be organized in different ways—for instance, by augmenting an existing agency, by establishing a new agency, by supporting an existing quasi-governmental organization, or by creating a new public-private partnership. The choice of organizational arrangement—as well as the mechanism used to provide any federal funds to it—would affect both the entity's independence and its accountability.

- The level of funding required for a new or augmented entity would depend largely on what its additional activities would involve. Synthesizing existing studies or analyzing available data on medical claims would be less expensive than conducting new head-to-head clinical trials to compare treatments but could also yield less definitive results. Having more health records available in electronic form would facilitate the use of existing data for research (if privacy concerns could also be addressed).

- To affect medical treatment and reduce health care spending in any meaningful way, the results of comparative effectiveness analyses would have to be used in ways that changed the behavior of doctors, other health professionals, and patients. For example, the higher-value care identified by comparative effectiveness research could be promoted in the health system through financial incentives—the payments doctors receive or the cost sharing that patients face. Making substantial changes in payment policies or coverage under the Medicare program to reflect information on comparative effectiveness would almost certainly require legislation.

- If the corresponding changes in incentives were made, generating additional information about comparative effectiveness seems likely to reduce health care spending over time—potentially to a significant degree. The precise impact, however, is difficult to predict. Given the time necessary to conduct the research, to alter incentives in a manner reflecting the results, and to affect behavior through changes in information and incentives, significant cost savings would probably take a decade or more to materialize.

Background on Past and Current Efforts

In weighing the options for expanding or reorganizing federal efforts on comparative effectiveness, it is useful to define what that term means and to consider the arguments for a federal role. Reviewing past and current efforts—by private and public organizations in the United States and by other countries—also sheds light on several issues and challenges likely to arise in any future U.S. efforts.

What Is Comparative Effectiveness?

As applied in the health care sector, an analysis of comparative effectiveness is simply a comparison of the impact of different options that are available for treating a given medical condition for a particular set of patients. Such studies may compare similar treatments, such as competing drugs, or they may analyze very different approaches, such as surgery and drug therapy. The analysis may focus only on the relative medical benefits and risks of each option, or it may go on to weigh both the costs and the benefits of those options. In some cases, a given treatment may be found more effective for all types of patients, but more commonly a key issue is determining which specific types would benefit most from it.

Although some information about the effectiveness of new drugs, medical devices, or procedures is often available, rigorous comparisons of different treatment options are less common. Drugs and devices must be certified as safe and effective by the Food and Drug Administration (FDA) before they can be marketed in the United States, but with certain exceptions the regulatory process for approving new drugs and devices does not evaluate them relative to

alternatives. Furthermore, physicians commonly prescribe drugs for "off-label" uses—that is, for treating patients or conditions that have not been certified by the FDA.[3] Medical procedures, which account for an even larger share of total health care spending, can achieve widespread use without a systematic review. It may seem reasonable to assume that the benefits of a drug, device, or procedure will be similar for related conditions or a broader group of patients, and in many cases that may be true. Without hard evidence, however, decisions about what treatments to recommend often depend on the individual experience and judgment of physicians.

A recent example of a comparative effectiveness study indicates that careful analysis can sometimes disprove widely held assumptions about the relative merits of different treatments. The study, which involved patients who had stable coronary artery disease, compared the effects of two treatments: an angioplasty with a metal stent combined with a drug regimen versus a drug regimen alone.[4] Patients were randomly assigned to receive the two treatments, and although the study found that patients treated with angioplasty and a stent had better blood flow and fewer symptoms of heart problems subsequently, the differences declined over time.[5] More surprisingly, it found no differences between the two groups in survival rates or the occurrence of heart attacks over a five-year period.

That study examined only the comparative medical benefits of two treatments, but the term comparative effectiveness can also encompass studies that seek to determine which treatment is most cost-effective. Such studies seek to weigh any additional medical benefits of a more expensive treatment against their added costs. The benefits of different treatments are summarized as an increase in life expectancy or, more commonly, as an increase in quality-adjusted life years (QALYs) to account for effects on morbidity as well as mortality. By convention, cost-effectiveness analyses report results as the cost per QALY gained—so a lower number indicates a more cost-effective service. Related terms include cost-benefit analysis, technology assessment, and evidence-based medicine, although the latter concepts may not take costs into account.

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3. For drug manufacturers, the costs of conducting additional trials to demonstrate safety and efficacy for a broader set of patients or conditions may outweigh the benefits from the increased sales that would result.

4. In an angioplasty, a small balloon is surgically inserted into a clogged artery and then inflated to expand the opening; a stent—a small wire mesh tube—is added in an effort to keep the artery open.

5. William E. Boden and others, "Optimal Medical Therapy With or Without PCI for Stable Coronary Disease." *New England Journal of Medicine*, vol. 356, no. 15 (March 2007), pp.1503–1516. Other studies have found that angioplasty with a stent has clear medical benefits for patients who are undergoing a heart attack, reinforcing the point that results may differ among different types of patients.

Research in the Private Sector

In the United States, the private sector produces some assessments and comparisons of different treatments. One prominent source is the Technology Evaluation Center that is part of the Blue Cross Blue Shield Association. Its analyses are based on systematic reviews of the available literature, often relying on the results of clinical trials. The center produces about 20 to 25 new assessments of drugs, devices, and other technologies each year; the analyses consider clinical effectiveness but not cost-effectiveness. For-profit private-sector firms that specialize in technology assessments represent another source of information; the ECRI Institute and Hayes, Inc., are two of the larger firms providing that type of analysis. They evaluate medical and surgical procedures, drugs, and devices in return for a fee or on a subscription basis.

Organizations that are similar but operate as nonprofit entities—sometimes affiliated with academic or medical centers—include the Center for Medical Technology Policy and the Tufts-New England Medical Center's Cost-Effectiveness Analysis Registry (which provides an extensive list of the cost-effectiveness ratios that are available from published studies). In addition, some private health plans (most commonly, larger ones) use claims data for their enrollees to conduct their own analyses of comparative effectiveness.

Notwithstanding those current efforts, the private sector will probably not produce as much research on comparative effectiveness as society would value. The knowledge created by such studies is costly to produce—but once it is produced, it can be disseminated at essentially no additional cost, and limiting that dissemination may be difficult. As a result, private insurers and other organizations conducting research on comparative effectiveness might stand to capture only a portion of the resulting benefits and therefore would not invest as much in such research as they would if they took into account the benefits to all parties. In such a situation, economists have long recognized the need for government efforts to increase the supply of research to the socially optimal level.

Another reason for the limited availability of information on comparative effectiveness is that public-sector health insurance programs—which collectively account for about half of all health care spending—have not sought to make extensive use of it. In particular, the Medicare program has not taken costs into account in determining what services are covered and has made only limited use of comparative effectiveness data. It stands to reason that the limited demand for such research has reduced the supply correspondingly. Conversely, increasing the amount of credible and objective research that was available could facilitate moving Medicare toward what former program administrator Mark McClellan has called a "fee-for-value" system rather than a fee-for-service one.

Past and Current Federal Efforts to Assess Medical Treatments
In the United States, the federal government has a rather long but somewhat checkered history of involvement in comparative effectiveness research and related efforts. Federal involvement in assessing the effectiveness of new medical technology dates at least to the late 1970s and the short-lived National Center for Health Care Technology. Established in 1978 as part of the Department of Health, Education, and Welfare, it was given a broad mandate to conduct and promote research on health care technology, and it included an advisory board appointed by the Secretary to assist in setting research priorities. The center ceased operations in 1981, however, reflecting both changes in priorities for the new Administration and the Congress as well as opposition from some provider groups.[6] In that same period, the Office of Technology Assessment (OTA) was created as an advisory agency to the Congress covering a broad set of issues, including but not limited to health care. Over the years, it studied a variety of health care topics, including the costs and benefits of screening tests for several diseases. For a variety of reasons, however—which apparently had little to do with its health care studies—OTA was eliminated in 1995.

More recently, the Agency for Health Care Research and Quality (AHRQ) has been the primary federal agency supporting research on the effectiveness of medical treatments and their comparative benefits and costs. Established in 1989 as the Agency for Health Care Research and Policy, AHRQ is an arm of the Department of Health and Human Services (HHS). It currently has a staff of about 300 and an annual budget of about $300 million, which primarily funds research grants to and contracts with universities and other research organizations covering a wide range of topics in health services.

AHRQ has undertaken a number of initiatives related to comparative effectiveness. One such step—in collaboration with the American Medical Association and America's Health Insurance Plans, a coalition of insurance companies—has been the creation of a national clearinghouse for treatment guidelines, which are designed to summarize the available medical evidence on appropriate treatments for various conditions. AHRQ has also established about a dozen evidence-based practice centers around the country, generally with an affiliation to a university; those centers analyze and synthesize existing evidence about treatments and technologies. Some studies sponsored by AHRQ have examined only the relative clinical benefits of different treatments, while others have also analyzed their cost-effectiveness. Research on comparative effectiveness accounts for only a portion of AHRQ's budget, however.

As with other agencies examining the effectiveness of medical treatments or evaluating medical technologies, support for AHRQ has varied over time. In the mid-1990s, controversies arose in connection with a panel that was seeking to review evidence and formulate guidelines about the treatment of back pain, and

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6. See Seymour Perry, "The Brief Life of the National Center for Health Care Technology," *New England Journal of Medicine*, vol. 307, no. 17 (October 21, 1982), pp.1095–1100.

partly as a result, the agency faced the prospect of elimination. Ultimately, the agency was retained, but its funding was reduced from prior levels. Since then, its overall budget has generally been maintained (at least in nominal terms) or increased. Most recently, section 1013 of the Medicare Modernization Act of 2003 authorized AHRQ to spend up to $50 million in 2004 (and additional amounts in future years) to conduct and support research with a focus on "outcomes, comparative clinical effectiveness, and appropriateness of health care items and services (including prescription drugs)" for Medicare and Medicaid enrollees. Actual funding for that initiative has been $15 million per year.

Other federal agencies also engage in various activities related to comparative effective-ness research. The National Institutes of Health (NIH)—also part of HHS—is the largest federal sponsor of clinical research, primarily in the form of clinical trials. Although comparative effectiveness is not a focus of its research, over the years a number of trials have been sponsored that compare treatments head to head. The Department of Veterans Affairs also has a substantial research program that reviews evidence from the clinical records of its patients, focusing particularly on the clinical effectiveness of treatments. The department also sponsors evidence reviews through a technology assessment program.

The Centers for Medicare and Medicaid Services (CMS) has also sponsored some research on comparative effectiveness. When making decisions about what services are covered by Medicare, CMS generally considers only whether devices and procedures are effective. It has sponsored some studies comparing the effectiveness of different treatments but has done so largely to determine whether to establish separate payment rates for similar treatments. For example, CMS is currently cosponsoring a trial with NIH that may eventually compare the effects of daily dialysis for kidney patients with the conventional treatment of dialysis three times per week. If daily dialysis proves more effective for certain patients, CMS could modify its payment policy to cover the additional costs of more frequent treatment.

Comparative Effectiveness in Other Countries

Other developed countries also face challenges financing health care costs and have taken various steps to assess the comparative effectiveness of treatments. Many of those countries establish overall budgets for their national health systems and use comparative effectiveness analysis to help determine which treatments and procedures will be covered or how they will be reimbursed. Perhaps the best known example is the National Institute for Health and Clinical Excellence (NICE), which was established in 1999 as part of the United Kingdom's national health service. It provides guidance on the use of new and existing medicines, procedures, and treatments and on appropriate treatments for specific diseases. With a staff of about 200 and an annual budget of about 30 million pounds (roughly $60 million), NICE does not fund new clinical trials or other forms of primary data collection but, rather, bases its determinations on systematic reviews of existing research.

Other countries such as Australia, Canada, France, and Germany have similar review processes. Discussions have sometimes focused on those countries' procedures for reviewing prescription drugs, but all of them have systems in place to evaluate medical and surgical treatments and technologies as well. It is therefore worth noting that, for all the attention that prescription drugs receive, they currently account for less than 15 percent of total U.S. health spending. Therefore, if additional research in the United States on comparative effectiveness focused only on medications, the impact would probably be much smaller than if that research encompassed the whole spectrum of medical care.

Options for Organizing and Funding Federal Research Efforts

The approach that is taken for organizing and funding any increased federal efforts to support research on comparative effectiveness will play an important role in determining their impact. Many of the options that have been proposed seek to coordinate and centralize existing activities through one entity—which would tend to give any conclusions it reached more weight—but there might also be value in developing several competing sources of information about comparative effectiveness.

Options that have been put forward for organizing federal research on comparative effectiveness include the following (each of which could have many variants):[7]

- Expanding the role of an existing agency that already conducts or oversees research on health services generally—and comparative effectiveness specifically—such as AHRQ or NIH.

- Creating or "spinning off" a new agency, either within the Department of Health and Human Services or as an independent body that is part of either the executive or the legislative branch. The Federal Trade Commission and the Medicare Payment Advisory Commission (MedPAC) are potential models for such an option.

- Augmenting an existing quasi-governmental organization, such as the Institute of Medicine or the National Research Council. Such entities are often Congressionally chartered, but they are not subject to regular governmental oversight. Even so, the Institute of Medicine receives most of its funding from government agencies, which is provided to finance specific studies that have been requested.

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7. For a discussion of this issue, see Gail R. Wilensky, "Developing a Center for Comparative Effectiveness Information," *Health Affairs,* Web Exclusive (November 7, 2006), pp. w572–w585.

- Establishing a new public-private partnership to oversee and direct research. That option could be structured in various ways, but one such approach would be to set up a federally funded research and development center (FFRDC). FFRDCs are not-for-profit organizations that can accept some private funding but which get most of their funding from a federal agency that provides oversight and monitoring.

Regardless of how those efforts were organized, several potential mechanisms could be used to fund them (either individually or in combination). Federal spending could be authorized and appropriated annually, as with other discretionary programs. Alternatively, funding could be drawn from Medicare's hospital insurance trust fund (which is financed primarily by payroll taxes) or specified as a percentage of mandatory federal outlays on health insurance programs. Instead of or in addition to using existing sources of revenues, another set of funding options would require direct contributions from the health sector. For example, a new tax on health insurance premiums or other payments within the health sector could be established, with the resulting revenues dedicated to research on comparative effectiveness.

A comparison of those organizational and funding options for a new or expanded entity indicates that trade-offs may arise between the entity's independence and ability to reach controversial conclusions, on the one hand, and its accountability and responsiveness to policymakers and to other interested parties, on the other. For example, funding through appropriations would allow lawmakers to assess the new entity's contributions and accomplishments and to balance spending on those efforts against other federal priorities on an annual basis. But at the same time, some observers have raised concerns that annual appropriations would leave a new entity vulnerable to outside political pressure and thus reluctant to undertake controversial studies or to reach conclusions that might generate opposition from affected groups. In that view, the elimination of agencies engaged in such research that were funded by annual appropriations—or in the case of AHRQ, the threat of elimination—suggests the need for a different arrangement.

Alternatively, housing the new activities in an organization that was at "arm's length" from the federal government, and establishing automatic or dedicated funding mechanisms, would give the new entity greater autonomy. To be sure, lawmakers could change any funding formula that had been established, mitigating the insulation from outside pressure. For example, payment rates to doctors, hospitals, private health plans, and other providers under Medicare have been adjusted frequently in response to concerns about their levels, even though such payments are not subject to annual appropriations. Conversely, to the extent that automatic or dedicated funding mechanisms did limit the influence of outside pressure, they also would raise questions about how the entity set its priorities and allocated resources—and how it would be held accountable for those decisions.

Under any option, a governing council or advisory board could be established to serve several functions: providing guidance to the entity and establishing priorities for its research projects, creating an independent process for reviewing and approving the findings that resulted from that research, and serving as a channel for interested parties to participate in its deliberations. For example, the council or board could include representatives of major federal health programs, private insurers, health care providers, and drug and device manufacturers—as well as members of the general public and disinterested policy experts. Alternatively or in addition, a regular process could be established for getting input from interested parties. The types of participants on any council or board and the manner in which members were chosen and replaced would have to be determined carefully to avoid giving one perspective undue influence. At the same time, trade-offs could arise between the extent to which a broad range of views and interests were represented and the ability of the council or board to make timely decisions or to reach consensus on contentious issues.

Another organizational issue is whether to establish a single or highly centralized entity or, instead, to design a more loosely coordinated system encompassing several distinct centers to produce independent analyses. Many of the options that have been proposed seek to centralize research activities through one entity—partly to address concerns about the lack of coordination among current U.S. efforts. An advantage of that centralized approach is that it would tend to give more weight to any conclusions reached. At the same time, that potential for having a greater impact could also lead the organization to adopt findings that were watered down to reach consensus. An alternative, more decentralized approach could give individual research centers more latitude and foster competing perspectives. However, a more pluralistic approach could involve some redundant efforts and, if it yielded any conflicting findings, would leave users with the task of reconciling the results.

An additional consideration that arises—particularly if a new entity is created—involves start-up costs and other implementation challenges. If funds were directed through an existing federal agency, some ongoing costs for additional staffing would be incurred, but the support infrastructure would largely exist already. By contrast, establishing a new agency or public-private partnership could require a greater effort before research activities could commence. At the same time, a quasi-governmental organization or public-private partnership could have more flexibility to develop and maintain its staff than a new or existing federal agency would. Creating a new source of revenues (such as a tax on health insurance premiums) to help fund research efforts on comparative effectiveness would also involve time and administrative costs.

Issues and Challenges in Comparing the Effectiveness of Treatments

The appropriate organizational form for any new or expanded federal entity, along with the mechanism and level of funding, depends in large part on what activities it would carry out. For example, analyzing existing data would require a different set of skills—and would cost less—than overseeing new clinical trials that compared different treatments. Whatever approach was taken, communicating the results of the analyses to doctors, patients, and health insurers in ways that each audience found useful would probably be an important function.

Methods of Research

The approach that would probably be easiest to implement would be to review and summarize the results of existing studies. For example, even though existing studies may only compare a single treatment to a placebo, the results of several studies could sometimes be combined to measure treatments against one another. Such activities would be comparable to some of the work that AHRQ is already undertaking and to some current efforts based at universities or other public and private research centers.

In pursuing that approach, one challenge is that some analyses have indicated that clinical trials sponsored by interested parties—which are often the only source of such data—are more likely than independent studies to find favorable results.[8] Even without that problem, another potential limitation is that existing information may not be sufficient to reach definitive conclusions, either because studies use different methodologies or analyze different populations of patients, or simply because they yield conflicting findings. For example, there are a range of independent studies available that examine different screening techniques for colorectal cancer, each of which provides an estimate of the cost per enrollee for each increase in QALYs. But a recent review of those studies conducted by MedPAC suggests that reaching a firm conclusion about which approach is most effective or most cost-effective would be difficult because their results vary considerably.[9]

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8. See Justin E. Bekelman, Yan Li, and Cary P. Gross, "Scope and Impact of Financial Conflicts of Interest in Biomedical Research: A Systematic Review," *Journal of the American Medical Association,* vol. 289, no. 4 (January 22/29, 2003), pp. 454–465; Stephan Heres and others, "Why Olanzapine Beats Risperidone, Risperidone Beats Quetiapine, and Quetiapine Beats Olanzapine: An Exploratory Analysis of Head-to-Head Comparison Studies of Second-Generation Antipsychotics," *American Journal of Psychiatry*, vol. 163, no. 2 (February 2006), pp. 185–194; and Jeffrey Peppercorn and others, "Association Between Pharmaceutical Involvement and Outcomes in Breast Cancer Clinical Trials," *Cancer,* vol. 109, no. 7 (April 2007), pp. 1239–1246.

9. Medicare Payment Advisory Commission, *Report to the Congress: Increasing the Value of Medicare* (June 2006), pp. 232–233.

In other cases, though, the existing evidence may permit more clear-cut determinations. Britain's NICE, for example, has been able to analyze many different treatments on the basis of their cost-effectiveness and to develop an extensive set of clinical guidelines and technology assessments relying solely on systematic reviews of available studies. It is also worth noting that "inconclusive" studies or comparisons may still be valuable, in that they could simply indicate that different therapies have equivalent benefits or are equally cost-effective. If, instead, inconclusive results reflect substantial differences in the studies' findings or a lack of sufficient analysis using rigorous methodologies, then generating new evidence may be necessary.

A somewhat more challenging approach than reviewing existing studies would be to fund new analyses comparing medical treatments using existing data sources, such as health insurance claims records. An advantage of that approach is that it could provide new information to help resolve uncertainties about treatments at relatively low cost. A central difficulty in such studies, however, is accounting for differences in patients' health status that play a role in determining which treatment they get—which can make simple comparisons misleading. Patients with more severe heart disease, for example, are more likely to receive invasive and expensive surgical procedures such as angioplasty or a bypass operation. But the greater severity of their condition may also make them more likely to have a subsequent heart attack and more likely to die, so a comparison to patients receiving less aggressive treatments—who are not as sick, on average, to begin with—could understate the benefits of more aggressive treatments. To address such problems, researchers might be able to exploit geographic differences in treatment patterns to compare the effects of different treatments on comparable types of patients. Expanded use of electronic health records could also facilitate more sophisticated statistical analyses, assuming that issues regarding access to and privacy of those records could be addressed.

The method of research that would probably yield the most definitive results is one employing randomized controlled trials comparing treatments head to head, but that approach would also be the most expensive and would take the longest to conduct. The main advantage of random assignment is that it ensures that any differences in outcomes reflect true differences among treatments and not confounding differences among patients. But detecting differences that are statistically significant—that is, unlikely to have arisen simply by chance—can require a substantial number of patients to participate, and they must generally be followed for several years. Ethical issues can also arise if one set of participants is assigned a treatment that is generally considered less effective, although such concerns are less likely to arise when significant uncertainty exists in the medical community about the relative benefits of different treatments. Because the number of trials that could feasibly be conducted at any given time is limited, significantly expanding comparative effectiveness research would therefore be likely to require a combination of randomized trials and other research methods.

Scope of Analysis and Dissemination of Results

The results of clinical trials and other comparisons of treatment options will address most directly the relative medical benefits of those options, but an important question is whether federal research on comparative effectiveness would also seek to assess the cost-effectiveness of treatments. There are arguments both for and against doing so.

An argument against having the federal entity assess which treatments are most cost-effective is that doing so may be unnecessary. If that entity generated detailed data about the treatments studied (including any ripple effects on other types of care, such as hospital readmissions), health plans and others could use relevant prices to calculate cost-effectiveness ratios. Furthermore, the evidence that some areas of the country spend substantially more on health care but do not have better health as a result suggests that improvements in the efficiency of health care delivery could be obtained without having to address trade-offs between costs and benefits—with the first step being to reduce the use of those treatments that do not provide more medical benefits than alternative, less expensive therapies.

Ultimately, however, achieving the greatest possible gains in the efficiency of the health sector would require assessing both the benefits and costs of different treatments to see whether the added benefits of more-expensive options were worth their added costs. Having the new or expanded entity analyze cost-effectiveness would also lend more legitimacy to that approach and would promote a consistent and transparent methodology for such calculations. Those considerations argue for having the entity assess cost-effectiveness.

Another question is whether assessments would be limited to procedures and treatments or would also seek to evaluate the performance of individual doctors. In particular, the data from medical records that are used to compare the effectiveness of different treatments for a given type of patient could also be used to analyze the quality with which doctors provided each treatment. The potential gains from such analysis include identifying doctors who deliver high-quality care and encouraging doctors who are not performing as well to improve—and doing both on the basis of objective evidence. At the same time, concerns could arise that evaluating doctors would detract from the focus on identifying effective procedures. Further, controlling for differences among patients that could affect individual doctors' ratings could be even more challenging than controlling for differences among patients when comparing treatments. Although such an approach could have a larger impact on health care than examining treatments alone, it could also be highly controversial.[10]

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10. CMS has taken some initial steps toward assessing the quality of care that individual doctors provide. The Tax Relief and Health Care Act of 2006 allows for modest bonus payments under Medicare to doctors who elect to report information to CMS on certain measures of the care they provide in 2007. Although CMS will be able to provide feedback to doctors on how their performance compares to their peers', the payments

Whichever method of research was used to generate new findings, achieving consensus about their implications could prove challenging. For example, although there may be substantial agreement within the scientific community about the relative benefits of avoiding different adverse outcomes—such as degrees of disability and risks and side-effects of surgery—converting those differences into the metric of quality-adjusted life years may nevertheless raise concerns among patients and other interested parties. Similarly, deciding how broadly or narrowly any findings apply would be an important consideration, because some treatments may be more effective for certain subgroups of patients than for an average patient. That consideration would also affect the design of the studies and the comparisons that would be undertaken. Finally, determining which treatment was most cost-effective for a given population would involve placing a dollar value on an additional year of life, which has in the past generated public controversy—even though researchers have developed estimates of that value reflecting choices that individuals are observed to make.

Communicating the results of research to doctors, patients, and health insurers would probably be an important activity for any new or augmented entity focused on comparative effectiveness. Providing information to both technical and nontechnical audiences that was useful and accurate would be challenging. A particular difficulty might be conveying the degree of uncertainty surrounding conclusions.

Potential Implications for Health Care Spending

To affect medical treatment and reduce health care spending, the results of comparative effectiveness analyses would ultimately have to change the behavior of doctors and patients. For any large-scale changes to occur, the new or expanded entity would have to generate new findings for a substantial number of medical conditions—which would take many years. To affect behavior, those findings would then probably have to be incorporated into the incentives for providers and patients, a process of adjustment that might also take time.

Medicare is effectively precluded from taking cost into account when making decisions about coverage and would probably need new legal authority to adjust payments to providers or cost-sharing requirements for enrollees to encourage the use of more cost-effective care. For their part, private insurers might not face legal barriers to limiting coverage of treatments that were shown to be less effective but still might be reluctant to do so if Medicare continued to cover them. Beyond the analyses themselves, then, many steps would need to be taken before

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doctors receive do not depend on that performance, and the measures that have been chosen cover areas of substantial consensus in the medical community about appropriate treatment protocols (for example, prescribing beta blockers to patients who have had a heart attack).

spending on comparative effectiveness translated into savings for federal programs and the health care system.

Potential for Savings on Health Care

Predicting the impact that research on comparative effectiveness could have on health care spending is difficult because it is hard to know what that research will show. In some cases, the research could provide clearer evidence than exists today that the benefits of a treatment (such as a screening examination) outweigh the costs—in which case spending on such treatments could increase.

As a general rule, however, the fee-for-service reimbursement system by which health care is currently financed—especially in Medicare—typically provides financial incentives for doctors and hospitals to adopt new treatments and procedures broadly even if hard evidence about their effectiveness is not available. For their part, insured individuals generally face only a portion of the costs of their care and, consequently, have only limited financial incentives to seek a lower-cost treatment. Private health insurers have incentives to limit the use of ineffective care but are currently constrained by a lack of information, by the turnover of enrollees when they change insurance coverage, and by public concerns about overly aggressive management (as was evident in the recent "backlash" against managed care plans). Over the long term, therefore, additional objective information about the relative costs and benefits of treatments—if adopted by insurers and accepted by doctors and patients—seems more likely to reduce total health care spending than to raise it.

Getting to the point where additional research on comparative effectiveness could have a noticeable impact on health spending would itself take several years. In addition to the time required to get the new activities under way, a lag would exist before results were generated—particularly if they depended upon new clinical trials. Initially, the available results would probably address a relatively small number of medical treatments and procedures; additional time would have to elapse before a substantial body of results was amassed. And in areas of medicine that involve significant levels of spending, several studies could be needed before a consensus emerged about the appropriate conclusions to be drawn—even if those studies did not generate conflicting results. For all of those reasons, it would probably be a decade a more before new research on comparative effectiveness had the potential to reduce health care spending in a significant way.

Possible Responses Under Private and Public Insurance Plans

To affect medical treatment and reduce health care spending, the results of comparative effectiveness analyses would ultimately have to change the behavior of doctors and patients—that is, to get them to use fewer services or less intensive and less expensive services than are currently projected. Bringing about those changes would probably require action by public and private insurers to incorporate comparative effectiveness information into their coverage and payment policies in order to affect the incentives facing doctors and patients.

Although private insurers could choose not to cover drugs, devices, or procedures that were found to be less effective or less cost-effective, the insurers would have a number of additional options as well. They could simply provide more information to patients and doctors or make that information public, which could improve compliance with treatment guidelines. For example, the use of medicines known as beta blockers, which is recommended following a heart attack to prevent recurrence, has grown substantially in recent years—apparently as a result of requirements for health plans to report the share of patients who receive prescriptions for them.[11] Alternatively, insurers could require enrollees to pay some or all of the additional costs of more-expensive treatments that were shown to be less effective or less cost-effective (in which case enrollees would have to decide whether the added benefits were worth the added costs). Or insurers could adjust payments to doctors and hospitals to encourage the use of more-effective care.

The steps that private insurers took could both affect public spending and be affected by public programs' responses to additional information about comparative effectiveness. To the extent that changes instituted by private insurers affected doctors' methods, there could be spillover benefits for public programs—because physicians typically serve patients of both types of programs and tend to use the same general approach to care. However, private insurers might be reluctant to pursue such approaches aggressively if public insurance programs were not adopting similar methods. In addition, private insurers might be slow to cover treatments or screening exams that took a long time to generate savings in other health costs, either because of turnover in their membership or because of questions about the benefits of providing coverage for routine services. (A preventive service could be cost-effective overall but the additional savings to the insurer that result from covering it could still be less than the costs of providing that coverage to all enrollees.)

To reduce spending under Medicare on the basis of comparative effectiveness research would very likely require additional legislative authority both to allow relative benefits and costs to be considered and to modify the financial incentives in that program. Under current law, Medicare does not appear to have the authority to take costs into account when making decisions about what treatments are covered; regulations have been proposed in the past that would have used

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11. Since 1996, the National Committee for Quality Assurance (NCQA), a not-for-profit organization that provides information about health care quality, has required private health care plans to report that information. The average share increased from 63 percent in 1996 to 95 percent in 2005, and as a result, NCQA has now adopted a more stringent measure (which tracks actual use of those drugs). See National Committee for Quality Assurance, "New HEDIS® Measures Track Childhood Lead Screening, COPD Management; Retirement of Beta-Blocker Measure Marks Major Accomplishment in Cardiac Care" (news release, February 21, 2007), available at web.ncqa.org/tabid/254/Default.aspx.

costs as a factor, but those proposals generated opposition and were ultimately withdrawn.[12] As a result, Medicare will generally cover any treatment or procedure that has medical benefits, regardless of its cost or its effectiveness relative to alternative therapies. Recently, Medicare officials developed an initiative that provides provisional coverage for new treatments that have uncertain medical benefits—but also requires the resulting evidence about their effects to be analyzed so that a more informed final decision on coverage can be made using those data. That approach, however, does not involve comparing different treatments to see which is more effective, nor does it take the costs of treatments into account.

Medicare currently has somewhat more flexibility regarding the payments it makes for covered services, which can take comparative medical benefits (but not costs) into account on a limited basis. For example, in order for a hospital to receive an additional payment for using a new device (known as a "pass-through" payment), the device must be shown to provide a substantial clinical improvement for Medicare beneficiaries compared with currently available treatments. (Over time, payments to hospitals for new technologies are incorporated into Medicare's prospective payment rates.) In addition, Medicare has adopted a "least costly alternative" payment policy for certain types of items, under which it will not cover the additional cost of a more expensive product if a clinically comparable one is available that costs less. That policy has been applied to payment for durable medical equipment and to certain comparable drugs, but wider application to services such as surgeries or other treatments and procedures would probably require additional authority.[13]

If the necessary changes in law were made, Medicare could use information about comparative effectiveness to promote higher-value care. For example, Medicare could tie its payments to providers to the cost of the most effective or most efficient treatment. If that payment was less than the cost of providing a more expensive service, then doctors and hospitals would probably elect not to provide it—so the change in Medicare's payment policy would have the same practical effect as a coverage decision. Alternatively, enrollees could be required to pay for the additional costs of less effective procedures (although the impact on patients' incentives and their use of care would depend on whether and to what extent they had supplemental insurance coverage that paid some or all of Medicare's cost-sharing requirements).

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12. The Medicare statute essentially requires that program to cover any items or services that are deemed "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." See section 1862(a)(1)(A) of the Social Security Act.

13. For further discussion about the use of information about comparative effectiveness under Medicare, see Medicare Payment Advisory Commission, *Report to the Congress: Issues in a Modernized Medicare Program* (June 2005), pp. 180–182.

More modest steps that Medicare could take would include smaller-scale financial inducements to doctors and patients to encourage the use of cost-effective care. Doctors and hospitals could receive modest bonuses for practicing effective care or modest cuts in their payments for using less effective treatments (although the evidence to date about the effect of such pay-for-performance initiatives on health spending is somewhat mixed).[14] Likewise, enrollees could be asked to pay only a portion of the additional costs of less efficient procedures. Or Medicare could simply provide information to doctors and their patients about their practices, which would create some pressure for doctors to use more-efficient approaches. Adopting more modest measures to incorporate the findings of comparative effectiveness research, however, is likely to yield smaller savings for the program. It is also worth noting that under current law, policies that could affect the use of physicians' services by Medicare enrollees will not change the program's spending unless the targets for spending (under what is known as the Sustainable Growth Rate system) are also changed; otherwise, payment rates for physicians would be adjusted automatically to keep total spending unchanged.

As for Medicaid, state officials generally determine what specific services are covered—subject to broad federal requirements—and are reimbursed by the federal government for a portion of the resulting costs using formulas specified in law. Because enrollees have low income, options for adjusting cost-sharing requirements to encourage the use of cost-effective care may be limited. Furthermore, a substantial portion of Medicaid spending pays for long-term care services such as nursing homes for elderly and disabled enrollees, which would probably not be affected by comparative effectiveness research. At the same time, most of the poor mothers and children enrolled in the program receive their care through a private health insurance plan under contract to Medicaid, so spending for them would be directly affected by any changes that private insurers made. Another portion of Medicaid spending goes to cover cost-sharing requirements and payments of premiums for enrollees who are also on Medicare, so the impact on that spending would depend largely on what the Medicare program did.

An additional issue that would arise in applying the results of comparative effectiveness studies in Medicaid is that states would ordinarily stand to capture only a portion of any savings that were generated. Federal matching rates under Medicaid currently range from 50 percent up to about 75 percent, and, by CBO's estimates, the federal government now covers 57 percent of the costs of health services provided by that program. In principle, those financing arrangements would reduce incentives for state Medicaid officials to limit coverage of less effective services—because, on net, states would see only a portion of those costs (or a portion of the savings). Some coordination between state and federal officials might therefore be required to incorporate the results of comparative effectiveness research. At the same time, many states recognize the growing fiscal

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14. See Congressional Research Service, *Pay-for-Performance in Health Care*, CRS Report RL33713 (December 12, 2006).

burden posed by Medicaid costs, and several of them have already expressed interest in such research. For example, more than a dozen state Medicaid programs are involved in a project (affiliated with the Oregon Health and Sciences University) assessing evidence about the relative safety and effectiveness of competing drugs in the same class.

Conclusion

The United States is on an unsustainable fiscal path, and the primary determinant of the nation's long-term fiscal balance is health care costs. The substantial variation in health care costs per beneficiary across the nation, in a fashion unrelated to health outcomes, strongly suggests that opportunities exist to reduce those costs without impairing health—underscored by the lack of relative evidence on "what works and what doesn't" for many health care interventions. Expanded research on comparative effectiveness, if linked to changes in incentives for providers and patients, offers a promising mechanism for reducing health care costs to a significant degree over the long term while maintaining or improving the health of Americans.

Chairman STARK. Thank you very much.

Dr. Miller?

STATEMENT OF MARK MILLER, Ph.D., EXECUTIVE DIRECTOR, MEDICARE PAYMENT ADVISORY COMMISSION

Dr. MILLER. Chairman Stark, Ranking Member Camp, and distinguished Members of the Subcommittee, much of MedPAC's work is devoted to improving the efficiency of the Medicare Program either through reducing unnecessary costs or improving the quality of care for the dollars that we do spend.

The Commission is acutely aware of the long-run sustainability problems facing the Medicare Program. In addition to what Peter has said, I would add that the Part A trust fund currently looks like it will be exhausted in 2019. At historical rates of taxation, Medicare will consume 24 percent of personal and corporate income tax by 2030. The rate of change in part B premiums and copayments is faster than beneficiaries' incomes, making Medicare more and more unaffordable.

Medicare needs a broad range of policy changes to gain control of spending without sacrificing quality. One of the changes is to better understand what works in health care and what does not work. Comparative effectiveness analysis evaluates the relative effectiveness of drugs, devices, therapies, and procedures. The outcomes of this analysis can be evaluated in terms of clinical outcomes, such as mortality and morbidity; functional outcomes, like quality of life and patient satisfaction; and economic outcomes, such as cost-effectiveness.

The private sector is unlikely to produce this type of information on the scale that is needed because it is costly and what it has produced can be used by anyone, including their competitors. More-

over, private payors fear litigation on being the first to act on comparative effectiveness information. We also point out that there is recent research in JAMA and other clinical journals that indicate that the results of studies sometimes are influenced by the source of funding.

There is a lot of positive work being done by Federal agencies, AHRQ, NIH, CMS, and VA. Here the Commission, however, has two concerns. No Federal agency has its mission and budget devoted solely to the production of competitive effectiveness information, and consequently, the information will not be produced on a sufficient scale.

Second, none of these agencies are organized and funded in a way that allows them to be truly independent. For the Medicare Program, competitive effectiveness information could be used to differentiate payment among providers to encourage the pursuit of evidence-based medicine. It could be used to avoid higher cost, expensive services when there is no clinical evidence that they are better than existing treatments. Other researchers have discussed the idea of requiring manufacturers to enter risk-sharing relationships where payments are rebated to a payor if a product does not perform as expected.

The Commission has examined this issue over the last 3 years, and in our forthcoming June report, we recommend that the Congress charge an independent entity to sponsor comparative effectiveness research and disseminate it to patients, providers, and payors.

To be clear, this organization would not be involved in coverage and payment policy decisions. It would generate information only, information to be used by patients and providers in making clinical decisions, and by payors to determine coverage and payment.

The Commission has discussed the characteristics of this entity. It should be independently governed and have a stable funding source. I will return to those two points. It should have transparent processes in terms of the agenda-setting, the research results, and the methods used. It should seek input from all stakeholders, establish consistent research methods, and establish ethical standards for the conduct of this research. As I mentioned, it should disseminate the information.

Returning to governance, the Commission has concerns that any Federal agency is truly independent when it comes to financing and disseminating unpopular studies and results. The Commission, however, is also equally concerned that a wholly private organization would not be transparent and objective enough to assure credibility. The Commission favors a public/private governance structure that would resolve these concerns and broadly represent patients, providers, and payors in the two sectors.

On financing, and public financing specifically, the Commission discussed a continuum of options, from the appropriations process to mandatory funding streams. The Commission favors a stable funding source, and on balance that probably means a mandatory source would be more stable while retaining congressional oversight.

Similarly, the Commission discussed a continuum of private financing mechanisms, from voluntary donations to taxes. Again, the

Commission favors a more stable funding stream, and some researchers have suggested, for example, proposing a small tax on health insurance premiums to fund this effort.

In closing, the Commission was also concerned that this endeavor not entail creating or recreating existing resources. There is an available infrastructure in the Federal agencies, the states, and the private sector. Based on new authority, AHRQ has created research networks and networks to disseminate study results. One could envision an entity with a public/private governance structure which sets an agenda, sponsors research that is conducted by both private organizations and Federal agencies, and then disseminates the information to patients, payors, and providers.

I look forward to your questions.

[The prepared statement of Mr. Miller follows:]

MEDPAC Medicare Payment Advisory Commission

TESTIMONY

Producing Comparative-Effectiveness Information

June 12, 2007

Statement of
Mark E. Miller, Ph.D.

Executive Director
Medicare Payment Advisory Commission

Before the
Subcommittee on Health
Committee on Ways and Means
U.S. House of Representatives

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Chairman Stark, Ranking Member Camp, distinguished subcommittee members, I am Mark Miller, Executive Director of the Medicare Payment Advisory Commission (MedPAC). I appreciate the opportunity to be here with you this morning to discuss comparative-effectiveness research. MedPAC constantly seeks improvements in Medicare efficiency, as evidenced in our work improving the accuracy and equity in Medicare's payment policies, pay-for-performance, coordination of care, and the subject for today—comparative effectiveness. Improving efficiency involves getting better quality with fewer resources and getting more of the right care. One way we recommend to do so is to develop more comprehensive information on the comparative effectiveness of health care services.

The current trends in public and private health care spending are unsustainable. Even though substantial resources are devoted to health care in the U.S., the value of services furnished to patients is often unknown. Many new services disseminate quickly into routine medical care with little or no basis for knowing whether they outperform existing treatments, and to what extent. Increasing the value of health care spending requires knowledge about the outcomes of services. Comparative effectiveness—a comparison of the outcomes of different treatments for the same condition—could help all public and private payers to get greater value from their resources.

There is not enough credible, empirically based comparative-effectiveness information available to patients, providers, and payers to make informed treatment decisions. Comparative effectiveness is a public good because the benefits of the information accrue to all users, not just to those who pay for it. Because it is a public good, a federal role is necessary to produce the information and make it publicly available. Consequently, the Commission recommends that the Congress should charge an independent entity to sponsor credible research on the comparative effectiveness of health care services and disseminate this information to patients, providers, and public and private payers.

Such an entity would:

- Be independent and have a secure and sufficient source of funding;

- Produce objective information and operate under a transparent process;
- Seek input on agenda items from patients, providers, and payers;
- Reexamine comparative effectiveness of interventions over time;
- Disseminate information to providers, patients, and federal and private health plans; and
- Have no role in making or recommending coverage or payment decisions for payers.

There are different ways to carry out a federal role. The Commission prefers a public–private option, reflecting the benefit of comparative-effectiveness information to the government, private payers, and their patients. Funding could come from some public and some private sources or alternatively from public sources only. An independent board of experts should help develop the research agenda and ensure that the research is objective and methodologically rigorous. The entity's primary mission would be to sponsor studies that compare the clinical effectiveness of a service with its alternatives. This research may involve synthesizing existing analyses or sponsoring new analyses. We emphasize that the entity would not have a role in how payers apply this information—that is, coverage or payment decisions. Instead, it would produce and disseminate comparative-effectiveness information to payers, providers, and patients who would then decide how to use it.

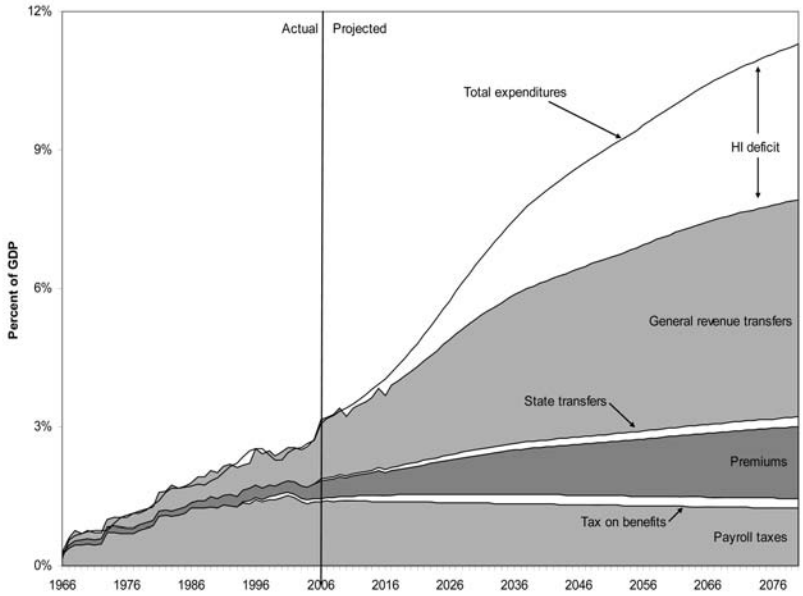
Context for Medicare payment policy

Medicare was designed to help ensure access to medically necessary care for the aged and disabled. Many analysts give Medicare credit for improving the economic position of its beneficiaries. Today, however, Medicare and other purchasers of health care in our nation face enormous challenges for the future. One challenge relates to the wide variation in the quality and use of services within our health care system, with quality often bearing no relationship or even a negative relationship to spending. Analysts point to geographic variation in spending as evidence of inefficiency and waste. Although spending is rising, it is not clear that beneficiaries are seeing commensurate increases in the quality of their care or their health. A second challenge is that health care spending in general and Medicare's spending in particular has been growing much faster than the economy. Forces such as the broad dissemination and use of newer medical

technologies can be beneficial but it can also unnecessarily contribute to higher costs if the innovation is adopted without evidence that it is superior to existing treatments and is used in populations where it is not effective. The forces that are driving these spending trends are common to both public and private payers. Because of these forces, the Commission and others have continually warned of a serious mismatch between the benefits and payments the program currently provides and the financial resources available for the future.

Figure 1 shows the Medicare trustees' view of the future of Medicare financing. Total expenditures for Medicare will take up an increasing share of the nation's gross domestic product (GDP) and quickly exceed dedicated financing. In their most recent report, the Medicare trustees project that, under intermediate assumptions, the hospital insurance (HI) trust fund (which finances Part A of Medicare) will be exhausted in 2019. There is no provision to use general revenues to cover Part A services once the HI trust fund is exhausted. Consequently, either those expenditures will have to cease or some new source of financing will have to be found. For other parts of Medicare (Part B and Part D), general tax revenues and premiums automatically increase with expenditures. Those automatic increases will impose a significant financial liability on Medicare beneficiaries, who must pay premiums and cost sharing, and on taxpayers in general. For example, if income taxes remain at their historical average share of the economy, the Medicare trustees estimate that the program's share of personal and corporate income tax revenue would rise from 10 percent today to 24 percent by 2030.

Figure 1. Medicare faces serious challenges with long-term financing



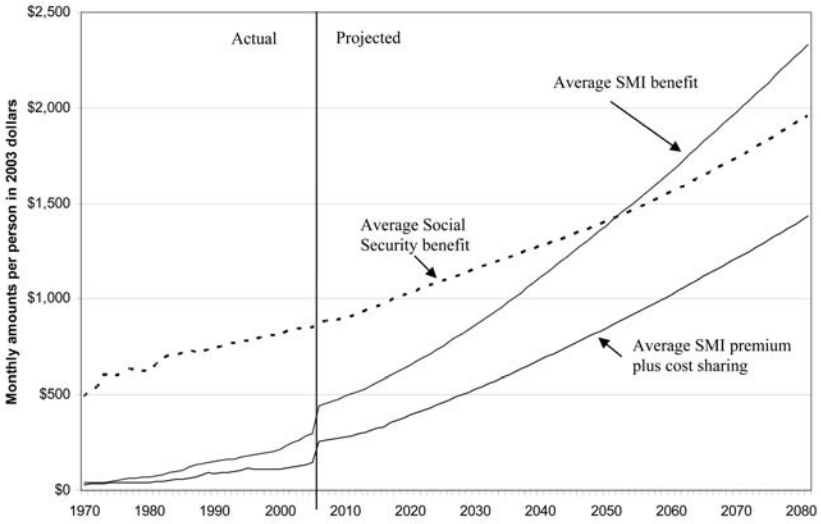
Note: GDP (gross domestic product), HI (Hospital Insurance). Tax on benefits refers to income taxes that higher income individuals pay on Social Security benefits that are designated for Medicare. State transfers (often called the Part D "clawback") refer to payments from the states to Medicare for assuming primary responsibility for prescription drug spending.

Source: 2007 annual report of the Boards of Trustees of the Medicare trust funds.

Figure 2 shows that between 1970 and 2005, the average monthly Social Security benefit (adjusted for inflation) increased by an annual average rate of 1.6 percent. Over the same period, average supplementary medical insurance (SMI) premiums plus cost sharing and average SMI benefits grew by annual averages of 4.5 percent and 5.9 percent, respectively. In the 2003–2006 period, Part B premium increases offset 20 percent to 40 percent of the dollar increase in the average Social Security benefit. For 2007, the increase in the Part B premium offsets 13 percent of the Social Security benefit increase. Medicare trustees project that between 2006 and 2036,

the average Social Security benefit will grow by just over 1 percent annually (after adjusting for inflation), compared with 3 percent annual growth in average SMI premiums plus cost sharing.

Figure 2. Average monthly SMI benefits, premiums, and cost sharing are projected to grow faster than the average monthly Social Security benefit



Note: SMI (Supplementary Medical Insurance). Average SMI benefit and average SMI premium plus cost sharing values are for a beneficiary enrolled in Part B and (after 2006) Part D. Beneficiary spending on outpatient prescription drugs prior to 2006 is not included.

Source: 2007 annual report of the Board of Trustees of the Medicare trust funds.

Policymakers will need to use a combination of approaches to address Medicare's long-term sustainability. Use of comparative-effectiveness information is one approach, as it has the potential to increase the value of the health care spending that is going to occur. It is possible that comparative effectiveness could reduce spending if, among clinically comparable services, less costly services replace more costly services. Since Medicare heavily influences many aspects of health care, policymakers should keep in mind that the program could play a leading

role in initiating change. At the same time, broad trends in the health care system affect the environment in which it operates, and Medicare needs to collaborate with private payers who face similar pressures from growth in health spending.

Defining comparative effectiveness

Comparative-effectiveness analysis evaluates the relative impact of medical services, drugs, devices, therapies, and procedures used to treat the same condition. Effectiveness means the outcomes of clinically relevant alternatives provided to patients with diverse clinical characteristics in a wide variety of practice settings. The outcomes that researchers assess in comparative-effectiveness studies may include: clinical outcomes, such as mortality and major morbidity; functional outcomes, such as quality of life, symptom severity, and patient satisfaction; and economic outcomes, including cost effectiveness.

The private sector does not systematically produce and disseminate objective comparative-effectiveness information

In some instances, manufacturers conduct studies assessing the clinical and cost effectiveness of their products but some researchers have critiqued these studies and raised concerns that these efforts may not always be objective and available to the public. Researchers have shown that bias in drug trials is common and often favors the sponsor's product. Possible sources of bias in industry-sponsored trials include: (1) the dose of the drug studied, (2) the exclusion of patients from the study population, (3) the statistics and methods used, and (4) the reporting and wording of results. Some are also concerned that not all manufacturers disseminate studies that show negative results of their services and treatments.

Pharmacy benefit managers, health plans, and other large providers (e.g., hospitals) consider a service's clinical effectiveness, cost, and cost effectiveness, particularly for their drug formularies, but do not necessarily make their evaluations public. These groups often focus on proprietary internal studies related to their health care practices. Few private sector groups systematically produce clinical and cost-effectiveness information and make it available to the

public. One exception is the Technology Evaluation Center established by Blue Cross Blue Shield Association, which relies on reviewing the existing literature to compare the clinical effectiveness of alternative services and posts it studies on the internet.

Concerns about liability might affect some private plans' use of cost-effectiveness information in their decision-making process. For example, some health plans reluctantly agreed to cover high-dose chemotherapy with autologous bone marrow transplant for breast cancer partly in response to the threat of litigation, despite its high cost and the lack of evidence that it was effective.

Furthermore, one could argue that comparative effectiveness is a public good because it demonstrates:

- "Nonexcludability": Once comparative-effectiveness information is publicly available, it is difficult to stop other groups from using the research free of charge.
- "Nonrivalness": One group's use of the information does not detract from its use by other groups.

Conducting this type of research is costly and, when it is publicly available, its benefits accrue to all, not just to those who pay for it. Although private plans have some of the data to conduct this research, they lack incentives to support it at the needed levels. Economic theory argues that the private sector will underproduce services (or in this case information) that meet this definition and that a government role is necessary to ensure that a sufficient supply is available.

Conducting comparative-effectiveness studies is not the primary focus of any federal agency

Some federal agencies do conduct comparative-effectiveness research, including CMS, the Agency for Healthcare Research and Quality (AHRQ), the National Institutes of Health (NIH), and the Department of Veterans Affairs (VA). However, their efforts are not substantial enough or coordinated enough to affect needed change.

CMS's efforts

CMS assesses the clinical effectiveness of services when making national coverage decisions. The agency bases these assessments partly on reviewing available literature about the service. In addition, CMS gathers information about a service's clinical effectiveness through registries and clinical trials for services the agency might not have covered in the past because of insufficient data about the service's clinical value. In some cases, CMS supplements its research by sponsoring outside groups, such as NIH, to conduct head-to-head trials and AHRQ and the Medicare Evidence Development & Coverage Advisory Committee to conduct and review assessments of the medical and economic implications of the use of health care services.

AHRQ'S efforts

AHRQ compares the clinical effectiveness of alternative treatments under a provision in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) that mandated the agency to conduct and support research with a focus on outcomes, comparative clinical effectiveness, and appropriateness of pharmaceuticals, devices, and health care services. Beginning in 2005, the Congress appropriated $15 million per year for the agency to fulfill its MMA mandate (the MMA authorized up to $50 million for this research effort). To fulfill the MMA mandate, AHRQ has: (1) put processes in place to select topics for analysis, review, and synthesis of the scientific literature, and to obtain input from the public and private sectors; (2) developed the infrastructure to conduct comparative-effectiveness research and translate the information to providers and patients; (3) completed eight studies, with more than 30 studies in progress; and (4) disseminated the research findings to users.

Outside of the MMA mandate, AHRQ has conducted studies examining both the clinical effectiveness and cost effectiveness of services for CMS and NIH. For example, on behalf of CMS, AHRQ assessed the cost effectiveness of fecal occult blood tests.

Conducting comparative-effectiveness research is not AHRQ's main mission, although the agency's efforts in this area are significant. Its primary mission is to conduct and sponsor health services research—the multidisciplinary field of scientific investigation that studies how social

factors, financing systems, organizational structures and processes, health technologies, and personal behaviors affect access to health care, the quality and cost of health care, and the health and well-being of the U.S. population.

NIH's efforts

NIH is the largest federal sponsor of clinical trials that compare a therapy to its alternatives—head-to-head trials. For example, NIH and CMS cosponsored the ongoing head-to-head trial comparing more frequent hemodialysis with thrice weekly (conventional) hemodialysis for patients with end-stage renal disease.

VA's efforts

VA also sponsors head-to-head clinical trials and cost-effectiveness analyses specific to its patient population. Since 1994, the VA has required a formal cost-effectiveness analysis from manufacturers of drugs that have small differences in quality but large differences in cost compared with their alternatives. The VA routinely requests manufacturers to submit clinical and economic data and incorporates this information into the drug reviews used in the formulary decision-making process.

The United States needs to produce more credible comparative-effectiveness information

The Commission finds that not enough credible, empirically based comparative-effectiveness information is available for patients, health care providers, and payers to make informed decisions about alternative services for diagnosing and treating most common clinical conditions. For private-sector groups, conducting this type of research is costly and, when it is made publicly available, the benefits accrue to all users, not just to those who pay for it. Although several public agencies conduct comparative-effectiveness research, it is not their main focus and their efforts are not conducted on a large enough scale.

Consequently, the Commission recommends that the Congress should charge an independent entity to sponsor credible research on comparative effectiveness of health care services and

disseminate this information to patients, providers, and public and private payers. Other organizations and policy analysts from disparate points of view have reached a similar conclusion, including Blue Cross/Blue Shield Association, America Health Insurance Plans, Gail Wilensky, Marilyn Moon, and Uwe Reinhardt. (Complete bibliographic citations are available in our forthcoming June 2007 report to the Congress.)

Comparative information could help payers make better policies

Several ways for both public and private payers to use comparative-effectiveness information in the payment process include:

- Creating a tiered payment structure that pays providers more for those services that show more value to the program;
- Creating a tiered cost-sharing structure that requires lower cost sharing for those services that show more value to the program;
- Not paying the additional cost of a more expensive service if evidence shows that it is clinically comparable to its alternatives; and
- Requiring manufacturers to enter into a risk-sharing agreement, which links actual beneficiary outcomes to the payment of a service based on its comparative effectiveness. This idea requires that manufacturers rebate the payer for services that do not meet expectations for their effectiveness.

Public and private payers might use comparative-effectiveness information to prioritize pay-for-performance measures, target screening programs, or prioritize disease management initiatives. A pay-for-performance program could link providers' bonuses to the provision of services that are clinically effective and of high value.

More comparative information could help support better decision making by patients and providers

Many new services disseminate quickly into routine medical care without providers knowing whether they outperform existing treatments, and to what extent. For example, a recent study showed that inexpensive diuretics may control hypertension as effectively as expensive calcium-channel blockers.

The FDA's regulatory process for approving new technologies does not in general generate evidence that shows a service's effectiveness relative to its alternatives. (For certain conditions, such as cancer and AIDS, clinical trials often compare the most accepted treatment with a new treatment.) Most manufacturers conduct studies that show the efficacy and safety of their drug or biologic relative to a placebo (inactive) agent. For devices, the FDA requires safety and effectiveness information only for high-risk devices, such as stents, that pose a significant risk of illness or injury to patients. (The FDA approves most devices for marketing in the United States based on their similarity to previously approved devices.) Finally, for new diagnostic and surgical procedures, less clinical information is available because the FDA does not review their safety and effectiveness.

Once the FDA approves a drug, few manufacturers initiate further studies that examine its: (1) long-term safety, (2) effectiveness in patients not included in the approval clinical trials, or (3) effectiveness relative to its alternatives.

Patients have some information about differences among health care providers and the prices they charge but often they have little or no information about how well different treatments work. CMS and some private payers post information about the quality of care certain providers furnish but disseminate little information to consumers on the effectiveness of alternative medical services.

As copayments and deductibles rise, patients may become more value conscious and their demand for comparative information may increase. For example, Kolata (2006) reported that few

patients are choosing to undergo lung-volume-reduction surgery partly because of information from an NIH-sponsored comparativeness effectiveness study that compared the surgery's clinical benefits and costs to medical treatment.

Functions and activities of a comparative-effectiveness entity

Whether the entity is new or an existing group, it will need to conduct and sponsor comparative-effectiveness research. Comparative research involves synthesizing existing data and research from the scientific literature. Another option is to design studies that use administrative claims data from payers. Electronic medical records might become a source of important data for comparative-effectiveness research if providers widely adopt information technology. When existing data sources do not provide sufficient information on comparative effectiveness, the entity will need to sponsor clinical trials to generate the data needed to assess comparative effectiveness.

The entity will need in-house staff with experience in designing and conducting comparative-effectiveness research. To not duplicate expertise, the entity could contract out research to public agencies and research groups with experience in conducting comparative-effectiveness research and communicating the information, such as AHRQ and its evidence-based practice centers.

The organization should be aware of the comparative-effectiveness research done by other organizations such as AHRQ, CMS, NIH, and the VA. Coordination with public and private groups would ensure that agencies do not duplicate research.

Key process issues that the entity will need to address include:

- Identifying research priorities: To carry out its activities effectively, the entity needs to develop a clear rationale for selecting the services to study. For the entity's research to be relevant, its users—patients, providers, and public and private payers—should help inform the agenda.

- Producing unbiased information: Some clinical and cost-effectiveness studies show biases of investigators and their sponsors. Ensuring that analysts work objectively will be a critical issue. Ethics rules would help ensure that analysts working on behalf of the entity avoid involvement in any real or apparent conflict of interest. Ethics rules would address issues such as whether analysts can accept compensation from outside sources and requirements for regularly reporting financial interests.
- Ensuring transparency and stakeholder input: The entity's process and methods for conducting research should be publicly documented and available to all stakeholders. Throughout the process, the entity should provide opportunities for all stakeholders to review and comment on the research methods and findings.
- Reexamining a service's effectiveness over time: Reasons for a service's revaluation include its use in populations not examined by the original study, new information about the service's clinical effectiveness, and a change in practice patterns that affects the use or cost of the service.
- Disseminating information to all users: Circulating the findings from the comparative-effectiveness research to multiple audiences of different levels of sophistication, in culturally appropriate and consumer-friendly ways is a key task and should not be isolated from the review process. Rather, the entity needs to view dissemination as a crucial component of producing comparative-effectiveness research. Otherwise, the findings may not reach all potential users.
- Developing human capital: An adequate supply of qualified researchers will be needed to conduct comparative research. The entity could develop programs that train investigators and institutions to do the research.

Structuring an entity to examine and report on comparative effectiveness

The Commission has begun to explore the pros and cons of different ways to configure and finance the entity that produces comparative-effectiveness information. At this point in our deliberations, the Commission prefers a public–private option, reflecting the benefit of comparative-effectiveness information to the government, private payers, and their patients. An independent board of experts should help develop the research agenda and ensure that the research is objective and methodologically rigorous. A public–private entity might address some stakeholders' concerns about too much federal government involvement but still provide for strong public sector involvement and oversight. A public–private entity might provide a better balance of different perspectives than an entity that is either all public or all private.

In evaluating the different governance and funding options, policymakers might consider whether: (1) users will judge the research as being objective, credible, and produced with minimal or no conflict of interest and bias; (2) the entity is independent of various stakeholders and political pressures; and (3) the entity is stable.

Different organizational options for a comparative-effectiveness entity include:

- Expanding the role of an existing federal agency, such as AHRQ, NIH, or CMS;
- Establishing a new federal agency either within or outside of the executive branch;
- Establishing a new public–private entity; or
- Establishing a new private sector entity.

Some are concerned about creating a new federal bureaucracy. Others are concerned that payers will ultimately use the information to ration health care and that it puts payers in the position of directing medical decisions. Providers and patients may not view the research as being sufficiently objective if a payer, such as CMS, houses the entity. Either a new or an existing executive branch agency may not be independent enough to take on difficult research questions and disseminate unpopular research findings. Another disadvantage of expanding the scope of an

existing federal agency is that certain stakeholders who do not support conducting comparative-effectiveness research could place funding for all its functions at risk.

A public–private entity with an external board is another option to consider. For example, the Federal Reserve System, the central bank of the United States, has a unique structure that enables it to operate independently within government but not independent of government. Although the Federal Reserve is required to report to the Congress on its activities, neither the president nor the Congress approves its decisions. The Federal Reserve consists of a federal agency (the Board of Governors) and private entities (12 federally chartered corporations known as Federal Reserve Banks). Unlike most other federal commissions, the Federal Reserve is a self-financing entity; it does not receive congressional appropriations.

Other examples of public–private entities include federally funded research and development centers (FFRDCs) and congressionally chartered nonprofit organizations. The 37 existing FFRDCs are organizations that an executive branch agency sponsors but an academic or private organization operates and that can perform work for organizations other than the sponsoring agency. By contrast, congressionally chartered nonprofit organizations do not have a "parent" agency and can receive more funding from the private sector.

Another option is to establish a comparative-effectiveness entity within a private sector entity—for example, a new or existing independent nonprofit group could take the lead generating comparative-effectiveness information. A private sector entity would minimize concerns about the government's influence on the research agenda and the entity's findings. On the other hand, it would be difficult for the federal government to fund such an entity without being involved in its governance. Some stakeholders who are already uneasy about the influence of manufacturers on clinical trials and reviews might be concerned about the potential for bias if a private sector group took the lead to generate comparative-effectiveness information.

Under any option, the Congress could establish an external board composed of independent experts to advise the entity about research priorities and to provide oversight for conducting research might promote transparency and the credibility of the findings.

In addition to the governance, the independence and stability of the entity will also depend on its funding. For example, an entity that relies on federal appropriations might be more susceptible to year-to-year fluctuations than an entity with mandatory funding (e.g., from the Medicare trust fund). Each year, the Congress considers the spending for services financed from appropriations. By contrast, the statute guarantees spending for services financed from mandatory sources, although the Congress has the ability to change even mandatory funding.

Voluntary contributions from private groups—such as private payers and manufacturers of drugs, biologics, and medical devices—could also be vulnerable to budget uncertainties. Private sponsors might decide to withhold or withdraw funding for any number of reasons, such as disagreeing with the selection of a service for consideration. The influence of private groups that directly fund the research on a study's design and findings could be a concern.

Some combination of mandatory public and private funding might be a more stable source of financing for an entity that is likely to be under pressure from stakeholders. Possible sources of mandatory funding include:

- Drawing funds from the Medicare trust fund (which is financed primarily by payroll taxes);
- Drawing funds from general tax revenues;
- Imposing a tax on the nation's annual outlays for health care services (as suggested by Uwe Reinhardt (2004)); and
- Imposing a dedicated tax on products that threaten human health, such as tobacco, products with trans fats, and alcohol.

Conclusion

Little objective, credible, and high-quality information is publicly available that compares the effectiveness of health care services furnished to patients. Comparative-effectiveness research is costly to generate and private sponsors have difficulty recouping the costs of producing the research because other users will not pay to use the research once it is publicly available. There is no federal entity whose sole mission is to conduct and disseminate comparative-effectiveness research. Consequently, the Commission recommends that the Congress should charge an independent entity to sponsor credible research on comparative effectiveness of health care services and disseminate this information to patients, providers, and payers. Use of such information has the potential to increase the value of health care spending and might reduce spending if, among clinically comparable services, less costly services replace more costly services.

Chairman STARK. Well, I would start right there. All of you have touched on this issue of who would be in charge or what kind of a bureaucracy or agency would handle this work. Mark, I direct this to you: Does there exist in our world today an agency, whether it studies defense or space or is there an agency that would meet the standards that you suggest?

Dr. MILLER. The Commission discussed a couple of models that one could use. The notion of like a Federal Reserve Board, where you have a board that is appointed and operates with some degree of independence. There are arrangements in the Federal agencies where you have combinations of the Federal agency and a not-for-profit corporation, which can take Federal and private dollars to execute agendas.

Chairman STARK. Such as?

Dr. MILLER. There is a list in our testimony. But these things can be things like a Jet Propulsion Laboratory associated with NASA, things I am not necessarily expert in. But there is a list of them in our testimony.

The concern there would be in a situation like that whether the Federal agency would be truly able to operate independently. I think that is what drove the Commission in the direction of considering a public and private governance structure that would be able to set the agenda and direct the research. There are a couple of models out there that people could work with.

Chairman STARK. Dr. Clancy, your agency has been suggested as a repository or operator of all this. What do you think we should do? Do you want us to put it in AHRQ and cut you loose from HHS, or what would you suggest?

Dr. CLANCY. Well, first let me say that the Department and Secretary Leavitt have been very supportive of this work, and he believes that this is quite critical to a focus on getting better value in health care, which I think you and your colleagues share a strong interest in as well.

We believe that doing this research well and rapidly and bringing the kind of information to patients and clinicians that they

need today is, by definition, a team sport, and that we have the teams and infrastructure in place to make the most of an investment as rapidly as possible. If one starts all over again, it is a little bit like that movie, "We Are Marshall." Right? You can get there, but it is going to take some time to build a new infrastructure and so forth.

More important, I think that we are very proud of the relationships that we have built with a variety of stakeholders. Even some industries that were worried about work that we were doing came around when we were done to say thank you. We were treated fairly. This was transparent. We had a say. To the extent that we had information to share that could also be shared broadly, you were there to help us, and so forth.

So, I think that we have begun to set a track record here and that that is an important consideration.

Chairman STARK. But it would be my understanding that the Secretary, whoever that might be, could sequester the results of your reports at any time. For example, if Tommy Thompson were back in that seat and you came out with something criticizing Swiss cheese, there is no way that report would reach the public under any circumstances, I think, the way you are structured. Is that not correct?

Dr. CLANCY. No. Actually, for this program, that is not correct, in part because we have set it up to be transparent from beginning to end, including posting the draft reports. In fact, those draft reports are often covered by electronic newsletters and so forth with people voicing their concerns or issues or other particulars they want to raise. We think that is great because

Chairman STARK. What you are suggesting is AHRQ now can operate without any political influence on the results of its work?

Dr. CLANCY. That has been our record with this program, yes.

Chairman STARK. That is good to know.

Dr. Orszag, just one question. I am afraid I know the answer. But it is often troublesome to us, good and bad, I guess, that we can't get scored for savings where we are not required by law to spend the money. For example, everybody in this room would probably agree that for every dollar we spent on early childhood preventive medicine, we would save $5 over the next 10 years of that child's life. But the $5 we save you won't score us as a savings because we are not required to spend it.

Is there any thought, any hope, that weI guess you would call it more dynamic scoring, but that would turn the whole budget process on its head. But is there any way out of that dilemma, where the prospective, I guess, social savings to the country as a whole would help us?

You mentioned, and you bring it out: We spend five times as much on medical care today as we spend on the whole automobile industry. Think about that, and look at all the traffic jams we have. But we are spending five times as much in our gross domestic product on medical care as we do on automobiles, which is something to think about when you are commuting.

But what about is there any chance we could find a different way to score some kinds of savings?

Mr. ORSZAG. Let me say things three things. The first is and the preventive medicine example that you raised often has very long-term payoffs in terms of cost savings. The budget window, which is chosen by the Congress, not by CBO, has been five to 10 years. So, that is one inherent limitation in this process that in many cases, cost savings over very long periods of time are just outside the window that you normally look at.

The second thing is that CBO is reexamining many issues to see whether there are offsetting behavioral responses and other things that do not get into dynamic scoring, which involves macroeconomic responses. There are a variety of questions that we are currently reexamining as new evidence comes to light. We would welcome evidence that would help us in that effort.

The final thing is on dynamic analysis itself, CBO and the Joint Committee on Taxation and other official entities have in recent years started to do dynamic analysis on some legislative proposals. We are reexamining how we do that also so that to the extent that on the spending side of the budget there are things that have high economic returns and evidence in that favor, that could be incorporated at some point into the process.

But we are currently just reexamining the evidence to build the evidence base, and we are not at the point where we are able to do that yet.

Chairman STARK. Thank you.

Mr. Camp?

Mr. CAMP. Thank you, Mr. Chairman.

Dr. Miller, do I understand that one of the models that you are suggesting for this might be similar to the testimony we are going to be hearing in a few minutes from Dr. Wilensky about maybe having a federally funded research and development center that is mainly funded by the government but attached to AHRQ? Is that one of the examples I thought I heard you describe?

Dr. MILLER. Yes. That is one of the models that is reviewed in our report. The various pros and cons of that are talked through. I would just say that in making that point, the concern would be that the Federal agency that it is attached to would have the latitude to disseminate research, set an agenda and disseminate research, even if it was reaching conclusions that are unpopular.

I think that is why the Commission was moving more toward some governance structure that was more separate than a Federal agency. But it is one ofyes, it is one of the models.

Mr. CAMP. You mean your concern is that the Federal agency would disseminate information that is unpopular?

Dr. MILLER. It would be unable to disseminate such information.

Mr. CAMP. Unable to because of political interference?

Dr. MILLER. Correct.

Mr. CAMP. Dr. Orszag, you mentioned that comparative effectiveness with the right incentives could be a real help. I notice in your written testimony you mention that there might be the incentive might be to pay for additional costs of less effective treatment, for example, the concern being that and I would ask both you and Dr. Clancy to comment on this there are certain chronic conditions

that have unique circumstances that respond to different treatments or different drug regimens.

There may not be one medication that fits every particular situation. Just for example, there are 15 drugs to treat patients with epilepsy, and two patients with epilepsy could suffer the exact same seizures but they require different medications based on their body composition or other factors.

How can we ensure that a system that has comparative effectiveness ensures each unique patient has access to the medication that is most effective?

Mr. ORSZAG. Well, and as my written testimony emphasizes, one of the goals of comparative effectiveness research should be to identify the sub-populations for which different treatments or interventions are more or less effective so that it is not such a blunt conclusion.

Incentive structures could then be tied off of that more disaggregated, more nuanced data. I agree with you that a blunt approach could not only be counterproductive, but backfire. One of the goals of this effort, presumably, would be to get a finer level of disaggregation about what works and what doesn't.

Mr. CAMP. All right. Dr. Clancy, any comment?

Dr. CLANCY. Yes. Just to make the point that the question you are raising in my mind reinforces exactly the importance of this kind of research. You know, today the vast majority of patients who are lucky enough to have insurance actually do make differential decisions based on tiering of pharmaceutical benefits and so forth.

Oftentimes they have to do that in the absence of information, and their clinicians actually don't have bits of information, but it is not organized in a way that helps them sit down with a patient and say, these are the options that would be best for you.

So, that is actually the vision we have of how this information would work.

Mr. CAMP. Do you have any thoughts just on Dr. Miller's comments that if this research were connected with a Federal agency, they would be unable to release anything unpopular givenhow do you square that with your other comments about the transparency?

Dr. CLANCY. Well, the point about transparency is that you have got broad engagement of many people in health care who care a lot about the information. So, you will be hearing from the American College of Physicians and others in the next panel. If they care about it, they are going to be saying, okay, so where is it, I mean, in the event that something that has not been in our experience were to occur. That is actually very, very helpful.

Not only that, they become a very helpful and supportive dissemination partner because at the end of the day, I am an internist. Many internists would actually prefer to get information that is coming from the College of Physicians than from any government agency. I don't take that personally; it is just because the College brings a certain level of credibility to it.

So, we see that engagement throughout the process as quite critical to the success of this work.

Mr. CAMP. All right. Thank you. Thank you, Mr. Chairman.

Chairman STARK. Thank you. Mr. Doggett?

Mr. DOGGETT. Thank you for your testimony.

Dr. Clancy, if I might inquire if you about a specific that may have some implications for other kinds of services, and that is imaging, for which Medicare has seen such an increase in cost.

While comparative effectiveness information is certainly useful in looking at imaging, I hear concerns voiced by radiologists that this greatly increases the administrative burden and that it encourages insurance companies to require precertification and other types of utilization management restrictions to limit imaging services.

How do we ensure that the comparative effectiveness information is used to improve quality without weighing down the health care provider with greater administrative burdens?

Dr. CLANCY. First, let me say that I am very pleased that we have had a number of collaborative opportunities and ongoing relationships with the College of Radiology and others. In many ways, that college kind of gets the work we do more than some others, which is a good thing.

I don't think you can entirely guard against it. But I do think if the information is transparent both in terms of what are the facts and what do we not know, then people have good grounds to ask questions and to push back if there are policies that are actually getting in the way of what is good patient care.

Mr. DOGGETT. I know that you have done one report on the effectiveness of noninvasive diagnostic tests for breast abnormalities. Do you have plans to investigate the comparative effectiveness for any other conditions where imaging is used as a diagnostic tool?

Dr. CLANCY. I don't know, but I will be happy to provide that answer in writing. I don't have a good list with me.

Mr. DOGGETT. Sure. Should comparative effectiveness data also be used to develop imaging certification standards that would assure that the provider is properly trained to provide the imaging scan, has suitable equipment, and has the training to read the scan effectively?

Dr. CLANCY. We think that is very important in terms of getting at dimensions of improving quality of care. But I would say that most people would say that is not a part of comparative effectiveness per se.

Mr. DOGGETT. Thank you very much.

Dr. Orszag, you talked about the regional differences that exist. How do you take the comparative effectiveness information and disseminate it in a way to reduce those regional variations?

Mr. ORSZAG. Well, the first step is to develop the information because a lot of that variation is arising in situations where there is no evidence on what works and what doesn't. Therefore, doctor norms in different parts of the country take hold which are not based on scientific evidence and therefore don't translate into improvements in life expectancy or other metrics of health quality even though they cost more. So, the first thing is the provision of the information.

As I think most of the written testimony emphasized, whatever entity is designed to do this or expanded to do this kind of research would have to pay a lot of attention to the dissemination of the information to health professionals. Having a more developed HIT

backbone, health information technology backbone, could facilitate that.

Then finally, to the extent that the information is ultimately incorporated into financial incentives for providers or for patients, that is a very direct way of signaling information.

Mr. DOGGETT. I was interested also in the graph that you had because it is so dramatic. Do you have it broken down into a percentage as to how muchif you assume that health care costs to Medicare continue rising at the current rate, how much is attributed to just an increase in the population of aged beneficiaries and how much of it is related to rising cost?

Mr. ORSZAG. Yes. In fact, on that first chart, the bottom dotted line is precisely what you identified, the demographic effect. So, there are more beneficiaries, and they are getting older, and that drives up cost. But that cost increase is pretty modest, and if I added Social Security to the curve, it would be a little bit more.

It is much, much smaller than how much is driven by the rate at which health care costs grow compared to income per capita. I think we have woefully under-invested in options that could help bend that curve, which is the central long-term fiscal challenge facing the country.

Mr. DOGGETT. Thank you all.

Chairman STARK. Mr. Ramstad?

Mr. RAMSTAD. Thank you, Mr. Chairman. I want to thank all three of you true experts for your testimony.

Dr. Orszag, I have a question. My overriding concern here, and it is really quite compelling, I believe, is that this new standard or model, the comparative effectiveness analysis, call it what you will, that it could end up denying patients lifesaving medical technology, appropriate medical technology.

I have seen the empirical data, and they all suggest, at least the studies I have seen, that medical technology saves dollars in the aggregate rather than costing dollars. Some policy-makers don't understand that, I realize. But anyway, that is not my question, but I think it needs to be taken into account.

My question is this: How would we ensure under this new paradigm, if you willhow would we ensure that complex study results, such as evaluation of a surgical procedure versus a medical therapy, be properly conducted and analyzed? What would be the mechanism to ensure such a quality study?

Mr. ORSZAG. Well, a few comments. First, I think the institutional design of the entity or entities that were charged with conducting this kind of analysis would have to include standards for how the research would be conducted.

So, for example, that the researchers not have financial ties to the companies that might be producing certain things; that the statistical techniques usedand I want to pause on that for a second because I do think if we are going to significantly expand this kind of research, it is not likely that we will be able to rely solely on randomized trials.

So, the expanded use of statistical analysis of health records, basically, will be necessary. Having a dramatically expanded system of electronic health records would facilitate the kind of rigorous

studies that could provide detailed analysis of sub-populations in a way that we currently only have a limited ability to do.

Mr. RAMSTAD. So, you think it would be better able to consider highly nuanced situations across sub-populations?

Mr. ORSZAG. With an expanded electronic health record backbone, there would be a much greater ability to study sub-populations, yes.

Mr. RAMSTAD. Dr. Clancy, I see you shaking your head affirmatively. Would you care to comment?

Dr. CLANCY. Yes. I would just like to reinforce that. Our 2008 budget request includes a request for $15 million, with which we will be launching a partnership with private sector health care organizations that have made the investments in electronic health records so that we can actually, in effect, work with them to create a distributed network both to do the kind of work that Dr. Orszag just described, but also to make sure that those organizations can use the findings as rapidly as possible, which is, I think, a point here that I don't want us ever to lose.

Dr. MILLER. If I could just——

Mr. RAMSTAD. Please, Dr. Miller.

Dr. MILLER [continuing]. I mean, one other part of the structure is to be sure that the results are open to public review and comment, much like you have in an academic process, so that other researchers and other analysts and other parties can comment on the work.

Mr. RAMSTAD. Of course, there would be a mechanism for the dissemination to all concerned parties, patients, as well as providers, practitioners.

Let me ask you a final question, if I may, Dr. Miller. One of the things I have learned over the years is the effectiveness of a medical device often depends on the skill of the physician using the device. Certainly physicians have to learn how to best use the device, determine which patients are the appropriate candidates for treatment, and so forth.

How can we make sure that the comparative effectiveness device is assessed in the context of physicians developing the skills to use that particular device?

Dr. MILLER. Well, I think a lot of this research tries to see how the given intervention works in a real world setting. So, part of the research can actually address the skills that are needed toif it happens to be a device or a particular procedure. Some of that can be built into the study itself. The idea here is real world use of the intervention.

Mr. RAMSTAD. So, we are not going to determine comparative effectiveness before doctors develop the skills to use whatever device?

Dr. MILLER. When you have a controlled trial, you are actually doing the procedure or testing the drug itself. Some of what you would need would come out of that process.

Mr. RAMSTAD. Well, thank you. My time is up. I appreciate your responses.

Thank you, Mr. Chairman.

Chairman STARK. Mr. Pomeroy, would you like to inquire?

Mr. POMEROY. I sure would, Mr. Chairman. Thank you.

I want to especially congratulate Dr. Orszag for his testimony. He couldn't have laid it out more clearly. We are heading to a financial train wreck. Health spending is the driver, the largest single driver of this fiscal train wreck ahead, and that if you look at it, we are seeing money pour out of the Treasury in differing ways across the country, ways that don't seem to be getting us anything in terms of health care return.

So, getting to the bottom of that one, you just couldn't have laid that out more clearly for us. I wouldn't think there would be any bipartisan disagreement across this panel. We have got to get to the bottom of that. Data and the analysis of it, capturing outcome data, procedural data, trying to get our hands around it, is a way to do it.

We have been talking about this, however, since I was insurance commissioner. I remember this coming up in the late eighties, early 19nineties. I thought, ah-hah, this is really going to advance the practice of medicine in this country. Man, we have just gotten almost nowhere. I am a littlewell, anyway, we have to get it right away.

Now, I have heard from some associations that essentially the procedure for data collection and outcome analysis launched by legislation we passed is not built on a collaborative basis at all and doesn't haveit is not going to work very well. Dr. Clancy, can you reflect on those concerns?

Dr. CLANCY. I am not sure which legislation that you are referring to. I am pleased with the collaborations that we have had to date, but I would be happy to follow up on specific concerns that you have been hearing.

Mr. POMEROY. Did Committee on Ways and Means toward the second half of last year do something about data?

Dr. CLANCY. You may be talking about physicians reporting on quality.

Mr. POMEROY. Yes.

Dr. CLANCY. Yes.

Mr. POMEROY. That would be an essential component of this effort, wouldn't it?

Dr. CLANCY. No. It is a little bit separate. Where physicians might be involved

Mr. POMEROY. But equality data will illustrate what you are paying for that is providing value versus what you are paying for that is not providing value in terms of expanded health outcomes. Correct?

Dr. CLANCY. What the quality data is looking at right now are those areas, just a few, where we are pretty sure what the right thing to do is. For example, diabetics should have a certain type of test done, surgeons should be doing something to minimize the occurrence of infections after surgery, and so forth. It is a very small subset of samples.

I think where many physicians are feeling frustrated right now, particularly those in small practices, is that it feels like a burden and not much value added. That is a concern we take very seriously. It is a bit peripheral to our topic of conversation today.

At the same time that they are not really loving that quality reporting, a number have been coming to us saying, we want to cre-

ate our own registries. Some have done that. The Society of Thoracic Surgeons is probably the best example.

But the orthopedists, the College of Surgeons, and many others, the bariatric surgeons, all want to collect information so that they can get at some of the questions that your colleague was asking Dr. Orszag about, about physician skill, about potential harms, and how people do over time. We are very much looking forward to working with them on that.

Mr. POMEROY. It strikes me that as clear as this is conceptually, getting into it is quite difficult, thenwho works it up, what is measured, how you measure it. Dr. Miller, I do see the quality tying directly into this whole effort at trying to evaluate what is unnecessary to pay for and trying to get at disparate practice patterns across the country, with an eye on cost savings.

What is MedPAC's response to what passed late last year relative to quality reporting?

Dr. MILLER. I think again we are talking about two slightly different issues. But just toI do think I understand where you are going. Just to address your issue, one tack that we took when we were talking through the collection of quality data for physician services is we think that a lot of information can be collected from the claim stream.

So, for example, if a physician ought to be, for a diabetic, ordering certain types of tests or having eye exams or foot exams, that type of thing, some of that information, whether it occurred because they are billing for it, can be collected through the claim stream without a significant burden on the physician themselves.

Now, I want to be clear. This is not to say that we don't think there may be information that should come from the physician themselves. For example, we talked about the notion of physician offices reporting on their functionality. Do they have the ability to do a patient register? Do they do those types of things? But there is a lot of information that can be collected from the claim stream without putting a burden on the physician.

Now, just one last point. The connection here is if we have comparative effectiveness information through analysis, clinical trials, that type of thing, that can tell you which measures you might want to be collecting from physicians.

Mr. POMEROY. Thank you. Thanks, Mr. Chairman.

Chairman STARK. Mr. Becerra.

Mr. BECERRA. Thank you, Mr. Chairman. Thank you to the three of you for your testimony.

Dr. Clancy, I may make a mistake here, and forgive me if I do. But I believe you know my wife fairly well, Dr. Carolina Reyes.

Dr. CLANCY. I certainly do.

Mr. BECERRA. I know that if she knew that you were here today, she would want me to pass along a hello because I know she always speaks so very highly of you.

Dr. CLANCY. Thank you. Likewise.

Mr. BECERRA. Thank you. Dr. Miller, MedPAC and others have said we need to do more when it comes to figuring out how to best compare different services, devices, and all the rest to cut back on the costs of health care. MedPAC is probably going to issue a re-

port that says that we need to do more on comparative effectiveness to get better results. Right?

Dr. MILLER. On Friday.

Mr. BECERRA. Okay. Dr. Orszag, I think you have talked about, as Mr. Pomeroy said, this looming crisis in our budgeting and how health care is such a big part of it. I think most people would agree that if we do a good job with this comparative effectiveness, we are going to save some money.

But I don't believe that you are prepared or we are prepared to see, coming out of those who do the analysis of how this affects dollars, you are going to come out and say, this scores well and has a big savings for us, at least not at this stage.

Dr. ORSZAG. What I would say is this holds substantial potential to reduce costs over the long term if it is implemented aggressively. Savings over the next decade is a lot harder because you have to get this thing up and running, you have got to do the studies, and then you have got to get it implemented.

So, if you are looking at bending the curve over the long term, there might be a material effect. If you are looking for cost savings over the next 10 years, that is a much harder thing.

Mr. BECERRA. If we had a bill that would provide a chunk of money so that Dr. Clancy could do more research, how would you score it?

Dr. MILLER. Over the next 10 years or over

Mr. BECERRA. Ten years is our horizon.

Dr. ORSZAG. Yes. Over the next 10 years, again, I would not be expecting any significant cost savings over that period.

Mr. BECERRA. So, Dr. Clancy, now I come to you. I believe you have about $15 million or so to try to do some of this research. You were authorized to get up to 50 million, but you got 15 through the appropriations process, far less than what you were authorized to get, far less than you probably needed to be authorized to get, but you have 15 million.

If we were to go legislation in this PAY–GO world where we have to pay for everything that we propose that is new spending, we are going to have a tough time figuring out how to get you the dollars you need to do the research we need so we can start saving the money that everyone acknowledges that we can gain from this.

So, it seems like we are in this awful dilemma, this Catch-22, where we know that there are savings. We know long term they will be there. But for our purposes, we can't score them as savings, and as a result you get these meager allocations of money through the appropriations process, which never leaves you enough time and resources to do the research that will prove what we say we know.

So, I am wondering if you can help us out of this quicksand and tell us, how can we persuade our colleagues that we must do much more than just provide $15 million in research dollars so you can do the work to prove the effectiveness of this?

Dr. CLANCY. Well, first of all, that is a great question. Thank you very much. The MMA, Section 1013, I think only had a limit for the first year. You are right that it took the appropriations another year to catch up.

I do think that we have heard considerable private sector interest in being part of a serious public/private collaboration, and I think that is a good thing, with all the caveats about minimizing conflicts and so forth. I think that may be part of the answer.

Ultimately, I think the answer is going to be in the return on investments. I think that we are beginning to make a downpayment now. We will actually let a contract in the next few weeks to see the extent to which we can take advantage of all the investments that organizations have made in electronic health records to create network where we can learn much faster.

Beyond that, if Dr. Orszag can't help you out, I have to say I would defer to his expertise.

Mr. BECERRA. You mentioned the private sector funding. Obviously, the folks in the private sector have a massive interest in this as well. My concern is, as we said before, we need these firewalls to make sure that the influence doesn't drive us in the wrong direction.

You believe that we could create those firewalls, that the tendencies wouldn't be to try to direct the research in ways that benefit those from the private sector who are providing the resources?

Dr. CLANCY. I think with this public/private partnership, we will have a terrific opportunity to begin to test that. We are going to start off with issues that no single health care system is big enough to address on its own. We are actually going to be examining the impact of breakthrough treatments, sometimes referred to as personalized health care, to find out how rapidly those treatments are diffused. Do they have the impact that is expected that we see in the laboratory? What happens to them when they are used off-label, and so forth.

I think that might be one framework to begin. I think the concern is this private sector interests are coming up to say, I like this study, and I will contribute here but not over here. I think a robust framework that addresses the issues you raised would need to mitigate that concern.

Mr. BECERRA. Thank you. Thank you, Mr. Chairman.

Chairman STARK. Mr. Kind, would you like to inquire?

Mr. KIND. Great. Thank you, Mr. Chairman. I want to thank our guests here today, too, for your testimony and your help and your recommendations and guidance on this issue.

We in Wisconsin have been very fortunate and quite delighted with the whole collaboration for health care quality that has been assembled between our providers. It is a volunteer basis, but they are establishing standards, reporting requirements, transparency. It appears to be really paying great dividends now, especially in light of a recent report issued by the Federal Agency for Healthcare Research and Quality ranking Wisconsin hospitals number one in this endeavor. We appreciate that recognition.

But of course, Wisconsin too is one of the lower reimbursed states in the nation when it comes to the Federal programs and Medicare reimbursement rates. So, there is a great interest and drive for outcomes-based or performance—based measures and standards which will drive these reimbursements.

But to me, it seems the key is making sure that we have got a totally integrated health information technology system out there.

Governor Doyle just announced a statewide project for all of our providers. But how we get there and how soon we get there is going to be crucial.

As far as establishing the standards, the measurements, the effectiveness, which would then drive reimbursements and best practices throughout the country, my question is: Can we get there without mandating it, without the threat of no Medicare reimbursements unless you have HIT fully in place?

But if we can do it through an incentive basis, what is the best incentives to provide? Because this is expensive, and right now there is very little financial incentive for some providers to do it. A lot of providers are, but there is proprietary interest being built up now with the systems that they are using.

The question is, can we integrate that across the bod? What type of incentives should we be looking at to help drive the whole HIT movement throughout the country so we can establish these standards and measurements and start doing some real comparison across the board?

So, we be looking at accelerated depreciation for these hospitals who are implementing these systems, or to the providers of these HIT systems through the Tax Code? Should there be grants offered to hospitals for training purposes for implementing HIT technology? Should we be looking at grants for lean or Six Sigma programs with our health care providers, too, to go after the low-hanging fruit? Dr. Miller?

Dr. MILLER. Yes. The Commission looked at this issue a couple of years ago. It didn't rule out things like the grants and trying to put money on the table to bring people together in a community. But I think the feeling of the Commission was the first and strongest signal, and I think there has been some reference to this elsewhere to start to build it into the payment system.

For example, does a physician's office have the capability to have patient registries? Does it have prompts to say that for my diabetics, I need to do this next test? You wouldn't say, I am paying you to purchase this software, but it would say, your payments will be increased if you have this capability, and then let the market work in behind it to say what is the best way to get that capability.

Then you change the return on investment ratio that right now, a physician's office will look at it and say, I have a lot of expenditures but I am not sure what I am getting back. If you can change that ratio, you can change the incentive. Then we made recommendations for hospitals and managed care plans, et cetera.

The point was that the first signal should be through the payment system to say, if you have these capabilities or these measures, your payments will increase from——

Mr. KIND. This would be on a temporary basis, I assume. Otherwise we are paying more money to try to make providers more efficient and more outcomes-oriented.

Dr. MILLER [continuing]. No. The Commission's view was that paying for these kinds of outcomes should be something that would be an ongoing basis so that we don't payand I think this was a statement made early onwe don't pay the same to each provider. We pay more to the providers who have better quality outcomes,

greater capabilities to track their patients. This would be on an ongoing basis.

Then they did talk about some of those other things that you talked about. But I think their feeling was, first let's get Medicare to drive this signal pretty hard through its payment system.

Mr. KIND. All right. Dr. Clancy?

Dr. CLANCY. Yes. First let me just say we work closely with the Wisconsin Collaborative for Healthcare Quality, and they are terrific. So, I just wanted to let you know that.

Mr. KIND. Good.

Dr. CLANCY. Second, we have been supporting a grants program of close to $200 for the past several years, evaluating the impact of selected applications of health information technology on improving quality and safety, with a special focus on those providers in rural and underserved areas. We also support these health information exchange projects, similar to what Governor Doyle would like in six states right at the moment.

So, we have a resource center that I think can give a lot of lessons to providers. Having said that, I think we do keep coming up against the issue of what is the incentive to adopt and what is going to make it worthwhile. It is an issue we are pushing on very hard right now in the Department.

As we speak, the American health information community is meeting today. You are likely to see a demonstration coming out of CMS in the near future. There are a number of demonstrations ongoing now that I think get right at this incentives issue.

The issue I am working on very specifically, and we recently heard from the collaborative, which was great, is how can we make sure that certified electronic health records in the very near future include the functionality to report on quality.

Right now, providers who have made that investment have sometimes been disappointed after they made a big investment only to find out that there is no way to just hit the F7 key; for example, up go the quality measures. But that problem will get solved over the next year or so, and it will include the reminders. We don't want to get better at driving by figuring out how to drive faster through the rear view mirror. We need to do the right thing to begin with.

Mr. KIND. Great. Thank you. Thank you, Mr. Chairman.

Chairman STARK. Mr. English, would you inquire?

Mr. ENGLISH. Thank you, Mr. Chairman, and thank you for the opportunity.

I was intrigued by one of Mr. Ramstad's remarks to Dr. Orszag, and I guess I would like to reframe it as a question to Dr. Clancy. Specifically, how will you update the comparative effect of this measure to be reasonably sure that you are not dampening the innovation in patient treatment and medical devices that is occurring today?

If a plan, for example, limits access or bases coverage on formulas derived from comparative effectiveness studies, how does the plan avoid penalizing doctors who are on the cutting edge and who are trying new surgical techniques or new interventions to help their patient?

Dr. CLANCY. Thank you. That is a concern that many people have. We are committed to updating our reports to reflect the latest changes in science. We recognize in particular that for devices, this is a particularly unique challenge because they are constantly being updated.

This is an area where clinical trials are unlikely to be the answer to that particular question. In fact, we think it is very consistent with the kind of observational studies we are funding right now through a network that we call DEcIDE, and would be very interested in additional input on this question.

Because as these devices get better and as we learn more and can collect information about which patients benefit and under what circumstances, we will all be better off. Again, we think that transparency throughout the process, from setting the agenda to framing the questions to reviewing the reports and so forth, is the greatest protection against information being used in a way that is contrary to patients' interests.

Mr. ENGLISH. Doctor, I think that is a good answer. I guess my concern would continue to be a process one, that simply how can you as a government entity stay on top of this in realtime and stay on top of current practice? But that is something that I will monitor and welcome the opportunity to engage with you on.

Dr. Miller, right now clearly there are significant gaps between what we know based on current science and evidence and what actually gets implemented into everyday clinical practice. In your view, shouldn't we be doing more research to get at the best approaches to closing some of those gaps?

Dr. MILLER. If I understand the question, the answer is yes. That is a lot of what we were talking about today and will be discussed in the report that is going to come out on Friday. But maybe I didn't quite understand.

Can I say one thing about?——

Mr. ENGLISH. Go ahead.

Dr. MILLER [continuing]. You asked about the stifling of innovation.

Mr. ENGLISH. Yes.

Dr. MILLER. I think one thing that all of us should keep in mind is that innovation investment is occurring now, and it is doing that on the basis of a very fragmented information basis, and in some cases information that is not completely unbiased.

I think one of our arguments here is that if we want a market to work well, we shouldn't be afraid of complete information. I think your concern about being sure that we are on top of it is well taken. But right now the information is very fragmented and incomplete, but driving lots of investment and lots of dollars.

Mr. ENGLISH. Well said. I will yield back the balance of my time.

Chairman STARK. Thank you. Ms. Schwartz, would you like to inquire?

Ms. SCHWARTZ. Thank you, Mr. Chairman. Thank you for the opportunity.

I guess I should say that there are two particular reasons why I am here, and I think I am looking at Dr. Clancy because my understanding is that you do a pretty good job of what you do. Having

one of the evidence-based practice centers13 of them having one of them in my district, and I have visited with them and asked people in the community or providers and payors, and tremendous respect for the information that comes out of ECRI, which is in Plymouth Meeting, Pennsylvania. I think they do a good job, and your shop as well.

So, I think you have already answered the question that has been asked, which seems like a reasonable one, is why create a new system to do this when we already have one that is really a public/private partnership in a way already? Because there are these eleven, in some cases private, in my case, I assume they all are evidence-based research institutes that actually do this work on your behalf and helps you do all the work that you do.

Is that not true, that there is a mechanism in place now, and as was pointed out before, if you actually just do more of what you are doing, again with the right priorities, that you could have more of an effect in controlling some of the cost, or at least providing information to the providers and to the usually hospitals and doctors to know that they are using the most effective treatments and devices?

Dr. CLANCY. The vast majority of the investments we make in this program are indeed to private sector entities. Some are at academic medical centers. Some, like ECRI, are freestanding independent institutes or like Blue Cross Blue Shield Tech Association and so forth.

So, yes, I would say that this is very much a public/private partnership. Thank you for your comments on ECRI. They are also very, very interested in this issue and making contributions.

Ms. SCHWARTZ. I know that they would be happy to do more if they the funding to do that. I hope to be a part of this.

Do you have any evidence yet about when you do do a comparative study and get that information out, that you have even anecdotal information coming back, sayingfrom hospitals or physician practices that they have changed their behavior because of information you have put out?

Because that is the point, I think, that Dr. Orszag made, is that we need to have some sense that it is being used in the real world of health care. Someone is taking that action, saying I used to use this treatment because I always did, and I am not up on the evidence but your information actually made a difference. Or, in fact, I was buying the cheapest thing out there, and your information has actually helped me buy something else because it is more effective.

Dr. CLANCY. We have information that a variety of organizations have been very, very enthused about this information. Much of it is anecdotal and more like case studies. We work very closely with the College of Physicians that you will be hearing from, from a variety of consumer groups. Consumer Reports takes advantage of information that is produced by another one of the evidence-based practice centers, and so forth.

I think it would probably be more helpful if I could get you a thoughtful written response to that question.

Ms. SCHWARTZ. I think it would be helpful to the Committee, in particular as we move forward, to make sure that it is being

used, and it is being used in a timely fashion and, of course, kept up to date.

My other than question may actually be for Dr. Orszag more. That is: You suggested that because of the regional differences, that the I assume doctors and hospitals are not using evidence-based information as they make their decisions. What do you think they are making their decisions on?

Mr. ORSZAG. A lot of the variation seems to occur where there simply is no evidence. So, I will give you an example. You fracture your hip. You go in for surgery. The variation in surgery costs for hip fractures is very small across the United States.

For the follow-up costs of that hip fracture surgery, there is no evidence on whether you should go see your doctor four times a month or twice a month. Should you get an MRI or not? Should you do physical therapy or not? There is just no evidence.

For the follow-up costs of the hip fracture surgery, there is a lot of variation. I think what happens is in some parts of the country, the doctors have been trained in a particular way or believe that a certain thing works without any scientific evidence behind that. That is what happens.

Ms. SCHWARTZ. So, the standard of practice is just different, in a way?

Mr. ORSZAG. The doctor norms differ. That is why you see this variation even within relatively small geographic areas, where different doctor groups are practicing in different ways.

Ms. SCHWARTZ. Do you think cost comes into this, that peopleare you suggesting that even the decision about what device you might buy, that cost comes into that as much as information about how effective it is? Is it cost? Is it availability? Is it who comes to the hospital and sells it? That is what I was wondering about, too. Is it based on just access to the information?

Mr. ORSZAG. Our payment——

Ms. SCHWARTZ. Which then speaks to how do we get at the good information broadly enough so that that actually is available in helping to make these conditions?

Mr. ORSZAG [continuing]. Our payment system seems to accommodate or facilitate these variations in doctor norms because especially within Medicare, we basically provide, we pay for, whatever doctors order, to a first approximation. So, if in one area doctors practice in a certain way, they get paid for that, and if in another area they practice in a more cost-effective way, they get paidthe payments reflect that.

So, the payment system is playing a role, and it is accommodating this variation in doctor norms.

Ms. SCHWARTZ. All right. Dr. Clancy, did you want to comment on that at all?

Dr. CLANCY. I think the availability of facilities and providers in a particular area often has a lot to do with, say, the follow-up costs or other examples of variation. So, for example, if there are few physical therapies in an area, doctors are going to order less of it, as compared with a community where there are a lot of terrific physical therapists, and so forth.

When you look at different providers and how they are distributed across the country, it kind of makes you scratch your head. But that clearly, I think, does have an impact on norms as well.

Ms. SCHWARTZ. All right. Thank you for your indulgence, Mr. Chairman.

Chairman STARK. Thank you. Do any of the Members have any other burning issues? Before I thank the panel for your patience and your efforts in helping us wind our way through this process. Thank you very much.

Our next panel will be led of by Dr. Gail Wilensky, who is a Senior Fellow at Project Hope, formerly a director of CMS.

Dr. David Dale, who is president of the American College of Physicians.

Ms. Gail Shearer, who is the Director of Health Policy Analysis for Consumers Union.

Dr. Susan Hearn, who is the Senior Project Manager in Environmental Health and Safety at the Dow Chemical Company of Midland, Michigan.

Dr. Steve Teutsch, who is the Executive Director of Outcomes Research and Management for the Office of Scientific and External Affairs at Merck and Company of West Point, Pennsylvania.

Welcome the panelists. Without objection, your testimony will appear in the record in its entirety. We would ask you to summarize for us or add to it in any way that you are comfortable.

Gail, do you want to lead off? You have to turn your mike on.

STATEMENT OF GAIL WILENSKY, Ph.D., SENIOR FELLOW, PROJECT HOPE, BETHESDA, MARYLAND

Ms. WILENSKY. I should know that by now. Thank you, Mr. Chairman and Members of the Subcommittee. It is a pleasure to be here. The comments I am going to be making reflect my training as an economist, my experience at HCFA and MedPAC, and also my membership on a Committee established by Academy Health to look at the issue of placement, structure, and financing of comparative effectiveness research. But my comments here reflect my personal views and not those of these organizations.

I have included in my testimony an article that was published online in Health Affairs late last year that lays out my thinking on some of the fundamental issues regarding placement financing and functions. This has been a very topical subject, and the comments today reflect some of the evolution in my thinking since then.

The rationale for such a center, I think, has been stated well. We have an unsustainable rate of spending growth, and we have that in a world where there is clear and persistent indications of problems with both patient safety and with quality.

To be sure, better information will not by itself be enough to moderate spendingyou have heard that from several people beforeand maybe not even enough to alter practice behavior. Changing the incentive structure that faces patients and clinicians, using comparative clinical effectiveness information along with cost data to set reimbursement rates, and a whole myriad of other changes will be needed. the other hand, without better information on what works when, for whom, provided under what cir-

cumstances, it is hard to imagine how the U.S. will learn how to spend smarter.

I have been advocating for a center that would have an information function rather than a decisionmaking function as it would pertain both to coverage decisions and reimbursement decisions, although I primarily see the information in such a center as informing better clinical decisionmaking and helping in the design of smarter decisions regarding reimbursement, as opposed to setting any additional criteria for coverage. These are different and fundamental roles compared to some of the centers that exist in other parts of the world.

I believe that the function for such a center should be to fund new research, synthesize existing research, and make sure that information is available about what is likely to result from using different treatment options for different subgroups in the population.

We need to be functioning on medical conditions rather than specific interventions or therapeutics; that is, cardiovascular disease or orthopedic surgery, and not a particular device. We need to be sure medical procedures are being included, and not just look at a particular therapeutic or medical device.

We need to recognize that technologies are rarely always effective or never effective, and that the role for a center is to inform decisionmaking about the likelihood that a favorable outcome will occur. We need to recognize that it is likely that the outcomes will differ for different subgroups in the population. As was asked in the previous panel, we need to understand that this is a dynamic process and not a once done, finished forever process.

I believe that the characteristics of the data help determine where the center might best lie. The data needs to be regarded as objective, credible, transparent, protected from the political process and also from the interest of affected parties. It needs to be timely and understandable.

To me, having looked at the various choices, I believe the best combination is a federally funded research and development center like the Lawrence Livermore Labs attached to AHRQ, close but not too close to government, enough to give it a little protection in terms of both the view of the private sector and the academic and other communities.

It is one that would be sponsored by an executive branch agency, AHRQ, and make sure that it has a strong tie to AHRQ. I think it is important that the center have both intramural, that is, in-house research and extramural, that is, contract research capability.

The governance also needs to make sure that it can stand the test of credibility, objectivity, and transparency; staggered-year appointments by the Executive Branch, maybe subject to Senate confirmation, so that no one administration has too much control, with specialized scientific boards.

In terms of funding, I think you can make an argument for direct appropriation. But given the realism of the difficulties that might present, I think you could also make an argument for a contribution from the Medicare trust fund and also one that has an assessment on privately covered lives because the payors will be the major users.

Let me summarize, then. I believe such a center would be an information center and not a decisionmaking center, providing credible information to clinicians, patients, and payors to use to make better decisions. I think it would have many important purposes, including the development of a reimbursement system in which copayments could be tiered to what makes the most sense clinically and economically, informed by credible, objective, transparent data.

Different payors can and should make different decisions. If Medicare is to be able to make use of this kind of information, it will need to have additional authority in setting reimbursement rates according to what makes sense for various subgroups of the population. I believe the agency would be one of the many changes that needs to occur if we are ever to learn how to spend smarter on Medicare. Thank you.

[The prepared statement of Ms. Wilensky follows:]

Prepared Statement of Gail Wilensky, Ph.D.,
Senior Fellow, Project Hope, Bethesda, Maryland

Mr. Chairman and Members of the Subcommittee: Thank you for inviting me here to testify on strategies to increase information on comparative clinical effectiveness. My name is Gail Wilensky. I am currently a senior fellow at Project HOPE, an international health foundation that works to make health care available to people around the globe. I have previously directed the Medicare and Medicaid programs as the Administrator of the Health Care Financing Administration and also chaired the Medicare Payment Advisory Commission. The views I am presenting here reflect my training as an economist, my experience at HCFA and MedPac and also my membership on a committee established in by AcademyHealth (the professional society for health services research) that considered the placement, structure and financing of comparative effectiveness research. My testimony today, however, reflects my personal views and not necessarily the views of Project HOPE, Academy Health or any other organization.

I am here today to discuss how to develop information on comparative clinical effectiveness (CCE) through the creation of a new Center for Comparative Clinical

Effectiveness. My testimony includes an article I wrote that was published on-line in *Health Affairs* last November which lays out my thinking on the fundamental choices regarding the placement, financing and functions of such a center. As a result of the many conversations that I have had about CCE with potential stakeholders, funders and supporters or opponents, my thinking has evolved since the original article. My current views are reflected in the following statement.

Rationale:

In a period when there is little consensus about how to reform American health care, there seems to be a developing consensus on the need for better information on comparative clinical effectiveness. Driving this interest is the recognition that the current rate of spending growth in health care (a long term average 2½% annual growth rate in health care faster than the economy) is simply not sustainable and that even with this spending growth, there are clear and persistent indications of problems with patient safety and with quality.

To be sure, better information will not by itself be enough to moderate spending and maybe not even enough to alter practice behavior. Changing the incentive structure that faces patients and clinicians, using comparative clinical effectiveness information along with cost data to set reimbursement rates and a whole myriad of other changes will also be needed. On the other hand, without better information on what works when, for whom, and provided under what circumstances, it is hard to imagine how the U.S. will be able to develop strategies that will allow the country to learn to spend "smarter" and without this, it is hard to imagine how we will lower the longer-term "excess" spending growth rate.

Role of the Center:

The interest in comparative clinical effectiveness information is neither new nor is it limited to the U.S. Other countries, however, have tended to focus their analyses primarily on pharmaceuticals and devices and their assessments tend to be an important or required element in coverage or reimbursement decisions for their national health systems.

I am advocating for a Center for Comparative Clinical Effectiveness that would have a different focus and serve an information function rather than a decision-making function—both as it may pertain to coverage or reimbursement decisions. Further, I am assuming that the information would primarily inform better clinical decision-making and help in the design of smarter decisions regarding reimbursement as opposed to setting new requirements for coverage. These are fundamental and critical differences in roles.

The purpose of the Center on CCE is to fund new research, synthesize existing research, disseminate and otherwise make available what is known about the likely clinical results of using different treatment options for different subgroups of the population. The focus therefore is on medical conditions rather than on specific interventions or therapeutics and needs to include medical procedures rather than only be limited to pharmaceuticals and devices. It also recognizes that technologies are rarely **always** effective or **never** effective (assuming that some time of approval process is required such as the FDA) and that the role of the center is to help inform various decision-makers about the probability that a favorable outcome will occur. Thus, comparative clinical effectiveness not only provides information that is comparative across various interventions but also recognizes that the outcomes may differ substantially for various subgroups of the population. Because of the nature of the discovery process and incremental changes that occur over time, it is important to recognize that investment in CCE needs to be thought of as a dynamic process and not once-done, finished forever.

Placement of the Center:

Over the past several months, there has already been a lot of discussion about where such a center should be placed and what kind of data should be included. In thinking about these issues, it is important to think about the characteristics that the information itself must possess if it is to serve the function envisioned for such a center. The most important are for the data to be regarded as **objective, credible, and transparent**—protected from both the political process as well as the interests of affected parties. The information should also be timely, span the full range of data available and be understandable to the various parties who want to make use of the data but the most important characteristics are those associated with "trust". Without that, the center won't be able to serve its fundamental reason for existing.

Some have argued the merits of keeping the Center directly within government, with many choosing to house it in the Agency for Health, Research and Quality, AHRQ, the place where the Medicare Modernization Act directed a limited amount of comparative clinical effectiveness analysis to occur. Others have argued the merits of keeping it outside of a direct involvement with government. While any placement will have its advantages and disadvantages, on balance the one that is most appealing to me is the use of a Federally Funded Research and Development Center, **FFRDC**, which is **attached to AHRQ**. These are entities that are primarily funded by government (minimum of 70%) and are sponsored by an executive-branch agency, which monitors its use of funds. There are several that have been around for many years. The Lawrence Livermore Labs is one of the larger, better known FFRDC's. This model best reflects the dictum of "close . . . but not too close to government" and also assures a close linkage with AHRQ, the lead agency for health services research which needs importantly to continue in that role. I also think the Center would be most effective if it had both **intramural** (in-house research) and **extramural** (contract research) functions as do both AHRQ and the NIH. The in-house researchers provide an important element of expertise and hands-on experience but my assumption is that much of the work would be contracted out to universities, free-standing research groups, etc.

Governance:

The governance of such a center is almost as important as its placement. Again, the key concepts are credibility, objectivity and transparency. This means a governing body that is reflective of all the major stakeholders, with staggered year appointments by the executive branch (and maybe subject to Senate confirmation) so that no one administration has too much control. Specialized scientific advisory boards would presumably be created for advice on particular comparative effectiveness studies, particularly those involving new research.

Funding:

Like any new entity, a Center for Comparative Effectiveness would require several years to reach a "steady-state" which I have assumed would be several billions of dollars. Because information is clearly a "public good" as the economist uses the term, my preferred funding would be by direct appropriation, as is the funding for

the NIH. That, however, may not be a realistic strategy. Another option is to combine funding sources that include monies from direct appropriations, a contribution from the Medicare trust fund and a small assessment on all privately covered lives. Although all will benefit from the availability of such information, thus the rationale for a direct appropriation, the payers will be especially advantaged by having this information available.

The Role of Costs:

The most controversial issue to date has been whether or not to include cost-effectiveness or cost-benefit analysis directly in a Center for Comparative Clinical Effectiveness. While I firmly believe the data made available by the Center should be used by payers in doing cost-effectiveness and cost benefit analyses and that funding to CMS should be made explicitly for this purpose, along with the ability of the agency to use such elements in their reimbursement decisions, I believe it is best to keep these functions housed separately. Payers would be wise to have their C/E and C/B analyses subject to the same criteria of credibility and transparency that are so critical to the acceptance of comparative clinical effectiveness information. This will be key to their acceptance and credibility although my expectation is that different payers would use the information differently in designing their reimbursement policies.

My rationale for the separation is two fold. One reason is technical. The concepts and decisions involved with C/E and C/B analysis are more controversial and subject to dispute: where in the life cycle is the technology and how much does that affect costs, whose costs are being measured—Medicare, small purchasers, large purchasers, etc, what functions are or are not absorbed by the purchaser, i.e. is the purchaser wholesale or retail, etc. In part because of these technical issues but also because of the more controversial nature of the implications of cost analyses, including the perceived threat that could result from these analyses, I believe combining the inclusion of cost analyses, particularly early on, will increase the political vulnerability of a center for comparative political effectiveness and since such information is the **most elemental building block** to learning how to spend smarter, it needs to be protected.

Finally, to reiterate, the Center for Comparative Clinical Effectiveness would be an information center, not a decision-making center, providing credible information for clinicians, patients and payers to use to make better decisions. Such information would have many important purposes including the development of a reimbursement system in which co-payments could be tiered to what makes the most sense clinically and economically, informed by credible, objective transparent data. Patients and clinicians that want more or want to choose differently should be able to do so but should need to pay more for their choices. Medicare does not currently have such authority in setting reimbursement rates and granting the agency this authority would be one of the many changes that would need to occur in learning to spend smarter under Medicare.

Chairman STARK. Thank you.

Dr. Dale?

STATEMENT OF DAVID DALE, M.D., PRESIDENT, AMERICAN COLLEGE OF PHYSICIANS

Dr. DALE. Thank you, Chairman Stark, Ranking Member Camp, and Members of the Subcommittee for this opportunity for the American College of Physicians to testify on comparative clinical effectiveness. I am David Dale, president of the College and professor of medicine at the University of Washington. I will highlight our positions on this issue and refer the Members to the written testimony previously submitted.

The College strongly supports congressional efforts to provide Medicare and all stakeholders with improved access to information about the relative strengths and weaknesses of various clinical products, procedures, services, based on the best available evidence from clinical effectiveness research.

From the perspective of a practicing physician, the increased availability of sound effectiveness data has direct clinical usefulness. For example, I regularly advise men about the diagnosis and treatment of prostate cancer and many other problems in my general internal medicine practice.

When a patient, a close friend, recently asked me for advice, I tried my best to give him a complete and unbiased comparison of the risks and benefits of various treatment strategies. But there is really very little comparative data available.

Similarly, women with breast cancer are currently treated with a wide range of therapies. We know relatively little about their comparative effectiveness, particularly the long-term effectiveness and the adverse effects of these therapies. But we could know much more through gathering data from current clinical practice if we had the mechanisms in place to do so.

The United States does not currently have a systematic means of producing the information to compare the relative effectiveness of drugs, durable equipment, therapies, and procedures. This is in marked contrast to the organized activities in a number of other countries, including Canada, Great Britain, Germany, and Australia.

The College recommends that the Congress take efforts, including allocation of secure and sustained funding, to support a trusted entity that systematically develops evidence on the relatively effectiveness of health care services.

The College believes that this trusted entity should be an unbiased and independent organization; have transparent procedures with strong stakeholder involvement, prioritized to ensure the evidence produced has the greatest impact; present its findings promptly in a way that is accessible and comprehensible to all stakeholders.

The entity in the United States that currently best matches this list of characteristics is the Agency for Healthcare Research and Quality, AHRQ. The College commends the efforts of AHRQ, and has recently urged Congress to increase its level of funding in a joint letter signed by the American Medical Association and over 80 other medical organizations.

The College believes that the greatest value of comparative effectiveness data is to help answer the question of what works best and for whom it works best, given the clinical conditions of the patient and the patient's preferences. We believe that the primary use of this information right now is for patient-centered care and counseling.

Better information will enable physicians and empower patients to engage in well-informed shared decisionmaking. Shared decisionmaking is a key and essential element for improving care through the patient-centered medical home, a model of care now supported by provider groups representing over 330,000 primary care providers.

The College is aware of suggestions concerning the potential use of comparative effectiveness data by Medicare and other payors to redesign their health benefits based on reimbursement or patient cost-sharing of comparative evidence on effectiveness. The College recognizes the potential savings obtained through this approach,

but we recommend that Congress proceed cautiously. Experience and evidence are required to determine the impact of such research on the quality of care and patient satisfaction before it is integrated into the payment process.

Finally, the College asks Congress to recognize the value of health information technology. Better health information at the level of the practicing physician will facilitate the collection, reporting, and aggregation of clinical data to support evidence-based research on a wide range of important clinical problems.

The pathway for development of comparative efficacy data is through implementation of interoperable health information technology throughout our health care system. Thank you.

[The prepared statement of Dr. Dale follows:]

Prepared Statement of David Dale, M.D., President, American College of Physicians

I am David C. Dale, MD, FACP, President of the American College of Physicians and professor of medicine at the University of Washington. The 123,000 internal medicine physicians and medical student members of the American College of Physicians congratulate Chairman Stark and the Members of the House Ways and Means Subcommittee on Health for convening today's hearing on "Strategies to Increase Research and Information on Comparative Clinical Effectiveness." **The College strongly supports Congressional efforts to provide Medicare and all stakeholders within the healthcare community with improved access to information about the relative strengths and weaknesses of various clinical products, procedures and services based on the best available evidence of clinical effectiveness**.

The Members of this Subcommittee are well aware of the significant problems that characterize our current healthcare system:

- the unsustainable growth in healthcare costs that affect both payers and beneficiaries; [1]
- the presence of significant quality gaps particularly when compared to other industrialized nations that spend much less on healthcare; [2]
- the presence of significant variation in healthcare costs throughout this country without any evidence that increased costs result in improved care.[3]

As stewards of the Medicare Trust Fund and the largest payer of healthcare services in the country, it is Congress' responsibility to address these problems and help ensure that our taxpayer funds are being used effectively to provide high quality care and achieve the best possible patient outcomes. The increased production and availability to payers, providers and beneficiaries of methodologically sound information from a trusted source on the effectiveness of alternative treatments would be a good step towards improving the value obtained from healthcare dollars spent.

The Public Need for Comparative Clinical Effectiveness Research

From the perspective of the practicing physician, the increased availability of sound comparative effectiveness data has direct clinical usefulness. Each day in the privacy of the examination room, patients are treated for conditions that have multiple treatment options. Here we are talking about treating a common condition like intermittent heartburn, to the more serious chronic conditions of high blood pressure or diabetes, to the more immediate life and death issues of to having to choose the best approach to treat diagnosed breast or prostate cancer. The availability of valid, comparative effectiveness data supplemented by the physician's clinical experience and professional knowledge, helps ensure that an effective treatment choice is made—one that meets the unique needs and preferences of the patient.

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[1] Kaiser Family Foundation. Trends and indicators in the changing healthcare market place. 2006. Accessed at http://www.kff.org/insurance/7031/index.cfm on May 9, 2007.

[2] Anderson G, Hussey PS. Comparing Health System Performance in OECD Countries: Cross-National Comparisons Can Determine Whether Additional Health Care Spending Results in Better Outcomes. Health Affairs. May/June 2001;20(3):219–32.

[3] Fisher, E., Wennberg, D., et al., The Implications of Regional Variations in Medicare Spending: Part 2, Health Outcomes and Satisfaction with Care, *Annals of Internal Medicine* 2003; 138:288–98.

The College has a long history of supporting evidenced based practice, and since 1981 has been developing evidenced-based clinical treatment guidelines through its Clinical Efficacy Assessment Program. In fact, I was part of the original panel of experts of this program and am currently Editor-in-Chief of "ACP Medicine," a continually updated, evidence-based reference of internal medicine published by the College. My own patient care experiences, as well as the College's experience in producing evidence-based analyses, supports the need for an objective, evidence-based and refereed source of information from a "trusted entity" to compare the effectiveness of alternative healthcare services.

The United States currently does not have a systemic means of producing comparative information on the relative effectiveness of drugs, durable equipment, therapies and procedures. The limited amount of comparative effectiveness data that is produced is done piece-meal, with little or no prioritization relative to the benefits it would provide to individual patients and the general population, little coordination or harmonization of clinical efficacy efforts, and uneven methodological standards for evaluating clinical efficacy and reporting the results to clinicians and patients. Often, evaluations are made on a "single therapy" basis without comparing such therapies to alternative treatments. The Federal Drug Administration assesses the safety and effectiveness of drugs, and to a less extent medical equipment, but the research it considers generally compares performance to no treatment (placebo) conditions, rather than to alternative products already in the market place. The National Institutes of Health (NIH) is this country's largest sponsor of clinical trials that compare alternative treatments, but funds for these studies represent only a small amount of their budget. The Agency for Healthcare Research and Quality (AHRQ) through Section 1031 of the Medicare Modernization Act (MMA) was authorized by Congress in 2003 to conduct and support research with a focus on outcomes, comparative clinical effectiveness, and appropriateness of pharmaceuticals, devices, and health care services. I will discuss more about this effort later in my testimony.

Private sector entities including pharmaceutical companies, pharmaceutical benefit managers, health plans and large provider groups also produce some comparative effectiveness data, but the details of these studies are often not transparent, access to this data is limited due to its proprietary nature, and there is evidence questioning the objectivity of some of these findings.[4]

This hodge-podge of comparative effectiveness efforts is in marked contrast to the activities conducted in a number of other countries, including Canada, Great Britain, Germany an Australia. Perhaps most recognized of these efforts is the National Institute for Health and Clinical Excellence (NICE) program in Great Britain,[5] which serves as a model of a coordinated, prioritized comparative effectiveness program designed to promote trust in its finding through transparency in its proceedings and strong stakeholder involvement at all levels of the process.

The College recommends that the Congress take efforts, including allocation of secure and sustained funding, to develop or support a trust entity that systematically develops evidence on the relative effectiveness of various alternative heathcare services.

While the College currently has no formal position on the structure of this entity (i.e. public, private or public-private), it believes that this entity should have the following characteristics:

- it should be an unbiased independent entity protected from both governmental and private sector influence to encourage trust in its findings.
- its proceedings should be transparent.
- it should involve stakeholders, including payers, providers and beneficiaries, at all levels of the evidence development process.
- it should have a prioritization process, informed by input from the stakeholder groups, that ensures that the comparative effective evidence developed will have the greatest impact in improving the quality and efficiency of care provided.
- it should support the development of all levels of evidence including formal review and synthesis of evidence already available in the clinical literature and the initiation of new research in priority areas where such evidence does not already exist.

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[4] Medical Payment Advisory Committee. Presentation by Nancy Ray on Comparative Effectiveness. April 12, 2007 Public Meeting. Access at http://www.medpac.gov/public_meetings/transcripts/0407_allcombined_transcript.pdf on May 9, 2007.

[5] Pearson D, and Rawlins, M. Quality, innovation and value of money. JAMA, Nov. 2005;294(20):2618–2622.

- it should have established processes that ensures that the comparative effectiveness findings developed are accessible in a comprehensive form to all stake holders and reported in a manner that is useful for clinicians and patients.

The entity that currently best matches this list of characteristics is the AHRQ. Through its Effective Health Initiative, this agency has established itself as a trusted source of comparative effectiveness data. Since its recent implementation, it has produced seven comparative effectiveness research reviews, it is in the process of developing at least six others and has initiated at least 14 new research projects. It has also made a substantial effort to ensure that their findings are accessible to consumers, providers and policy makers in a meaningful form. The College commends the efforts of the AHRQ and has recently urged Congress to increase its level of funding in a joint letter signed by the American Medical Association and over 80 other medical organizations.[6]

If AHRQ is to be the "trusted entity" to conduct effectiveness research, then it needs to be assured of sufficient and sustained funding to support its activities and be protected from the normal political influences that arise through the annual appropriations process. If Congress chooses to create a new entity rather than facilitate increased funding of the AHRQ to advance the development of cost effectiveness evidence, it should use lessons learned from AHRQ in developing this new entity and assure that the new entity is funded in a way that will protect it from political influences that may arise through appropriations.

Use of Comparative Effectiveness in Benefit Design Decisions

The College is also aware of suggestions concerning the potential use of this data by Medicare[7] (and other payers) to redesign their healthcare benefits by basing reimbursement and/or patient cost-sharing on the comparative evidence developed by the proposed entity. For example, those procedures that prove generally more effective could receive higher reimbursement and/or require a lower beneficiary co-payment. **The College, although recognizing potential savings obtainable through this approach, recommends that Congress walk down the path of using comparative effectiveness data in the Medicare benefit design slowly and cautiously.** It will take time for clinicians and patients to develop trust and have confidence in the evidenced produced from any new comparative effectiveness evidence producing entity. In addition, procedures will need to be developed to ensure that the unique needs of each patient can be recognized, and that clinical decisions are based upon what is best for this patient, rather than the economic incentives promoted by the benefit design.

The appropriateness of including "cost effectiveness" as an explicit element in comparative effectiveness research is complex and controversial. Cost means different things to different people: aggregate costs to a payers of services (Medicare), the economy (societal costs), the individual (in the form of out of pocket expenses, health care premiums, or individual tax payments to support public programs), or clinicians (whose professional value system often puts primacy of the individual patient's needs and preferences over societal costs) are very different from each other and will result in different value judgments. How the relative costs of a treatment and procedure should be weighted against the evidence of clinical effectiveness will involve value judgments that need to be made in an open, transparent, and methodologically sound basis that takes into account the different values that each stakeholder brings to the table**. For these reasons, the College suggests that federally-funded comparative effectiveness research should, at least in its early stages, focus on relative clinical efficacy rather than cost-effectiveness.** At the same time, however, **we support further discussion of how cost-effectiveness comparisons might be introduced into the evaluation process at a later stage and used, at least in part, to influence benefit design by Medicare and other programs.**

Comparative Clinical Effectiveness Research and Shared Decision-Making

The greatest initial value of developed comparative effectiveness data at this time is to help answer the question of what works best for whom and the use of this information in providing effective patient-centered treat-

[6] Joint letter on SGR legislative options sent to key Congressional Committee staff delivered on May 17, 2007.

[7] Medical Payment Advisory Committee. Presentation by Gail Wilensky and Marilyn Moon on Comparative Effectiveness. April 12, 2007 Public Meeting. Access at http://www.medpac.gov/public_meetings/transcripts/0407_allcombined_transcript.pdf on May 9, 2007.

ment. Comparative effectiveness research from a trusted entity will enable physicians and patients to engage in informed and shared decision-making on the most desired and effective treatment alternatives for that individual patient. Such shared decision-making is a key element of the **Patient-Centered Medical Home (PCMH)**. This care model—supported by the 330,000 primary care physicians represented by the American Academy of Family Physicians, the American Academy of Pediatrics, the American Osteopathic Association and the American College of Physicians and a coalition of large employers and consumer organizations—would ensure that treatment decisions informed by comparative effective evidence will be delivered in a coordinated, integrated manner. The model also emphasizes the importance of actively making treatment decisions a shared process between the patient and their personal physician. Research using an active shared decision making process, using available comparative effectiveness evidence, indicates it has the potential to reduce unwarranted variations in treatment among providers, increase patient accuracy in expected treatment outcomes, and provide patients with greater comfort in the treatment choice made.[8]

Finally, the College urges the Subcommittee to report legislation to create Medicare payment incentives for physicians to acquire and use health information technology (HIT) in their practices as a means of facilitating the collection and reporting of clinical data on effectiveness and facilitating evidence-based clinical decision support and shared decision-making at the point of care. The availability of clinical decision support technology at the site of care will make evidence-based comparative research readily available to physicians and their patients to support shared clinical decision-making between the physician and the patient. The College specifically supports H.R. 1952, the National Health Information Incentives Act of 2007, introduced by Representatives Charles Gonzalez (D–TX) and Phil Gingrey, MD (R–GA) to provide financial incentives to physicians through Medicare to adopt and purchase HIT.

Summary and Conclusion

In summary, **the College strongly supports Congressional efforts to provide Medicare and all stakeholders within the healthcare community with improved access to information about the relative strengths and weaknesses of various clinical products, procedures and services.** Towards this goal, the College recommends that the Congress take efforts, including the allocation of secure and sustained funding, to create or support a trusted entity that systematically develops evidence on the relative effectiveness of various alternative healthcare services. That entity should have the following characteristics:

- it should be an unbiased independent entity protected from both governmental and private sector influence to encourage trust in its findings.
- its proceedings should be transparent.
- it should involve stakeholders, including payers, providers and beneficiaries, at all levels of the evidence development process.
- it should have a prioritization process, informed by input from the stakeholder groups, that ensures that the comparative effective evidence developed will have the greatest impact in improving the quality and efficiency of care provided.
- it should support the development of all levels of evidence including formal review and synthesis of evidence already available in the clinical literature and the initiation of new research in priority areas where such evidence does not already exist.
- it should have established processes that ensures that the comparative effectiveness findings developed are accessible in a comprehensive form to all stake holders.

- **The Congress should give consideration to continuing to support the work of the Agency for HealthCare Research and Quality as the "trusted entity" for comparative effectiveness research, with secure and sustained funding that is not subject to the political pressures often associated with the annual appropriations process.**
- **The College believes that the greatest value of developed comparative effectiveness data at this time is to help clinicians and patients answer**

[8] O'Connor, A. et al. Modifying unwarranted variations in health care: Shared dicision making using patient decision aids. Health Affairs Web Exclusive, October 7, 2004. Accessed at http://content.healthaffairs.org/cgi/reprint/hlthaff.var.63v1?maxtoshow=&HITS=10&hits=10&RESULTFORMAT=&author1=%27Connor&andorexactfulltext=and&searchid=1&FIRSTINDEX=0&resourcetype=HWCIT on May 7, 2007.

the question of what works best for each patient and for clinicians to partner with patients in an informed and shared decision-making process when considering alternative treatment options, a key element of the Patient-Centered Medical Home.

- **The College recognizes the potential savings obtainable through comparative effectiveness research, but recommends that Congress walk down the path of using comparative effectiveness data in the Medicare benefit design deliberatively so that more experience is gained first in the impact of such research and its credibility with clinicians and patients. As confidence and trust in the process increases, steps could then be taken by Congress to create a method for incorporating such comparative effectiveness research into benefit design issues.**
- **Congress should recognize that inclusion of "cost effectiveness" as an element of the comparative evaluation process will introduce complex and controversial issues of how individual patients, purchasers, clinicians, and society assign a relative value to clinical effectiveness and cost. Such value judgments need to be made in an open, transparent, and methodologically sound basis that takes into account the different value systems that each stakeholder brings to the table. For these reasons, the College suggests that federally-funded comparative effectiveness research should, at least in its early stages, focus on relative clinical efficacy rather than cost-effectiveness. At the same time, however, we support further discussion of how cost-effectiveness comparisons might be introduced into the evaluation process at a later stage and used, at least in part, to influence benefit design by Medicare and other programs.**
- **The College asks Congress to recognize the value that a more systemized approach to developing comparative effectiveness evidence can be leveraged through:**
  - **The establishment of mechanisms to facilitate the implementation of health information technology (HIT) throughout the system**
  - **The implementation of the Patient-Centered Medical Home (PCMH) care model.**

Chairman STARK. Thank you.

Ms. Shearer?

STATEMENT OF GAIL SHEARER, DIRECTOR, HEALTH POLICY ANALYSIS, CONSUMERS UNION

Ms. SHEARER. Mr. Chairman, Members of the Subcommittee, thank you very much for the invitation to testify today on strategies to increase research on the comparative clinical effectiveness of medical treatments. We believe that legislation on this issue is the single most important investment you can make to moderate runaway health care costs and pave the way for a health care system that better meets the needs of all Americans.

Getting better value for our health care dollars is an essential building block for health reform, regardless of stripe of reform. In so-called consumer-centric models that embrace health savings accounts, consumers need to know where their dollars are most effective.

In a system of predominately employer-based health coverage, employers have a strong financial incentive to learn how to achieve the best health outcomes at the lowest cost. In a universal health care system, whether through an individual mandate, public/private expansions of coverage, or even a Medicare-for-all type of model, the key to success will be getting the maximum value from each premium or tax dollar spent.

This is why we believe so strongly in the need for a Marshall Plan-like commitment, to transform our knowledge base about the comparative effectiveness of medical treatments to fill the gaps in clinical research. Armed with this knowledge, providers and consumers could identify and choose the best treatment options, and payors could fine-tune benefit packages and modify cost-sharing amounts to encourage the most cost-effective care.

Today I want to concentrate on one public education program that we have developed at Consumers Union that uses the best available scientific evidence to help consumers, with their health care professionals, choose the most effective, safest, and affordable drugs. I highlight this work because it provides a tangible example of the potential that expanded government-funded comparative effectiveness research holds for improving health care quality and lowering health care costs.

Consumer Reports' best buy drugs is based on systematic reviews, unbiased medical reviews of the clinical research on drug comparative effectiveness, safety, and side effects conducted by the Drug Effectiveness Review Project. DERP is a preeminent example of the pioneering lead that the States have taken with financial support from AHRQ's funding of evidence-based practice centers in the world of evidence-based medicine, specifically, the research that is necessary to enable states and other health care payors to shape benefit policy based on unbiased scientific evidence.

Our best buy drugs program translates DERP's complex medical reports into consumer-friendly reports that provide information the public needs to understand the comparative effectiveness, safety, side effects, and costs of drug options.

One of the reports is attached to my testimony today. It is on proton pump inhibitors, which are anti-heartburn medicines. We found that there is not a large difference between the effectiveness of many drugs in this category. The big story, though, is that there is a tenfold difference between the monthly price of a heavily advertised purple pill, Nexium, and the over-the-counter alternative, Prilosec OTC, that the best science shows it is equally effective and safe for almost all of us.

A month's supply of Nexium costs about $193, which a month's supply of Prilosec OTC costs about $19 to $26. Having said this, I want to stress that we always urge consumers to consult with their doctors, and we urge all health plans to have effective and easy-to-use exceptions policies for the small amount of people who may not respond as well to one of the best buy drugs.

In most categories that we have studied, and we have studied 17 now, we have found that by switching from a high-priced, typically highly advertised brand drug to a best buy drug alternative, consumers can typically save between $1,000 and $2,000 a year. Helping consumers and health plans substitute effective, safe, lower-cost medicines for the newest heavily advertised alternative can save the nation billions of dollars without sacrificing quality.

In fact, better information about comparative effectiveness can help us as a nation improve health care quality by educating consumers, physicians, pharmacists, and policy-makers about the comparative effectiveness of alternative treatments.

Educating the public about low-cost, effective alternatives can help make health care treatments and prescription drugs more affordable. This in turn will increase the number of patients who can get the treatment or drug that they need, and ultimately improve health outcomes.

Consumers Union believes that it is appropriate for the government to fully fund and sponsor this important research, which should be available to all and constitutes the epitome of a public good. The benefits will be shared by every one of us who uses health care in this country.

Mr. Chairman, Members of the Subcommittee, the rapidly rising cost of health care threatens the budgets of Federal and state governments, and ultimately of health care consumers. We believe that establishing a new program with sufficient reliable funding to assess the comparative effectiveness of alternative treatments is a necessary part of the solution to this growing problem.

Enacting this legislation is probably the most important thing that you can do in this Congress to save lives and money, and to build a foundation for further reforms of our health care system. Thank you.

[The prepared statement of Ms. Shearer follows:]

Prepared Statement of Gail Shearer, Director, Health Policy Analysis, Consumers Union

Mr. Chairman, Members of the Committee:

Thank you for the invitation to testify on strategies to increase information on comparative clinical effectiveness and H.R. 2184, The Enhanced Health Care Value for All Act. We believe that this legislation is the single most important investment you can make to moderate run-away health care costs and pave the way for a health care system that better meets the needs of all Americans.

Consumers Union [1] is the independent, non-profit publisher of *Consumer Reports*, with circulation of about 7 million (*Consumer Reports* plus ConsumerReports.org subscribers). We regularly poll our readership and the public about key consumer issues, and the high cost of health care consistently ranks among their top concerns.

I would like to commend the Committee for holding this hearing. Health care costs currently consume about 16 percent of our gross domestic product. This percent is projected to continue to grow at a rate substantially higher than general inflation. It is imperative that as a nation we learn how to get better value from every health care dollar that we spend. We must not continue to pay $5 for a pill when there is an equally effective and safe pill that is available for 50 cents.

Getting better value for our health care dollars is an essential building block for health reform, regardless of the "stripe" of reform. In so-called "consumer centric" models that embrace health savings accounts, consumers need to know where there dollars is most effective. In a system of predominantly employer-based health coverage, employers have a strong financial incentive to learn how to achieve the best health outcomes at the lowest cost. In a universal health care system (whether through individual mandate, public/private expansions of coverage, or even a Medicare-for-all model), the key to success will be in getting the maximum value from each premium or tax dollar spent.

This is why we believe so strongly in the need for a Marshall Plan-like commitment to transform our knowledge base about the comparative effectiveness of med-

[1] Consumers Union is a nonprofit membership organization chartered in 1936 under the laws of the state of New York to provide consumers with information, education and counsel about goods, services, health and personal finance, and to initiate and cooperate with individual and group efforts to maintain and enhance the quality of life for consumers. Consumers Union's income is solely derived from the sale of *Consumer Reports*, its other publications and from noncommercial contributions, grants and fees. In addition to reports on Consumers Union's own product testing, *Consumer Reports* and consumerreports.org with more than 7 million paid circulation, regularly carries articles on health, product safety, marketplace economics and legislative, judicial and regulatory actions which affect consumer welfare. Consumers Union's publications carry no advertising and receive no commercial support.

ical treatments to fill the gaps in the clinical research. Armed with this knowledge, providers and consumers could identify and choose the best treatment options, and payers could fine-tune benefit packages and modify cost-sharing amounts to encourage the most cost-effective care. A commitment to funding and increased reliance on evidence-based, unbiased clinical research and synthesis of existing research should be a leading-edge building block for health care reform. What does this mean for coverage? Some possible examples:

- There might be zero co-payments for diabetic care and other medical treatments that are clearly proven and necessary to improve health outcomes. (Some insurers are already experimenting with this approach to provide early care that greatly improves health outcomes.)
- There might be zero co-payments for certain generic drugs, and much steeper co-payments for the equivalent, higher-priced brand name drug where appropriate.

Our health care work on behalf of consumers is varied. Our advocates work to improve quality (e.g., our Stop Hospital Infections campaign to require public reporting of hospital acquired infection rates), to improve safety (e.g., our Prescription for Change campaign to reform drug safety laws), and improve affordability (e.g., our work since 1936 in support of affordable health care for all). *Consumer Reports, Consumer Reports on Health, Consumer Reports MedicalGuide.org,* and *consumerreports.org* provide comprehensive information about a range of health insurance products, health conditions, and treatments. In addition, Jim Guest, CU's President and CEO, serves as a member of the Institute of Medicine's Roundtable on Evidence-Based Medicine, which has been convened to "transform the way evidence on clinical effectiveness is generated and used to improve health and health care."[2]

But today I want to concentrate on one consumer program that we have developed that uses the best available scientific evidence to help consumers, with their health-care professional, choose the most effective, safest, and affordable drugs. I highlight this work, because it provides a tangible example of the potential that expanded government-funded comparative effectiveness research holds for both improving health care quality and lowering health care costs. *Consumer Reports Best Buy Drugs®*[3] is based on systematic reviews—unbiased medical reviews of the clinical research on drug comparative effectiveness, safety, and side effects—conducted by the Drug Effectiveness Review Project (DERP). DERP, based at the Center for Evidence Based Policy at Oregon Health and Science University, coordinates the preparation of the careful (and heavily peer-reviewed) reports that are written by various Evidence-based Practice Centers which receive support from the federal Agency for Healthcare Research and Quality (AHRQ). DERP is a preeminent example of the pioneering lead that the states have taken—with financial support through AHRQ's funding of Evidence-based Practice Centers—in the world of evidence-based medicine, specifically the research that is necessary to enable states and other health care payers to shape benefit policy based on unbiased scientific evidence.

Our *Best Buy Drugs* program translates DERP's complex medical reports into consumer-friendly reports that provide information the public needs to understand the comparative effectiveness, safety, side effects, and cost of drug options.[4] Thanks to grants from a private philanthropy, The Engelberg Foundation, and the National Library of Medicine, Consumers Union is able to provide this information free-of-charge to the public. This is important, since one of our key target audiences is low-income consumers who use multiple drugs—the very people who are most in need of unbiased, accurate information.

Attached to my testimony is a description of *Consumer Reports Best Buy Drugs®* and a sample of a 2-page summary for one class of drugs, proton pump inhibitors (anti-heartburn medicines). As you can see from the table, there is not a large difference between the effectiveness of the drugs in this category. The big story, though, is that there is a ten-fold difference between the monthly price of the heavily advertised "purple pill" Nexium and an over-the-counter alternative (Prilosec OTC) that the best science shows is equally effective and safe for almost all of us. A month's supply of Nexium costs about $193, while a month's supply of Prilosec

[2] Charter and Vision Statement, Institute of Medicine Roundtable on Evidence-Based Medicine, http://www.iom.edu/CMS/28312/RT-EBM/33544.aspx. See also: Institute of Medicine. 2007. *Learning What Works Best: The Nation's Need for Evidence on Comparative Effectiveness in Health Care.* http://www.iom.edu/ebm-effectiveness.

[3] Reports can be downloaded for free at www.CRBestBuyDrugs.org.

[4] For a more detailed description, see Steven D. Findlay, "Bringing The DERP to Consumers: 'Consumer Reports Best Buy Drugs'," *Health Affairs—Web Exclusive*, June 6, 2006.

OTC costs $19 to $26. Having said this, I want to stress that we always urge consumers to consult with their doctors, and we urge all health plans to have effective and easy-to-use exceptions policies for the small amount of people who may not respond as well to one of the *Best Buy Drugs*.

We have completed reports for 17 classes of drugs that millions of consumers need today, including: statins to lower cholesterol, the high-blood pressure and heart disease medicines (ACE inhibitors, calcium channel blockers, beta blockers), anti-depressants, antihistamines, menopause drugs, attention deficit and hyperactivity disorder (ADHD), insomnia, and many more. We are working in six states (Arizona, California, Georgia, Maryland, Minnesota, and Pennsylvania) on pilot outreach projects to bring this information to as many diverse populations as we can. We are working with doctors, pharmacists, senior networks, libraries, state officials, health insurance companies, PBMs—basically any entity that shares the goal of improving health care quality while lowering health care costs. Under our free, information-sharing agreement with Medco Health Solutions, for example, we are exposing millions of consumers to *Consumer Reports Best Buy Drugs*® information when they click through to our drug reports via Medco's Internet tool, My Rx Choices, which helps members identify effective, lower-cost drug options. We are working with Tarascon, a PDA software provider, to provide summaries of our reports on physicians' PDAs to help them at the point of prescribing.

Helping consumers—and health plans—substitute effective, safe, lower-cost medicines for the newest, heavily-advertised alternative can save the nation billions of dollars without sacrificing quality. In fact, better information about comparative effectiveness can help us as a nation improve health care quality by educating consumers, physicians, pharmacists, and policy makers about the comparative effectiveness of alternative treatments. Educating the public about low-cost, effective alternatives can help make health care treatments and prescription drugs more affordable, and this in turn will increase the number of patients who can get the treatment or drug that they need and ultimately improve health outcomes. The stakes are huge. The table below shows estimates of annual savings for select drug categories for consumers switching from a high priced brand to a Best Buy Drug:

Category of Drug	Potential Individual Annual Savings
Statins (to lower cholesterol)	$1,300
Proton Pump Inhibitor (for acid reflux, ulcers, heartburn)	$1,740
NSAIDs (arthritis and pain)	$2,200
Anti-depressants	$1,200
Beta Blockers (high blood pressure)	$1,900

We have estimated that Medicare beneficiaries who select *Best Buy Drugs* in five leading drug categories, when selecting their Medicare Part D plan, can save up to $5,000 a year.[5] Those switching in just one drug category can typically save more than enough to cover the cost of their Part D premium. Needless to say, on an aggregate level, the potential savings to the nation's health care payers (both taxpayers and private payers) can be counted in the billions of dollars. And the key to realizing these savings is the basic scientific research, the clinical studies that compare drugs' effectiveness, and the systematic reviews that allow for an unbiased assessment of all clinical research that has been done.

The inclusion of Section 1013 in the Medicare Modernization Act represented a turning point in health care in the United States, and we thank you for that section. By way of background, it is important to keep in mind the short history of the highly successful comparative effectiveness program. Congressman Allen, Congresswoman Emerson and this Committee were instrumental in getting this non-controversial but pioneering provision into the Medicare Modernization Act.

[5] "Medicare Prescription Drug Benefit: Beneficiaries Can Lower Out-of-Pocket Costs While Getting Safe and Effective Drugs," Consumers Union, March 2, 2006.

We are very pleased with the work done to date to implement Section 1013. AHRQ has already released to the public reports[6] that provide consumer-friendly, unbiased reports about the comparative effectiveness of various options for a number of conditions. However, this work has been funded at a low level ($15 million/year), far less than even the level of funding authorized by the legislation. The expectation to date has been that Section 1013 as implemented by AHRQ would fund systematic reviews rather than actual new clinical trials that assess the comparative effectiveness of treatment options. In order to fund new comparative clinical trials, a significant commitment of resources and leadership will be needed in order to carry out research that will fill the gaps in our knowledge about comparative effectiveness of existing and future medical treatments. It is important to keep in mind that comparative clinical trials are expensive, and can cost between $40 million and $150 million.[7]

Consumers Union has endorsed legislation by Representatives Allen and Emerson to create a $3 billion comparative effectiveness trust fund, by diverting a fraction of each health penny into the fund.[8] The fund would be used by AHRQ, with the advice of a new advisory panel, to fund the needed research. The bill insures the principles that any research must be independent, scientifically based, transparent and public, and include input from all stakeholders, and cover the full spectrum of health care treatments.

Consumers Union believes that it is appropriate for the government to fully fund and sponsor this important research, which should be available to all and constitutes the epitome of a public good. The benefits will be shared by every one of us who use health care in this country.

With regard to governance of any new comparative effectiveness research effort, we urge you to make sure that the research is conducted independent of all the groups whose products and procedures it compares. Far too many clinical trials and research papers funded by product sponsors have been found to be distorted and biased. Even the nation's finest medical journals have found themselves duped by bad data and distorted results.[9] We agree with the principles that have been developed by the Alliance for Better Health Care, a broad coalition of consumer, labor, health plans, research organizations and employers, that works in support of research on comparative clinical effectiveness and dissemination of the research.[10] We commend AHRQ for the superb job it has done to date implementing Section 1013, and we would urge you to build on the work AHRQ has done by expanding the model of systematic reviews it has tremendous success carrying out. We urge you to give careful thought, and draw on the advice of experts in organizational structures, to assure that the structure to successfully implement this large responsibility is solid and assures high quality, transparent, independent research and analysis.

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[6] They have produced consumer guides on pain for osteoarthritis, and a report on gastroesophageal reflux disease (GERD). Other reports (mostly for medical professions) are on cancer, diabetes, the digestive system, heart and blood vessels, brain and nerve conditions, and mental health. The reports are available to the public at http://effectivehealthcare.ahrq.gov.

[7] "The Clinical Antipsychotic Trials of Intervention Effectiveness (CATIE) cost $42.6 million; the Antihypertensive and Lipid-lowering Treatment to Prevent Heart Attacks trial (ALLHAT) cost $125 million; the Study of Tamoxifen and Raloxifene trial (STAR) cost $118 million." Footnote 14, page 7–6, *The Future of Drug Safety*, Institute of Medicine of the National Academies, September 22, 2006.

[8] The amount proposed, $3 billion over five years, represents about.24 percent of projected funding over five years of about $12.3 trillion.

[9] PLoS Medicine, May 2005, Vol. 2, Issue 5 e138, "Medical Journals are an Extension of the Marketing Arm of Pharmaceutical Companies," by Richard Smith.

[10] Key principles include the need for a significant and stable investment, consideration of the full spectrum of health care treatments, scientific integrity and independence, transparency in all processes, stakeholder involvement, and accountability of all conduct. *See* Letter from Alliance for Better Health Care to Congressman Allen and Congresswoman Emerson, May 14, 2007.

Mr. Chairman, Members of the Committee, the rapidly rising cost of health care threatens the budgets of federal and state governments, and ultimately, the health of consumers. We believe that establishing a new program—with sufficient, reliable funding—to assess the comparative effectiveness of alternative treatments is a necessary part of the solution to this growing problem. A fully funded, thorough comparative-effectiveness effort would be a wise and cost-effective investment. We commend you for giving this legislation serious attention. Enacting this legislation is probably the most important thing that you can do in this Congress to save lives and money, and to build a foundation for further reforms of our health care system.

Chairman STARK. Thank you.

Dr. Hearn?

STATEMENT OF SUSAN HEARN, Ph.D., SENIOR PROJECT MANAGER IN ENVIRONMENTAL HEALTH AND SAFETY, DOW CHEMICAL COMPANY, MIDLAND, MICHIGAN

Ms. HEARN. Mr. Chairman, Ranking Member Camp, and Members of the Subcommittee, Dow thanks the Subcommittee for holding this hearing to examine the benefits of expanding the availability of comparative effectiveness research. We, along with members of the broader business community, believe that improvements in quality and effectiveness of health care are absolutely essential in addressing the many challenges facing health care.

Comprehensive, timely generation, and effective dissemination of comparative effectiveness research is paramount in making progress. Most unfortunately, this is one of the most significant voids in information we face today.

Dow provides comprehensive health care benefits to over 110,000 employees, retirees, and their dependents in the United States. In total, we spent over $300 million on health benefits in the U.S. last year, which is equivalent to about 31 cents a share or 25 percent of what we spend on research and development.

When you factor in indirect hidden costs to productivity from chronic diseases like obesity, the economic impact multiplies by a factor of 2 or 3. Absenteeism and presenteeism play a big role in pushing our costs up to $700 million a year, or about 70 percent of our R&D budget.

For the money we spend and for the peace of mind of our employees and their families, we want to ensure that we are getting the best value in health care available. Today, that is not the case.

Medical errors are the eighth leading cause of death in the United States, costing billions of dollars a year, and inappropriate care represents up to 30 percent of medical expenses. Comparative effectiveness research may greatly improve health care quality and patient outcomes, ensuring that consumers receive the best care at the best value.

It is extremely important that patients and payors are assured the delivery of quality evidence-based health care. With adequate funding, comparative effectiveness research can provide information to enable physicians to make better decisions based on the scientific information elicited in evaluating various treatment options.

Consumers too need comparative information to make better informed choices about their health care. As consumers are encouraged to get more involved in management of their health care, and

as consumer-driven health plans become more prevalent, consumers will need to know which treatments are more effective in treating their particular condition.

Currently there are relatively few clinical effectiveness research studies conducted each year. An increase in funding this research could pay off substantially by reducing ineffective treatments, thus improving the quality of care, improving health outcomes, and saving significant health care dollars.

The Agency for Healthcare Research and Quality conducts such research through their Effective Health Care program to examine the effectiveness of alternative treatments, and this research is producing good results and valuable information to help improve outcomes. At the current funding levels, this research, however, is just scratching the surface. We encourage Congress to significantly increase the funding for comparative effectiveness research.

This research has the potential to improve health care delivery and ultimately benefit the health of all Americans by reducing inappropriate and ineffective care. Employers like Dow will ultimately benefit from the availability of high-quality effective treatment and the potential cost savings that are expected through a significant reduction in wasteful spending on less effective, ineffective, or inappropriate care.

Our employees will benefit through improved health outcomes, and the peace of mind knowing that they have good information to help make better health care decisions for themselves and their families. This will also benefit Dow by reducing the stress and anxiety that can often accompany a personal or family illness. This indirect contribution to our productivity, having our employees at the top of their game always, will help us achieve our vision of being the most profitable, most respected, and largest chemical company in the world.

At Dow we have a very clear health strategy which emphasizes prevention, quality and effectiveness of care, and health system management. We are strongly committed and very engaged at the local and national levels, working with many partners to drive improvements and achieve better health outcomes as well as an improved economic picture.

However, we can only do so much without the critical information provided by comparative effectiveness research. We urge you to significantly increase funding for comparative effectiveness research and continue to support this tremendously important program, and expand the good work of the Agency for Healthcare Research and Quality. Thank you.

[The prepared statement of Ms. Hearn follows:]

Prepared Statement of Susan Hearn, Ph.D.,
Senior Project Manager in Environment Health and Safety,
Dow Chemical Company, Midland, Michigan

Mr. Chairman and Members of the Subcommittee, I am Susan Hearn, Dr.P.H., Senior Project Manager in Environment, Health and Safety for The Dow Chemical Company. The Dow Chemical Company (Dow) thanks the Subcommittee for holding this hearing to examine the benefits of expanding the availability of comparative effectiveness research. We, along with the broader business community, believe that improvements in quality and effectiveness of health care are absolutely essential in addressing the many challenges facing health care. Comprehensive, timely generation and effective dissemination of Comparative Effectiveness Research (CER) is

paramount in making progress. Most unfortunately, this is one of the most significant voids in information we face today. In this light, funding for CER is viewed as a key investment in both improving the health of people and reigning in future health care costs. As you have heard from so many, we must as a nation find solutions to the affordability of health care or we will continue to be at risk in the global economy.

Dow provides comprehensive health care benefits to over 110,000 employees, retirees and their dependents in the United States. In total, we spent over $300 million on health benefits in the U.S. last year—which is equal to about 31 cents a share, or 25 percent of what we spend on Research and Development.

When you factor in the indirect, *hidden* costs to productivity from chronic diseases like obesity, the economic impact multiplies by a factor of two to three. Absenteeism and presenteeism play a big role in pushing our costs up to $700 million per year or about *70 percent* of our R&D budget. For the money we spend—and for the peace of mind of our employees and their families—we want to ensure that we are getting the best value in health care available . . . and today, that is not the case.

Medical errors are the eighth leading cause of death in U.S., costing billions of dollars each year, and inappropriate care comprises up to 30 percent of medical expenses.

Comparative effectiveness research (CER) may greatly improve health care quality and patient outcomes, ensuring that consumers receive the best care at the best value. It is extremely important that patients and payers are assured the delivery of quality, evidence-based health care. With adequate funding, comparative effectiveness research can provide information to enable physicians to make better decisions based on the scientific information elicited in evaluating various treatment options. Consumers, too, need comparative information to make better informed choices about their health care. As consumers are encouraged to get more involved in management of their health care and as consumer driven health plans become more prevalent, consumers will need to know which treatments are more effective in treating their particular condition.

Currently, under authority granted by Section 1013 of the Medicare Modernization Act (MMA), the Agency for Healthcare Research and Quality (AHRQ) conducts research to examine the comparative clinical effectiveness and appropriateness of different treatments, and the ways that those treatments can be provided in a more effective and efficient manner. Since FY2005, AHRQ has received $15 million per year as funding for CER. AHRQ has already released final reports on treatment options for breast cancer, gastroesophogeal reflux disease (GERD), cancer-related anemia, low-bone density, depression and other conditions.

The findings released by AHRQ have just begun to show the value of CER for patients, providers, and health care payers. However, there is much more that can be done and, under current levels of funding, AHRQ is very limited in the types and numbers of studies it can conduct. To remedy this, and to ensure this research contributes fully to improving care and saving significant federal dollars, we request that Congress act to increase its investment substantially.

As a member of the Alliance for Better Health Care (ABHC), Dow supports the principles developed for prioritizing, conducting, disseminating, and using CER.

- CER has the potential to benefit the health of all Americans and is a true public good.
- Significant and stable investment is needed in CER—in the development of research methods and researchers, the design and conduct of studies, the scientific review of research, and the dissemination and communication of results—for it to reach its full potential.
- The scope of CER should address the full spectrum of health care treatments, including pharmaceuticals, devices, medical and surgical procedures, and other interventions.
- Scientific integrity and independence are paramount.
- CER should be based on scientific evidence employing an array of appropriate methods, such as randomized clinical control trials, observational studies, meta-analyses, and systematic technology assessment reviews.
- The processes for identifying research priorities, conducting research, validating the science, and disseminating results should be transparent.
- Any entity that commissions or conducts CER should involve stakeholders in setting research priorities and disseminating research.
- Board governance should assure accountability in the conduct and dissemination of CER.

Comparative effectiveness research has the potential to improve health care delivery and ultimately benefit the health of all Americans by reducing inappropriate

and ineffective care. Employers like Dow will ultimately benefit from the availability of high-quality, effective treatment and the potential cost savings that are expected through a significant reduction in wasteful spending on less effective, ineffective or inappropriate care. Our employees will benefit through improved health outcomes and the peace of mind knowing that they have good information to help make better health care decisions for themselves and their families. This will also benefit Dow by reducing the stress and anxiety that can often accompany a personal or family illness. This indirect contribution to our productivity—having our employees at the top of their game always—will help us achieve our vision of being the largest, most profitable, most respected chemical company in the world.

At Dow we have a very clear health strategy which emphasizes prevention, quality and effectiveness of care and health system management. We are strongly committed and very engaged at the local and national levels working with many partners to drive improvements and achieve better health outcomes, as well as an improved economic picture. However, we can only do so much without the critical information provided by comparative and effectiveness research. Our senior physician was a member of the Clinical Research Roundtable chartered by the National Academies. This group, which concluded its work in 2004, made strong calls for expanded effectiveness research and clinical effectiveness research.

We urge you to significantly increase funding for comparative effectiveness research and continue to support this tremendously important program and expand the good work of AHRQ.

The research that would be produced by this effort will be invaluable to doctors, other health professionals, and patients, as they increasingly demand to know the benefits of various treatment options for their conditions. It promises to significantly improve quality and safety as we learn more about what medical interventions work, how well they work, and which ones do not work.

Thank you for the opportunity to share our views.

Chairman STARK. Thank you.

Dr. Teutsch?

STATEMENT OF STEVEN M. TEUTSCH, M.D., MPH, EXECUTIVE DIRECTOR, OUTCOMES RESEARCH AND MANAGEMENT, OFFICE OF EXTERNAL MEDICAL AND SCIENTIFIC AFFAIRS, MERCK AND CO., INC., WEST POINT, PENNSYLVANIA

Dr. TEUTSCH. Good afternoon, Mr. Chairman and Members of the Subcommittee. I am Dr. Steven Teutsch, Executive Director of the Outcomes Research Group in the Office of External Medical and Scientific Affairs at Merck. Thank you for the opportunity to discuss issues of comparative effectiveness in health care.

Merck supports a role for comparative effectiveness analysis. We understand the needs of payors, providers, and patients for better information on what works and for whom, and believe that comparative effectiveness is an important mechanism for producing that information.

We are collaborating with America's health insurance plans to develop a road map to provide guidance on how comparative effectiveness can be incorporated into coverage decisions, and have cosponsored a forum last fall with AHIP and Kaiser Permanente on the same topic.

Companies such as Merck have extensive experience in the methods for assessing effectiveness as well. There is a lot at stake in a greater national effort to conduct systematic comparative effectiveness of medical treatments. Consumers and patients want continued access to new, possibly life-saving medical interventions. Providers want the ability to practice the best medicine for their patients and to keep up with the latest information. Payors want

rapid diffusion of scientifically valid information about what works best, for whom, and in what circumstances. Innovative suppliers like Merck want continued incentives to develop and market those treatments.

Finally, while comparative effectiveness analysis generally produced analyses at the group or sub-population level, patients and physicians want to find the best treatment for each individual. It will be important to bring the individual and population sciences and perspectives together to optimize patient management.

The science of comparative effectiveness has come a tremendous way in recent years, and there is a consensus about many of the methods. There remain a number of legitimate concerns about the scope of comparative effectiveness, as well as some specific methods and policy considerations. Among those are whether economic analyses should be included, and if so, from whose perspective.

What level of scientific rigor is needed for each type of decision? How do we assure transparency of the scientific process? Which observational methods are sound, replicable, and transparent? How best to proceed when the available evidence is insufficient?

Despite the worries and reservations, I think it is fair to say that there is an emerging consensus among various system stakeholders on the shape and purpose of a larger national effort to conduct comparative effectiveness. This emerging consensus seems to be shaping up as follows.

Comparative effectiveness analysis should be guided by input from a broad array of public and private stakeholders. It should be applied to the full array of health care interventions, including diagnostics, procedures, and devices, as well as drugs.

Resources should target research for diseases or conditions that impose a high clinical and economic burden on the health care system and society, and where the information can lead to improvements in health and efficiencies in the health care system. The analyses should be scientifically sound, rigorous, predictable, replicable, transparent, and fair.

New stable sources of funding are needed to generate evidence, since much of what is needed does not exist. We also need to further develop the methods, assure that the results can be used by decisionmakers, and develop the human capital necessary to perform the work.

Comparative effectiveness analysis should be conducted by an entity independent of payors, including the government payors, and industry. The results should inform clinical guidelines for use by medical professionals, quality improvement, as well as by payors for coverage and reimbursement.

There are other points that Merck would like to emphasize. Results should be used equally by payors and others when the results are positive and when the results are negative. For example, where the outcome of an evaluation is positive, payors should commit to reasonable coverage and encourage appropriate use.

As payors use comparative effectiveness analysis to help assess the value of an intervention, they should consider the short and long-term value to patients. The purpose should not be to hinder access to new technologies, but to assure their appropriate use. Comparative effectiveness information cannot be static. It must re-

main current with the state or the science, and thus there must be timely processes to incorporate new evidence.

Merck supports actions that bring new resources to bear on this work in this country. We believe that, properly implemented, it has great potential to assure better decisionmaking and improved clinical management. The pharmaceutical industry has a great deal of experience in this area, and we believe that we have a vision of a better future based on an expanded role for evidence-based medicine in general and comparative effectiveness in particular.

I thank you for your time, and would be pleased to answer any questions.

[The prepared statement of Dr. Teutsch follows:]

Testimony of
Steven M. Teutsch, M.D., M.P.H.

Executive Director,
Outcomes Research
External Medical and Scientific Affairs
Merck & Co., Inc.

Before the House Ways and Means
Health Subcommittee
June 12, 2007

Concerning
Comparative Effectiveness

Mr. Chairman and members of the Subcommittee, my name is Dr. Steven Teutsch and I am the Executive Director of Outcomes Research in the Office of External and Scientific Affairs at Merck & Co., Inc. I thank you for the opportunity to discuss comparative effectiveness analysis in health care.

I would like to provide you with a bit of background about me relative to this topic. At Merck, I am responsible for developing information to support the decision making of medical professional and payers. Part of the work involves applying comparative effectiveness methods to medical interventions using existing evidence.

My professional activities include work as a consultant to the U.S. Preventive Services Task Force and I am a founder of the Task Force on Community Preventive Services, which develops evidence-based recommendations on prevention. I also serve as a member of the HHS Personalized Health Care Work Group of the American Health Information Community (AHIC), a member of HHS Secretary's Advisory Committee on Genetics, Health and Society; and a member of the CDC's Evaluation of Genomic Applications in Practice and Prevention Working Group.

I have also done a good deal of research on the cost-effectiveness of disease treatment and prevention. Prior to joining Merck, I was the Director of the Division of Prevention Research and Analytic Methods at the CDC where I was responsible for developing CDC's capacity on economic evaluation and evidence-based practices.

Merck and Comparative Effectiveness

Merck has thought a great deal about the possibilities and implications of comparative effectiveness analysis as applied to the U.S. health care system. In fact, we have a long track record on issue.

For example, four years ago, we co-sponsored a forum on evidence based medicine and comparative effectiveness with the AARP. More recently, in November 2006, we cosponsored with America's Health Insurance Plans (AHIP) and Kaiser Permanente a Health Industry Forum meeting on the topic of comparative effectiveness. The session included thought leaders on the topic as well as full range of stakeholders. Also, Merck is working closely with AHIP to develop guidance on how evidence on comparative effectiveness can be used by payers for coverage decisions. My colleagues at Merck and I have written a number of articles on this topic.

Overall, Merck believes there is an important role for comparative effectiveness analysis in the U.S. health care system. Clinicians and patients are looking for up-to-date information about the best possible treatments and alternatives for individuals. We also understand and appreciate that payers are looking for better ways to determine value and create efficiency; valid comparative effectiveness analysis is a key component to achieving those goals. As Congress considers a new national comparative effectiveness effort we want to emphasize some characteristics that will be important for success.

Necessary Characteristics of the National Comparative Effectiveness Effort

Merck recommends that the Congress consider the following characteristics in expanding our national commitment to comparative effectiveness research:

- Any comparative effectiveness process should be scientifically sound, rigorous, predictable, replicable, transparent, and fair.

- The full range of health care interventions should be potential subjects of comparative effectiveness review – diagnostics, procedures, devices, as well as drugs. More recent thinking has posited that plan benefit design is a worthy subject for comparative effectiveness analysis. There is no sound policy or scientific rationale for limiting the analysis to one type of medical intervention.

- Comparative effectiveness work should focus foremost on diseases and conditions that impose a high clinical and economic burden on the health care system and society at the individual and/or population level and those technologies that provide the greatest opportunity for health and health care system improvement. Analysis should not primarily focus on a limited set of perceived high-cost interventions.

- Comparative effectiveness analysis should be guided by the input and counsel of a broad array of public and private stakeholders constituted for this purpose. In other words, a federal agency that only takes public comment on its research agenda is likely not sufficient to build confidence and support. Rather, what is needed is an independent organization whose agenda is more directly guided by the consensus of stakeholders.

- Entities conducting comparative effectiveness analysis should not make coverage or reimbursement decisions for payers. The new information will be used by the variety of payers in the U.S. system to make their own, independent coverage and reimbursement decisions.

- New, stable sources of funding are needed to generate comparative effectiveness evidence since much of what is needed does not exist. There is also a need to further develop the methods, assure that results can be used by decision makers, and develop the human capital necessary to conduct this work.

- Comparative effectiveness analysis should be conducted by an entity independent of payers (including the government payers), regulators, and industry; the analyses should be used to inform clinical guidelines for use by medical professionals for treatment, as well as by payers for coverage and reimbursement.

- Comparative effectiveness information cannot be static. It must remain current with the state of the science to inform interventions based on the best available information. Thus, we need to have timely processes to incorporate new evidence.

- Comparative effectiveness should be applied and adhered to in a uniform and consistent manner. For example, where the outcome of an evaluation is positive, payers, should commit to appropriate funding and encourage appropriate utilization.

- The purpose of comparative effectiveness should not be to hinder access to new technologies, but to assure their appropriate use.

- As payers use comparative effectiveness analysis to help assess the value of an intervention, they should consider the short and long term value to patients and the value to the larger system

- Comparative effectiveness must be able to value incremental advances in medical technology. Not all advances are 'blockbuster' in nature but have value for some patients and for the system overall as science advances and innovates.

Stakeholder Concerns

We believe these characteristics are important because there is a great deal at stake for patients, clinicians, suppliers, and society overall if comparative effectiveness is not done well. Failure to incorporate these characteristics will, in the long term, undermine our national investment in such work.

- Consumers and patients have concerns about continued access to new, possibly life saving, medical interventions,
- Consumers and patients are concerned that comparative effectiveness will reduce treatment options and choices.
- Providers have concerns about their continued ability to practice the best medicine for their individual patients.
- Providers are also concerned about their ability to keep abreast of the latest information and that the information is scientifically valid.
- Payers want rapid diffusion of scientifically valid information about what works best, for whom and in which circumstances,
- Innovative suppliers like Merck want continued incentives to develop and market innovative treatments even when those treatments represent incremental medical advances because those incremental advances may be on a path to substantial scientific advancement.

It is important to note that, while patients and clinicians want to find the best the treatment for each individual, comparative effectiveness analysis is generally conducted at the group or subpopulation level -- averages and means -- rather than at the individual level. It will be important to bring the individual and population sciences and perspectives together to optimize patient care. This is particularly true as we head into an era of highly individualized treatments and interventions using biomarkers and other diagnostic tools to identify the optimal treatments for individuals based on their conditions and genetic make-up. These types of interventions may not lend themselves

readily to the type of comparative effectiveness analysis we tend to think of today. We need to keep these new individualized technologies in mind as we build a national capacity for comparative effectiveness research.

Stakeholder guidance for the national comparative effectiveness research effort would help allay these concerns and help ensure that the process and system is transparent and responsive to the variety of needs, concerns and perspectives in our health care system today.

Strong stakeholder input and guidance into a national effort at comparative effectiveness is also important to forge a dynamic consensus on basic scientific and methodologic issues. Even though the science of comparative effectiveness has advanced considerably in recent years and there is a consensus about strong methodologic approaches to some of the central issues, there remain a number of legitimate concerns about the scope of comparative effectiveness as well as some specific methodologic challenges and policy considerations.

Some of these outstanding issues that would benefit from the consensus of stakeholders include:

- whether economic analyses should be included and, if so, from whose perspective;
- what level of evidence (scientific rigor) is needed for which type of decision;
- how to assure transparency of the scientific process;
- which methodologies, and particularly which observational methods, are sound, replicable, and transparent;
- how best to proceed when the available evidence is variable, non-existent, or insufficient; and
- how to find the right balance between the privacy and transparency when proprietary data could be useful to the comparative effectiveness analysis.

I'd like to take a brief moment to discuss further the last point above – the need for and use of proprietary data. There may be times when companies would like to provide data that could be useful or relevant to the research question at hand. However, if those data are proprietary, companies would typically need some protection from public disclosure in order to be comfortable providing that data. On the other hand, there is the very real need for transparency in analysis and results, and it may be difficult to say that a result was based on data that the public cannot access. These are very important issues that are best addressed by applying the criteria and principles I discussed earlier. If stakeholders do not trust the process, the effort will be of little use in the health care system.

Conclusion

Merck supports action to bring new resources to bear on comparative effectiveness work in this country. We believe that, properly designed and implemented, it has great potential to assure better decision making and improved clinical management. Key features of a new initiative would be analysis conducted by, or under the aegis of, an

independent entity guided by the variety health care stakeholders where the comparative effectiveness analysis is used by clinicians and patients, and informs the separate coverage and reimbursement decisions of payers.

The pharmaceutical industry has a great deal of experience in this area and we share a vision of a better health care future based on an expanded role for evidence-based medicine in general and comparative effectiveness in particular. We would like to work with you as you develop your legislative approach to this important issue.

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Chairman STARK. Well, thank you all. I guess, first of all, Dr. Teutsch, you are a member in good standing of PhRMA? You haven't been kicked out?

Dr. TEUTSCH. Yes. The company is definitely a member.

Chairman STARK. Dr. Hearn, you are a member in good standing of the National Association of Manufacturers? You haven't been thrown out?

Ms. HEARN. Right.

Chairman STARK. You are not going to lose your 501 status, I gather. Everyone is in good shape here. The questions, it seems to me, are that we should proceed with outcomes research or effectiveness research. There is a question of who, where, what. Gail gave us four choices in hers. But what entity does this?

The question of who pays for it, and I think that we get unanimity that everybody doesin some manner the taxpayers, and in some manner stakeholdersmaybe the docs have to kick in through the AMA; I don't knowbut that everybody pays some portion of the cost of maintaining this, and that the world has free accessand I

guess I am asking this of any of you; I will get aroundto the information. I can think of no reason other than to protect some personal identities that this information shouldn't be publicly available to researchers or companies or consumers or anybody that wants to use it.

So, I guess the next question is: How do we get started? How do I sell my colleagues on both sides of the aisle that we should proceed with this?

Let me start with Gail. You suggested, I think, most prominently as a model, if not the place to start, would be AHRQ. Is that a fair assessment?

Ms. WILENSKY. I believe the better strategy is to have what is called a federally funded research and development center attached to AHRQ. So, it would have the close linkage to AHRQ is very important. I would like just a little distance to try to make sure the objectivity and credibility is conferred.

Chairman STARK. I guess I would just ask if there are any of the witnesses who would have an objection to at least starting down this road. You are familiar, Dr. Teutsch, with some of the Federal bureaucracy and the health bureaucracy.

Dr. TEUTSCH. Yes. I spent 21 years at CDC, and I had the pleasure of working closely with AHRQ on a lot of its evidence-based development projects. They provide an incredible leadership.

We believe that there really should be some public/private partnership to make it work. Gail obviously has given us an example of what such a model might look like. We believe that there needs to be a structure that does that, but that there is also a group of stakeholders, as part of the leadership, that can guide the process to make sure it meets the needs of the users and all those who have important stakes in that information.

Chairman STARK. somebody suggested a Federal Reserve-like entity. But I am just thinking, as legislators, for us to create a Federal Reserve, the first problem would be finding a suitable site on the Mall. We would be competing with every former president for memorials there. That may be somewhat more ambitious.

But I am not so sure that a Federal Reserve-like structure attached to AHRQ isI guess it is one thing to say, how do we start? It would be wasteful, as far as I am concerned, to spend two or 3 years getting some kind of a commission to decide where are we going to start this entity. My instinct would be to say, start it with AHRQ and have some kind of a sunset three or four years out to see how they are progressing, and then legislators could make a change if it wasn't working.

Would there be anybody on the panel that would be uncomfortable with that sort of a procedure?

Ms. WILENSKY. The only hesitation and the answer is no. But as a temporary measure, if this grows to be the size that I think it needs to be, which is a couple billion dollars when we are spending $2 trillion on health care, that kind of a size would totally overwhelm AHRQ. AHRQ would become the Center for Comparative Clinical Effectiveness Analysis.

AHRQ is the only place where any health services research gets done. There are so many other questions that once this is started, I think it needs to be in a slightly removed place.

This is a discussion I have had with Carolyn Clancy on several occasions, and my understanding is she is quite comfortable with this not quite an AHRQ but directly linked to AHRQ because you want to make sure that there as I a close working relationship.

Chairman STARK. But using AHRQ as a model, with some additions.

Ms. WILENSKY. Right.

Chairman STARK. Dr. Teutsch, you mentioned something about the idea, and I am not so sure that we could sell that, as I that there be some requirement that where there is a savings, either an improvement in health or a cost savings to stakeholders, that it be required.

I am afraid, if that is what I understood your testimony to be, that we ought to have a mechanism for saying if something appears as Consumers Union might show us, that it saves us, as individuals, a lot of money.

I am not sure we could get much further than that, and I would be troubled by saying we would do anything except require that the information be put out there, and that the stakeholders, whomever they may be, use it as they choose without any mandates from us. I don't think politically that wouldbut maybe I misunderstood what you were saying.

Dr. TEUTSCH. Well, we are certainly not talking about mandates ensconced in legislation. But this is a partnership for which we all have to contribute in order to reach that common good of getting appropriate care to patients and getting the value for our health care dollar. That is going to require a commitment to a common goal on all parts so that we then develop the kind of quality improvement and reimbursement all parties align to try and deliver that value.

What we are talking about here is understanding where that value will be and providing that information. But we believe all stakeholders have to have a common commitment to that common goal.

Chairman STARK. I like the idea of a commitment, like a pledge of allegiance. But that is okay. But to memorialize it in legislation would trouble me some because as good a job as you may do, with something for my kids, if you don't get rid of the bubble gum flavor, they ain't ever going to buy a Merck product, I can tell you, regardless of what the commission would say they should do. So, there are some levels at which you may never get the consumers to march in lockstep.

Well, I guess I would just as soon give Dave Camp a chance to try and defeat what seems to be a unanimous recommendation here.

Mr. CAMP. No. I actually liked what I have been hearing.

Chairman STARK. Good.

Mr. CAMP. Thank you, Mr. Chairman. I think there is a lot of bipartisan support on this entire concept in the way to move forward. I think it has been a good hearing. So, thank you for having it.

I notice, Dr. Wilensky, in your testimony you mentioned that the political vulnerability of the center is probably the most critical

issue. Dr. Mark Miller earlier said if it is connected to a Federal agency, they won't deliver any bad news, this center.

I notice you have got a model where there is a tie to AHRQ, but somewhat independent. How do you think we best avoid this problem of the difficult issues? This will be very controversial information, I think, at times; obviously, very helpful at times as well.

Ms. WILENSKY. Right. There is no perfect placement. So, I want people to understand that. Everything is involving a tradeoff between credibility and independence, objectivity.

The removal of being exactly a part of AHRQ, although the legislation could describe how the information is able to be released to the publicI mean, that is something legislation could do I was more concerned. I have spoken to a number of groups, industry but academic health centers or individuals on the right and left of the political spectrum. The sense I had is having this function directly in government AHRQ, NIH, new agency left a lot of people feeling very uncomfortable. It was too close to government.

That was why, to me, having the FFRDC linked to AHRQ was appealing because on the other hand, you want to make sure you have accountability. I mean, there are a lot of ways to remove it from government. You could put it attached to the Institute of Medicine, which I think is another option. You could have it ms freestanding.

But if there is going to be a lot of public money here, I have heard from Members and congressional staff that there is in having make sure that there is a real accountability. That is why the notion of having it linked to AHRQ was so appealing as the best tradeoff, close but not too close, to government.

That seemed to strike the bell, so that I have moved forward in the last 6 months in my thinking of being more specific that I believe that is the best tradeoff. But I would certainly not object to other kinds of tradeoffs.

Mr. CAMP. Yes. Well, it is a good suggestion. You view a board similar to a MedPAC board, with a variety——

Ms. WILENSKY. Absolutely.

Mr. CAMP [continuing]. Of members that oversee this organization?

Ms. WILENSKY. You need to have all the stakeholders governing what goes onindustry, academia, patient advocates. The consumers have to be involved. If they are not there, they are going to be lobbing grenades from the outside.

So, the need to be on the governing board as to how decisionmakinghow priorities are set; making sure the information is fair and credible. Practicing physicians in addition to the academic medical Committee have to be represented. Everybody is going to be affected by this.

Mr. CAMP. I appreciate that. I wondered if anyone would like to comment. First of all, I want to thank you all for your testimony. It is very helpful.

I notice, Ms. Shearer, this best buy drugs program really looks at the presence of a single disease. Many people, particularly seniors, have multiple chronic illnesses and take multiple prescription drugs. It is really that dynamic that I think we have to be concerned about as we move ahead. My concern is if you look at the

best buy for a particular drug, it may not relate with the entire health regimen an individual is on. Can you comment on that?

Ms. SHEARER. Yes. That is a very, very important point. That really goes to the heart of why each of our reports says that recommends that the patient talk with their doctor. Each of the systematic reviews that form the basis of our analyses do look at comorbidities, and we do try to include that information. If a person has various conditions, there may be a different recommendation.

So, to the extent possible, we try to address that in our reports. But we always say that this is not about consumers picking their medicine, but they should talk with their health care provider.

Mr. CAMP. Last, Dr. Wilensky, you are viewing this organization has the bulk of its funding from government sources, but that there would be a significant private sector component to this as well. How do you see that?

Ms. WILENSKY. There are two ways to do that. The law allows for up to 30 percent of the funding to come from the private sector. It is frequent that these FFRDCs and there is a good description, I think, in MedPAC, and also the Institute of Medicine has a very good description of some existing FFRDCs. So, you can look at what is out there. How long. How big.

It could be through voluntary contributions. We have some very large foundations that are interested in this type of work, the Robert Wood Foundation. But also, several of the insurance companies when they have converted to for-profit status have set aside. These large foundations, they are all expressing an interest.

So, one possibility is to have that. Another is to have just a direct assessment. Then you could decide, does that really count for being private? Or if it is a direct assessment, is that public? I don't know what the legal ruling would be.

It is the flexibility, and particularly in the startup, but even ultimately having some private sector dollars in there to make people feel like they are directly a part of the process. But of course, you need to make sure there are a lot of rules in place so that you can't have that influence what goes on in terms of the studies.

But of course, that happens with FDA all the time. PhRMA companies do the trials or fund the trials. They just have to be subject to auditable results. They have to follow the rules or the results aren't acceptable to the FDA review process. So, we think there are some models as to how that part of it could work.

Mr. CAMP. All right. Thank you. Thank you, Mr. Chairman.

Chairman STARK. Mr. Johnson?

Mr. JOHNSON. Thank you, Mr. Chairman.

Dr. TEUTSCH. how do you ensure that comparative effectiveness research is not misused in ways to discourage medical advances, and how do we make sure that the research supports the quest for an implementation of new breakthrough therapies?

Dr. TEUTSCH. That would be a concern, of course, that a manufacturer would be likely to have, too. But we believe in the medications and the innovation that industry delivers. We believe that by developing products that provide real value, making sure that value is clearly understood, and then that we have the processes to help translate that so that the right patients get them at the

right time, are all ways to assure that that innovation is adequately rewarded.

So, we actually see this as very much part of the solution to stimulate innovation, and even personalized health care, as we go forward.

Mr. JOHNSON. So, the doctor combines it?

Dr. TEUTSCH. Well, doctors do need that information, and Dr. Dale can talk about it. It is very difficult to keep up with all the current information that is available out there. You heard earlier that there is a wide variation in care. What we want is not homogeneity of care. We want to have doctors with the right information to deliver the best information to patients.

When we talk about comparative effect issues, it doesn't mean one size fits all. It means understanding the tradeoffs among these different innovations to where they fit most appropriately into care, and how we take advantage of the diagnostic products and other kinds of information so doctors can make better decisions.

This feeds into the systems of decision support that will allow doctors to have the information that they need so that they can have the information that is scientific, but then weigh it, along with the uncertainties and the preferences and the values that the patients, the communities, and the profession holds to make better decisions.

Mr. JOHNSON. Thank you, sir. Thank you, Mr. Chairman.

Chairman STARK. Let me try one more, if I can try the patience of the panel.

In trying to legislate, trying to create this $2 billion giant whichI mean, I am trying to think of how you ease into this and can establish a protocol. For example, Dr. Dale, I don't think we could start right away with surgical procedures because I think you have got to wait 5 years or so to find out, not that you lived through the operation but how is your life five years later, to really study the effectiveness.

That gets me to the point thatand I don't mean to pick, Dr. Teutsch, on your industry, but we do have an awful lot of information about pharmaceuticals already, starting from the genesis at FDA. Zocor is the same Zocor in California as it is in Michigan as it is in Maine. So, we are not talking about differentthey may use it differently in different parts of the country.

But what if we started with that areaadmittedly, physicians would be involved because some physicians would administer the pharmaceuticals differentlyand then proceed, maybe take up the vices or physician practices, as we get the ability to collect the information.

Would there be any down side in that, just as a way to begin? Dr. Teutsch, could Merck live with that?

Dr. TEUTSCH. I think that that actually creates some issues. The reason is, the pharmaceutical side is a but like looking under the lamppost because we do have good information.

In fact, the real paucity of information tends to be on the utility of diagnostic devices and procedures. That is where some 90 percent of the cost is. So, it is going to be important to look at those technologies and help drive the generation of that information.

So, we do need to look broadly, and in fact not look where the information is best, but actually try to figure out where there is a paucity of information where decisions are sub-optimal because of the lack thereof.

Chairman STARK. Dr. Dale?

Dr. DALE. Well, I will just comment. I think there is room for good work in all those areas. For instance, in the follow-up on surgical patients, having an adequate record system to know what the long-term consequences are. For instance, in our country now with the rampant use of obesity surgery, what happens? For the next patient, how do you describe what is likely to happen to that person?

So, I think there is room in surgery and in devices. But I would also say in terms of the long-term use of drugs as well. Many side effects are not recognized in the early phase of clinical trials when it is clear that there is an effect. But the long-term consequences of use need to be better studied.

Ms. WILENSKY. I think if you want to affect spending, you really have to move away from just the drug focus. That is just 10 cents of the dollar. A study that was recently reported

Chairman STARK. I didn't imply that we wouldn't do it all. I am just saying at some point you have got to start.

Ms. WILENSKY. But I think if you think about a staggered research agenda, where you want to have some early wins because you want to make sure to everyone it is clear why this is good investment.

But looking at areas that either high cost or high volume, we could look at a couple of the major DRGs as to where are we spending our money, where there are significant differences about how you could go at delivering the care. There are a lot of dollars attached.

A recent study that was released that looked at the whole issue of stenting versus angioplasty versus conservative treatment of medicine versus bypass surgery indicated the kinds of questions that are still out there. It is only the first look at a broad-based set of questions in cardiovascular disease.

But cardiovascular disease, orthopedic surgeryI mean, these are areas where there is a lot of money and a lot of uncertainty in variation trying to inform who actually gains. Because the answer is almost always going to be for some people these aggressive interventions are really important.

The question is, what about the other groups? What can we say about how to help them that may result in a lot of reduced spending because they don't need such aggressive treatment? It is the binary all-or-nothing thinking that tends to get us in trouble.

If it is really important for one small subgroup of the population, does that mean it is useful for everybody that might have something that looks related? That is the kind of work that we have got to get started on or we will never be able to get Peter Orszag's money scored.

Chairman STARK. Is there anyone else who would like to comment before you go to lunch?

Ms. SHEARER. Well, I would just like to make one point. I think that Mr. Orszag gave us a very cautious read on potential savings.

I think it is important for the Committee to keep in mind that the drug effectiveness review product is already yielding huge savings on behalf of states that use that information for their Medicaid programs.

So, I think that there is tremendous potential. I think that it could be realized sooner than he may have thought in his cautious analysis.

Chairman STARK. Well, in the absence of any of the witnesses that would like to add any more comment to the record, I would ask Mr. Camp if we can keep the record open so that Dr. Clancy and others could respond to written questions by Members. You may find in the coming days that Members will send some of you written requests, which we would hope you might be willing to respond to for the record.

I want to thank you for your patience and your contribution to this very much. Thank you very much. The hearing is adjourned.

[Whereupon, at 12:44 p.m., the hearing was adjourned.]

[Submissions for the Record Follow:]

Statement of Advanced Medical Technology Association

We thank the Committee for holding this important hearing today on strategies to increase information on comparative clinical effectiveness.

AdvaMed is the largest medical technology trade association in the world. AdvaMed member companies produce the medical devices, diagnostic products and health information systems that are transforming health care through earlier disease detection, less invasive procedures and more effective treatments. Our members produce nearly 90 percent of the health care technology purchased annually in the United States and more than 50 percent purchased annually around the world. AdvaMed members range from the largest to the smallest medical technology innovators and companies. The medical technology industry directly employs approximately 350,000 workers in the U.S.

The Important Role of Research to Guide Clinical Decision-Making

AdvaMed is strongly committed to the principles of evidence-based medicine and we support comparative effectiveness research as a means to improve clinical outcomes and promote access to quality of care. Sound comparative effectiveness research can be used to assist patients and physicians in medical decision-making by identifying the relative advantages and disadvantages of alternative means to prevent, diagnose and treat disease.

For any government-funded comparative effectiveness research initiative, we believe that the following principles should be applied to ensure that comparative effectiveness research is carried out appropriately:

- *Patient-centered care and independent professional medical judgment*. Comparative effectiveness research should inform medical decisions, not replace medical judgment with national treatment formulas. Its objective should be to provide better evidence for physicians and patients to use in making individual clinical decisions for each patient's. unique condition.
- *Protecting patient access.* Comparative effectiveness research typically analyzes which medical intervention, **on average**, is usually more effective across a population. The intervention that is "generally best," however, may not be best for each individual patient. A determination of what may be more effective on average may not account for the age or sex of a patient. It wouldn't consider what is most effective under the presence of comorbidities or special patient care needs. Therefore, the entity should neither make recommendations nor decisions about coverage. In addition, comparative effectiveness research should not be used by Medicare, insurance companies, or other payers to deny coverage. Patients should maintain access to treatment options based on their needs and preferences, including the desire to receive

an intervention that may be determined to be on average less effective, but may be less painful or provide for shorter recovery times for the patient.

- *Setting priorities*. The comparative effectiveness research agenda must be prioritized and designed with pre-stated objectives, research questions, and stakeholder input. It should focus resources on areas that have major clinical significance and will have the greatest return on investment. The agenda development process must be open and include practicing physicians, patients, manufacturers, and other stakeholders.
- *Robust databases and analysis.* It is critical that effectiveness be evaluated over a period of time that is appropriate for the specific intervention being evaluated. Studies should be based on the time period over which all relevant benefits and other factors accrue, not set arbitrarily—at 30 or 60 days, or 1 year. In addition, any database that is used to assess the effectiveness of an intervention must include robust data on that particular intervention.

Using Clinical Information to Improve the Quality of Care and Efficiency of the Health Care System

- AdvaMed strongly supports using clinical information that exists or could be derived from comparative effectiveness research to improve patient care and reduce waste and unnecessary costs in the health care system. Improvements could include:
  - Advances in the quality of care provided, including the appropriate use of preventive, screening and diagnostic services and reduction in medical/medication errors;
  - Changes in clinical processes that eliminate practices that are not beneficial, as determined by a consensus of the peer-reviewed literature or by the relevant medical specialty societies; and
  - Improvements in administrative or health care delivery processes, such as through the use of information technology or the reduction of unnecessary emergency room use.

For example, for more than a decade medical researchers have known that people on ventilators should generally have their heads elevated. When the patients are lying down, bacteria can easily travel from the stomach, up to the mouth and breathing tube, and ultimately into the lungs, causing pneumonia. When people are propped up, gravity becomes their ally, but hospitals have had a hard time translating this scientific knowledge into better medical care. Patients frequently need to be put on their backs, to be bathed or to receive treatment, and once they are lying down, doctors and nurses, who are busy worrying about dozens of other things, don't always remember to move the bed back up. The solution is to set up a rule that every patient on a ventilator had to be sitting up. Making common-sense practice pattern changes such as these to reduce infections in the intensive care unit do not involve cutting-edge science, but can make a big difference, cutting the incidence of ventilator-associated pneumonia by more than 40 percent in some hospitals. It can be the difference between life and death for some patients.

We think there are potentially great opportunities for both quality improvement and cost savings in these types of health system changes. As a result, we believe that a government-funded comparative effectiveness research initiative should include this type of research involving health system changes that affect the management and delivery of health care items, services, and procedures.

Appropriate Uses of Comparative Effectiveness Research

Comparative effectiveness research should be used to inform medical decisions, not replace medical judgment with national treatment formulas. We recommend:

- *Studying clinical effectiveness only.* Patients should have access to the interventions that are best for them. Consequently, comparative effectiveness research should study clinical effectiveness only, with the goal to inform medical decision-making. As a result, quality of care and overall efficiency in the health care system should improve.
- *Recognizing the process of medical device innovation.* Medical device innovation is evolutionary, and the effectiveness of a particular product is dependent on the training, experience, and skill of health care professionals. Since many devices are a component of a medical procedure, introduction of a new product may require that physicians develop new skills. For example, the introduction of percutaneous transluminal cardiac angioplasty (PTCA) during the 1980s offered an alternative to cardiac bypass surgery but physicians needed additional training in order to perform the procedure. The existence of a "learning

curve" can be an important constraint on the speed of introduction of a new medical procedure.

As physicians gain experience with the device, they may be better able to identify patients who are suitable—or not—for the therapy. They learn how to recognize subtle anatomical differences that influence how best to perform the procedure. Experience also helps the clinician learn to tailor after care for the needs of a particular patient. A case in point is bariatric surgery for weight loss. Clinical practice guidelines recommend a training program involving at least 10 open procedures or 25 laparoscopic procedures performed under the supervision of a qualified proctor. The development of this training, experience and skill can have a major impact on patient outcomes.

Furthermore, research that is conducted too early may quickly become dated, and a snapshot of a particular device at a specific time may incorrectly state its relative effectiveness. Accordingly, studies on the comparative effectiveness of devices should consider the effect of training and experience upon outcomes, should be applicable to the current generation of technology, and should only be conducted when the technology has an experience base and is widely available and mature. Likewise, those using the studies should recognize these challenges and limitations.

- *Transparency and stakeholder input.* Comparative effectiveness research must be developed and conducted in an open and transparent fashion that incorporates stakeholder input. This must include all aspects of research to enhance the credibility of its conclusions, including the determination of research priorities, the research methodology, and opportunity to comment on the proposed findings through a formal peer review process. Stakeholders should include patients, physicians, hospitals, and experts from the medical device and diagnostics industry. Governance of any public-private entity should include representation of all stakeholders.
- *Defining quality and benefit appropriately.* Comparative effectiveness research should be both comprehensive and tailored to the specific intervention being evaluated. For example, because diagnostics are used to inform clinical decision-making, such technologies should be evaluated based on their impact on patient care management. Comparative effectiveness research should consider the influence of health-related quality of life (including disability reduction, functional status, reduction in pain, and overall patient satisfaction); work loss and productivity loss; patient adherence; patient preferences and lifestyle choices; symptom control; reduction in medical/medication errors and enhancement of patient and healthcare worker safety; and estimated long-term outcomes (which may result long after a clinical trial has ended).
- *Supporting personalized medicine.* For personalized medicine to flourish, comparative effectiveness research findings should be used as a reference, not a mandate, for individual treatment decisions. As scientific advances in technology continue, genomic and proteomic analysis, health information technology, and other innovations in health care have the potential to promote tailored treatment decisions for each individual patient's unique needs, thereby saving patients from unnecessary care and saving the health care system from the expense of trial-and-error approaches to therapy.
- *Communication of findings and conclusions.* Research findings should be communicated in a fashion that clearly acknowledges any limitations of the research and underlying data. Armed with the knowledge of which conclusions can and cannot be drawn, patients and physicians will be able to use the research findings appropriately for individual diagnosis and treatment situations. Details regarding the assumptions and data sources should also be readily available. At the same time, there should be a system for assuring that health professionals making decisions are aware of the findings of comparative effectiveness studies.
- *Congressional oversight.* Any government funded comparative effectiveness research initiative, whether conducted through existing agencies or a newly formed organization, should be subject to Congressional and executive branch oversight.

Conclusion

Thank you again for holding this important hearing. As supporters of evidence-based medicine, we look forward to working on this effort to deliver the right treatment to the right patient at the right time.

We believe that comparative effectiveness research is a means to improve clinical outcomes and promote access to quality care. It can be used to assist patients and physicians in medical decision-making for prevention, diagnosis and treatment.

However, comparative effectiveness research should be used to *inform* medical decisions, not replace medical judgment with national treatment formulas. It should enhance, not hinder independent professional medical decision-making. Since comparative effectiveness research looks at what is best on average for patients, protections must be established to ensure patient access to treatments, drugs, and devices that meet their individual needs.

Statement of Coalition for Health Services Research

The Coalition for Health Services Research (Coalition) is pleased to offer this testimony for the record regarding the promise of comparative effectiveness research. The Coalition's mission is to support research that leads to accessible, affordable, high-quality health care. As the advocacy arm of AcademyHealth, the Coalition represents the interests of 3,800 researchers, scientists, and policy experts, as well as 135 organizations that produce and use health services research.

Health care in the United States has the potential to improve people's health dramatically, but often falls short and costs too much. Health services research is used throughout the health care field to understand how to better finance the costs of care, measure and improve the quality of care, and improve coverage and access to affordable services. As an emerging science in the broader field of health services research, comparative effective research—where pharmaceuticals, medical devices and medical procedures used to treat the same conditions are evaluated for their relative safety, effectiveness, and cost—has great potential to improve health care quality and patient outcomes while ensuring that consumers receive the best care at the best value. When optimally funded, comparative effectiveness research has the promise to inform health care decisions that are:

- **Patient-specific**, enabling doctors to make individualized treatment decisions according to patient characteristics (sex, age, and race/ethnicity).
- **Evidence-based**, providing patients and practitioners with the timely, scientific information they need to evaluate which treatment options will help them achieve better outcomes.
- **Value-driven**, empowering patients to make informed decisions in the face of rising health care costs and myriad treatment options.

There are increasing examples that demonstrate how comparative effectiveness research provides the scientific basis needed to make better decisions when it comes to the care we give and receive:

- The Agency for Healthcare Research and Quality (AHRQ) found that episiotomies—a preemptory incision intended to prevent pregnant women from tearing tissue during labor—has no positive benefit, and probably results in more complications and causes more pain than if no incision was made during childbirth.[i] The report will save millions of women from having to undergo this painful procedure, not to mention the costs saved by eliminating the routine use of this procedure.
- Another AHRQ study found that drugs can be as effective as surgery in management of gastroesophageal reflux disease (GERD)—where stomach acid enters the esophagus, causing heartburn and potential esophageal damage.[ii] GERD is one of the most common health conditions among older Americans and results in $10 billion annually in direct health care costs. Knowing that, for the majority of patients, drugs can be as effective as surgery in relieving the symptoms could result in significant health care savings and improved quality of life.
- The National Institute of Mental Health (NIMH) found that, within a class of antipsychotic drugs, the older, less expensive drug (Perphenazine) was just

[i] Viswanathan, M., et. al. "The Use of Episiotomy in Obstetric Care: A Systemic Review," Agency for Healthcare Research and Quality (May 2004). Available on the Web at www.ahrq.gov/downloads/pub/evidence/pdf/episiotomy/episob.pdf.

[ii] Ip, S., et. al. "Comparative Effectiveness of Management Strategies for Gastroesophageal Reflux Disease," Agency for Healthcare Research and Quality (Dec. 2005). Available on the Web at www.effectivehealthcare.ahrq.gov/reports/final.cfm.

as effective and caused no worse side effects than the three newer, more expensive drugs in treating patients with schizophrenia. One of the newer drugs (Zyprexa) was slightly more effective in controlling systems than the other drugs, but at the cost of serious side effects.[iii] This study enables greater flexibility in care and informs patients and providers about costs and quality of care.

- **In a study of more than 2,200 patients funded mostly by the Veterans' Administration, researchers found that those who underwent non-emergency angioplasty—a procedure where a tiny wire-mesh tube called a stent is placed in an artery to hold it open—were no less likely to suffer a heart attack or die than those who took only aspirin and other medicines to lower blood pressure and cholesterol and prevent clots, along with adopting lifestyle changes.**[iv] The procedure, often performed to relieve chest pain and to reduce the risk of having or dying from a heart attack, costs about $50,000 and has become one of the most common medical procedures in the United States.

As these examples suggest, comparative effectiveness research can contribute greatly to better health care at lower cost. It is a true public good, providing a basis for improvements in our health care system that benefit the general public. Americans overwhelmingly agree. According to a 2005 *Research!America* survey, approximately 95 percent of Americas agree that it is important to support research that focuses on how well the health care system works and how it could work better, and that health care services should be based on the best and most recent research available.[v]

Despite the promise of, and general support for, comparative effectiveness research, this type of health services research by definition often results in "winners" and "losers," making the entity that commissions this research vulnerable and susceptible to attack. For example, if research based on post-marketing surveillance finds that device "A" has better outcomes and fewer risks than drug "B," one would expect the demand for device "A" to increase at the expense of drug "B." The manufacturer of drug "B" might then attempt to leverage the political process to discredit the research and, as has happened in the past, exert political pressure to substantially reduce the funding for, or even abolish the entity funding, the research.

Given the potentially controversial nature of comparativeness effectiveness research findings, in September 2005 AcademyHealth issued a report that provided guidance on the placement, structure, and funding of comparative effectiveness research (see appendix A).[vi] The AcademyHealth report recommended that comparative effectiveness research be established either within AHRQ or through the creation of a new entity that would, in varying degrees, be linked the lead agency for health services research. As part of this recommendation, the report identifies four structural options for the placement of this critical research function. These options range from fully embedding the comparative effectiveness function in an established federal agency to placing it, along with all other health services research, in a new, quasi-governmental organization (see also Appendix B):

- **Option 1:** AHRQ sponsors and conducts comparative effectiveness studies with oversight and guidance from an external board and panel of experts.
- **Option 2:** AHRQ sponsors and conducts comparative effectiveness studies with oversight and guidance from an external board and panel of experts, and establishes a Federally Funded Research and Development Center (FFRDC).[vii] The FFRDC would undertake syntheses of research commissioned

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[iii] Lieberman, J.A., et. al. "Effectiveness of Antipsychotic Drugs in Patients with Chronic Schizophrenia, " *New England Journal of Medicine*, Vol. 353, No. 12, pp.1209–1223 (Sept. 22, 2005). Available on the Web at http://content.nejm.org/cgi.content/abstract/353/12/1209.

[iv] Boden, W.E., et. al. "Optimal Medical Therapy with or without PCI for Stable Coronary Disease," *New England Journal of Medicine,* Vol. 356, No. 15, pp. 1503–1516 (April 12, 2007). Available on the Web at http://content.nejm.org/cgi/content/abstract/356/15/1503.

[v] Woolley, M. and S. Propst. "Public Attitudes and Perceptions about Health-Related Research." *Journal of the American Medical Association*, Vol. 294, No. 11, p. 1382 (Sept. 21, 2005).

[vi] *Placement, Coordination, and Funding of Health Services Research within the Federal Government*, AcademyHealth (Sept. 2005). Available on the Web at http://www.chsr.org/placementreport.pdf.

[vii] An FFRDC is a private, nonprofit organization that is sponsored by an executive branch agency. The sponsoring agency monitors, funds, and assumes responsibility for the overall activities of the FFRDC. While FFRDCs are not subject to federal personnel rules, the organizations are prohibited from competing for government contracts to ensure their independence, objectivity, and freedom from organizational conflicts of interest.

by AHRQ and others for the purpose of making comparative effectiveness findings.

- **Option 3:** With AHRQ remaining as currently structured, create a new, separate quasi-governmental entity for comparative effectiveness research.
- **Option 4:** Reconstitute AHRQ as a quasi-governmental entity, retaining most of its existing functions and adding comparative effectiveness research.

AcademyHealth assessed these four options against five principles designed to further guide policymakers' deliberations on comparative effectiveness research (see also Appendix C).

- Comparative effectiveness research is a subset of the broader field of health services research, so increased investments in comparative effectiveness research should not be at the expense of investments in a robust health services research portfolio.
- Given the potentially controversial nature of comparative effectiveness findings, this research must be based on scientific evidence and be kept separate from funding and coverage decisions.
- As a subset of the field of health services research, comparative effectiveness research must be closely linked to AHRQ—as the lead agency for health services research—to ensure that findings are consistent with the best available research, methods, and data.
- Since comparative effectiveness research as a public good requires significant federal investment and has the potential to affect the delivery and cost of health care for all Americans, the entity commissioning or conducting this research should be subject to congressional oversight.
- Stakeholders should be involved in developing the research agenda and ensuring the validity of the research produced. Ensuring transparency in the prioritization, conduct, and dissemination of research will promote public acceptance of the research findings and strengthen support for the program's mission.

The entity's overall funding and ability to recruit the expertise needed are critical factors that should inform the choice among these options—the best arrangement for a budget of $50 million might not be the best if $5 billion were to be made available for this function. It may also be desirable to have portions of this responsibility undertaken by a combination of entities. Under such a scenario, the lead agency for health services research might commission and undertake the research studies, an affiliated entity might do the assessments based on that research, and an independent quasi-governmental entity might develop consensus studies on the methods and data to be used for these studies and assessments.

Regardless of how this research program is structured and governed in the future, AcademyHealth and its Coalition recognize that comparative effectiveness research will require a significant investment to realize its potential. For example, some experts suggest that a robust comparative effectiveness program should be funded at a level of $4—$6 billion annually to meet the U.S. health system's demands. Comparatively, the Federal Government last year spent nearly $32 billion on health research, of which only 5 percent—about $1.5 billion—was apportioned to health services research. The Federal Government's comprehensive investment in comparative effectiveness research across the various agencies conducting and funding this work is unknown, as this information is not systematically collected. However, we do know that AHRQ's comparative effectiveness program was appropriated $15 million in fiscal 2007 (and $15 million in each of the previous three fiscal years).[viii, ix] Congress should increase and expand the sources of funding for conducting and coordinating a wide spectrum of comparative effectiveness research, including systematic reviews of existing literature, analysis of administrative data and clinical registries, and pragmatic, prospective, head-to-head trials. Doing so would ultimately help patients, providers, payers, and policymakers make rational choices about new and existing health services, and assure that our investments in basic and clinical research are integrated into health care delivery. After all, increased spending on new medicines and equipment is wasted if the system does not adopt these new treatments in a safe and efficient manner.

In addition, we believe that increased investment in comparative effectiveness research must be coupled with greater investment in the research infrastructure—the

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[viii] Catlin, A., et. al. "National Health Spending in 2005: The Slowdown Continues," *Health Affairs,* Vol. 26, No. 1, pp. 142–153 (Jan./Feb. 2007).

[ix] *Federal Funding for Health Services Research*, Coalition for Health Services Research (Dec. 2006). Available on the Web at http://www.chsr.org/AHfundingreport1206.pdf.

data, methods, and researchers needed to conduct this work and ultimately generate meaningful research and knowledge. **The field of health services research has experienced an erosion of investment in its methods, data, and particularly its researchers over the last several years. If left unchecked, these declining investments could threaten the field's capacity to address public and private sector research needs.**

In conclusion, the best health care decisions are based on relevant data and scientific evidence. Increased investment in comparative effectiveness research and the health services research infrastructure will show returns in improved quality, accessibility, and affordability. At a time when America is spending over $2 trillion annually on health care, we need research—now more than ever—to help us spend our health care dollars more wisely.

The Coalition appreciates the opportunity to submit this testimony for the record and looks forward to working with the Subcommittee as it continues to assess options for structuring and funding a robust comparative effectiveness research capability in the United States. If you have questions or comments about this testimony, please contact Emily Rowe, Director of Government Relations.

Appendix A: Committee on Placement, Funding, and Coordination of Health Services Research within the Federal Government

(Affiliations at time of committee appointment)

Sheila Burke, Committee Chair, Deputy Secretary and Chief Operating Officer, Smithsonian Institution
Jeanne Lambrew, Ph.D., Vice Chair, Associate Professor, Department of Health Policy, George Washington University
David Abernethy, Senior Vice President, Operations, HIP Health Plans
Michael Chernew, Ph.D., Professor, Department of Health Management and Policy, School of Public Health, University of Michigan
Jordan Cohen, M.D., President, Association of American Medical Colleges
Judith Feder, Ph.D., Dean of Public Policy, Georgetown University
Harold S. Luft, Ph.D., Caldwell B. Esselstyn Professor and Director, Institute for Health Policy Studies, University of California, San Francisco
Nicole Lurie, M.D., Senior Natural Scientist and Alcoa Chair, RAND Corporation
Donald M. Steinwachs, Ph.D., Professor and Chair, Department of Health Policy and Management, Bloomberg School of Public Health, Johns Hopkins University
Gail Wilensky, Ph.D., Senior Fellow, Project HOPE

Appendix B: Four Options for the Placement of Comparative Effectivenss Research

Option 1: AHRQ sponsors and conducts comparative effectiveness studies with oversight and guidance from an external board and panel of experts.	• AHRQ would remain the lead agency for health services research, supporting a broad health services research agenda, including comparative effectiveness. • AHRQ would establish an external board to oversee the development of the comparative effectiveness research agenda and a panel of experts to validate the science used to conduct comparative effectiveness studies.
Option 2: AHRQ sponsors and conducts comparative effectiveness studies with oversight and guidance from an external board and panel of experts, and establishes a Federally Funded Research and Development Center (FFRDC).	• AHRQ would remain the lead agency for health services research, supporting a broad health services research agenda, including comparative effectiveness. • AHRQ would establish an external board to oversee the development of the comparative effectiveness research agenda and a panel of experts to validate the science used to conduct comparative effectiveness studies. • AHRQ would also establish an independent FFRDC with the limited mission of reviewing and synthesizing comparative effectiveness research.

Option 3: AHRQ remains as currently structured and a new separate quasi-government entity is established to fund and conduct comparative effectiveness research.	• AHRQ would remain the lead agency for health services research, supporting a broad health services research agenda, but not comparative effectiveness. • A new quasi-governmental agency would be established, with both public and private funding, to conduct both intramural and extramural comparative effectiveness studies.
Option 4: AHRQ is reconstituted as a quasi-governmental agency retaining most existing functions and adding comparative effectiveness research.	• AHRQ reconstituted as a new quasi-governmental entity would conduct and fund health services research, including comparative effectiveness. • Those AHRQ functions that must be performed by a governmental entity, such as the Medical Expenditure Panel Survey (MEPS), would be transferred to other existing HHS agencies. • The new quasi-governmental entity could be supported by public and private funds.

Appendix C: Five Principles to Guide Decisions for the Placement of Comparative Effectiveness Research

Principle 1: Overall funding for the field of health services research should continue to support a broad and comprehensive range of topics.	• Recognizes that while comparative effectiveness research is important, it is a subset of the broader field of health services research. • Regardless of where comparative effectiveness research is placed, this principle stresses the need to fund a broad health services research portfolio.
Principle 2: Assessments should be based on scientific evidence and kept separate from funding and coverage decisions.	• Given the controversial nature of comparativeness effectiveness findings, this principle stresses the need for a structure that ensures the scientific integrity of comparative effectiveness research. • This principle stresses the need to separate the entity that funds and conducts these studies from the entity directly responsible for making coverage decisions.
Principle 3: Entity commissioning or conducting comparative effectiveness research should maintain close linkage to the lead agency for health services research.	• Recognizes that comparative effectiveness research is a subset of the broader field of health services research. • As such, comparative effectiveness research must be closely linked to the lead agency in order to ensure that findings are consistent with the best available research, methods, and data.
Principle 4: Entity commissioning or conducting comparative effectiveness research should be subject to congressional oversight.	• Since comparative effectiveness research has the potential to affect the delivery and cost of health care for all Americans, this principle recognizes that the Federal Government is responsible for ensuring that decisions about what health services and products should be provided are based on sound scientific research. • Since this research requires substantial federal funding (and would not be funded adequately by the private sector alone), this principle recognizes the need for appropriate congressional oversight of public funding to ensure accountability.

Principle 5: Entity commissioning or conducting comparative effectiveness research should involve key stakeholders to assure transparency of the methods and process, promote public acceptance of research findings, and support for the entity's mission.	• Given the controversial nature of comparative effectiveness research, this principle recognizes the importance of involving key private sector representatives in developing the research agenda and ensuring the validity of the research produced, thereby increasing public support for the research findings and the entity's mission. • As such, comparative effectiveness research must be funded in an open process to ensure that no one group is perceived as dominating the process and/or skewing the results.

Epilepsy Foundation
Landover, Maryland 20785
July 9, 2007

Chairman Pete Stark
House Ways and Means Health Subcommittee
1135 Longworth House Office Building
Washington, DC 20515

Dear Chairman Stark,

On behalf of the Epilepsy Foundation and the more than 3 million Americans living with epilepsy, I am pleased to submit the following comments in response to the Health Subcommittees' June 12, 2007 hearing on Strategies to Increase Information on Comparative Clinical Effectiveness.

The Epilepsy Foundation applauds the Committee's intent to address the issue of rising health care costs and the lack of evidence justifying extreme variations in the provision of medical services. We recognize many of the potential benefits to increasing, and making available, information on the relative effectiveness of health care services.

Yet we are also concerned that this information not be based solely on the limited perspective of random clinical trials and that the application of Comparative Clinical Effectiveness not be based upon, or utilized, for cost containment benefits only.

Epilepsy is a chronic neurological condition characterized by recurrent seizures. Individuals with epilepsy are at a two—to three-fold increased risk of death, as well as an increased risk of cognitive impairments, employment difficulties and personal isolation (due in part to the social stigmas associated with this condition).[i, ii, iii, iv, v, vi, vii, viii] Each year, approximately 200,000 individuals in the United States are newly-diagnosed with epilepsy.[ix] Although initial onset can occur at any age, epilepsy most commonly arises in either early childhood or old age.[x]

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[i] Cockerell OC, Johnson AL, Sander JW, Shorvon SD. Prognosis of Epilepsy: A Review and Further Analysis of the First Nine Years of the British National General Practice Study of Epilepsy, a Prospective Population-Based Study. *Epilepsia*. 1997; 38(1):31–46.

[ii] Hauser WA, Annegers JF, Elveback LR. Mortality in patients with epilepsy. *Epilepsia*. 1980;21:399–412.

[iii] Olafsson E, Hauser WA, Gudmundsson G. Long-Term Survival of People with Unprovoked Seizures: A Population Based Study. *Epilepsia*. 1998;39:89–92.

[iv] Zielinski JJ. Epilepsy and Mortality Rate and Causes of Death. *Epilepsia*. 1974;15:191–201.

[v] Nilsson L, Tomson T, Farahmand BY, Diwan V, Persson PG Cause-Specific Mortality in Epilepsy: A Cohort Study of More Than 9,000 Patients Once Hospitalized for Epilepsy. *Epilepsia*. 1997;38(10):1062–8.

[vi] Motamedi G, Meador K. Epilepsy and cognition. *Epilpesy Behav*. 2003;4(Suppl. 2):25–38.

[vii] Fisher RS, Vickrey BG, Gibson P, Hermann B, Penovich P, Scherer A, Walker S. The impact of epilepsy from the patient's perspective I. Descriptions and subjective perceptions. *Epilepsy Res.* 2000;41:39–51.

[viii] Sillanpää M, Jalava M, Kaleva O, Shinnar S. Longer-Term Prognosis of Seizures with Onset in Childhood. *N. Engl. J. Med.* 1998;338:1715–22.

[ix] Epilepsy Foundation. Epilepsy and Seizure Statistics. Available at: http://www.epilepsyfoundation.org/about/. Accessed on April 19, 2007.

[x] Centers for Disease Control and Prevention. Living Well with Epilepsy, Report of the 2003 National Conference on Public Health and Epilepsy. Available at www.cdc.gov/Epilepsy/pdfs/living_well_2003.pdf. Accessed on January 10, 2007.

Modern treatment of epilepsy relies primarily on the use of one or more antiepileptic drugs (AEDs) with the goal of preventing seizures.[xi] Other treatment options may include surgery, special diet and/or the use of a device to stimulate the vagus nerve.

Complete prevention of seizures remains elusive in approximately one in three patients with epilepsy. In these patients, the goal of treatment is to minimize the frequency and intensity of the seizures without unacceptable side effects from treatment. Epilepsy, and treatment to control seizures, is not a one size fits all condition. To manage patients with epilepsy effectively, patients need access to the full range of treatment options and physicians must tailor treatment for each patient to achieve maximum control of seizures while minimizing adverse side effects.[xii, xiii, xiv, xv, xvi]

As the discussion of Comparative Clinical Effectiveness moves forward the Foundation encourages that, throughout the process, two key principles be applied.

1. Evidence being considered and applied should be broad and inclusive.

While a comprehensive, and inclusive, approach to comparative clinical effectiveness and, in turn, evidence based healthcare can indeed lead to high quality healthcare and maximize patient outcomes, a limited approach, we fear, would limit access and, in turn, not offer people with epilepsy, and others living with chronic disorders, the optimal care that is available.

To assure a comprehensive approach to the topic of comparative clinical effectiveness the Epilepsy Foundation supports a model that encompasses a broad definition and application of what is accepted as "evidence". The Foundation feels strongly that treatment selection be based on a combination of scientific research, physician expertise and experience, and the patient's preferred outcomes, preferences and expectations.

We are fearful that a "one-size-fits-all" approach to treatment can result from strict reliance on "evidence" solely from random clinical trails and published studies that do not take into account diverse populations, co-morbidities, and other real world situations.

12. The process should be transparent and include consumer/patient involvement.

As decisions are made as to the structure, funding, and utilization of a comparative effectiveness entity we encourage that consumers/patients be considered a primary stakeholder and participant at every level.

We anticipate transparency and public comment periods will be included throughout the process and that patients/consumers will be encouraged to provide input. The Foundation would like to see that outreach to, and participation by, consumers/patients will encourage and empower them to be involved in research design, review and translation, dissemination, implementation and evaluation. Undoubtedly, government, researchers, funders, industry and payors will all play a critical role. Each

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[xi] Sander JW. The Use of Antiepileptic Drugs—Principles and Practice. *Epilepsia*. 2004;45(Suppl. 6):28–34.

[xii] EUCARE. European white paper on epilepsy: Pharmacological Treatment. *Epilepsia* 2003;44(Suppl. 6):33–4.

[xiii] Stokes T, Shaw EJ, Juarez-GA, Camosso-Stefinovic J, Baker R. Clinical Guidelines and Evidence Review for the Epilepsies: diagnosis and management in adults and children in primary and secondary care. Royal College of General Practitioners, London England. 2004. Link available at: http://www.nice.org.uk/guidance/CG20. Accessed on January 23, 2007.

[xiv] Glauser T, Ben-Menachem E, Bourgeois B, Cnaan A, Chadwick D, Guerreiro C, Kalviainen R, Mattson R, Perucca E, Tomson T. ILAE Treatment Guidelines: Evidence-based Analysis of Antiepileptic Drug Efficacy and Effectiveness as Initial Monotherapy for Epileptic Seizures and Syndromes. *Epilepsi*. 2006;47(7);1094–1120.

[xv] French JA, Kanner AM, Bautista J, Abou-Khalil B, Browne T, Harden CL, Theodore WH, Bazil C, Stern J, Schachter SC, Bergen D, Hirtz D, Montouris GD, Nespeca M, Gidal B, Marks Jr. WJ, Turk WR, Fischer JH. Bourgeois B, Wilner A, Faught Jr. RE, Sachdeo RC, Beydoun A, Glauser TA. Efficacy and tolerability of the new antiepileptic drugs I: Treatment of new onset epilepsy: Report of the Therapeutics and Technology Assessment Subcommittee and Quality Standards Subcommittee of the American Academy of Neurology and the American Epilepsy Society. *Neurology*. 2004;62:1252–60.

[xvi] French JA, Kanner AM, Bautista J, Abou-Khalil B, Browne T, Harden CL, Theodore WH, Bazil C, Stern J, Schachter SC, Bergen D, Hirtz D, Montouris GD, Nespeca M, Gidal B, Marks Jr. WJ, Turk WR, Fischer JH. Bourgeois B, Wilner A, Faught Jr. RE, Sachdeo RC, Beydoun A, Glauser TA. Efficacy and tolerability of the new antiepileptic drugs II: Treatment of refractory epilepsy: Report of the Therapeutics and Technology Assessment Subcommittee and Quality Standards Subcommittee of the American Academy of Neurology and the American Epilepsy Society. *Neurology*. 2004;62:1261–73

entity should strive to include the patient perspective and involvement in their work on this issue.

Recognizing the importance of the patient perspective in this on-going discussion, in early 2006 the Epilepsy Foundation became a founding member of the National Working Group on Evidence-Based Health Care. This group, comprised of consumers, caregivers, practitioners and researchers, is committed to promoting accurate and appropriate evidence-based policies. Information about this group, and our work, can be found at www.evidencebasedhealthcare.org.

Again, the Epilepsy Foundation is grateful for the opportunity to provide these comments to the dialogue on comparative clinical effectiveness and welcomes the opportunity to be a continuing resource and participant in this evolving issue. For additional information, or if we can be of further assistance, please feel free to contact me.

Sincerely,

Donna Meltzer
Senior Director of Government Relations

Statement of Mental Heath America

Mental Health America (formerly the National Mental Health Association) is the country's leading nonprofit dedicated to helping ALL people live mentally healthier lives. With our more than 320 affiliates nationwide, we represent a growing movement of Americans who promote mental wellness for the health and well-being of the nation—everyday and in times of crisis.

We applaud the Subcommittee on Health, Committee on Ways and Means of U.S. House of Representatives for holding a hearing to increase information on Comparative Clinical Effectiveness on June 12, 2007. We are encouraged by the new proposals to expand Comparative Clinical Effectiveness efforts and improve the overall quality and value of health care delivery in our country.

Mental Health America has followed the current national healthcare reform debate and witnessed the balancing act between access to safe and effective health care, cost and quality. In this environment of steadily rising costs, Mental Health America is concerned that the evaluation of "quality" of care is being used as a means of justifying cost-based decisions about the types and quantity of health services available. At every level of the debate—federal, local, public and private—the stakes are high for how this will impact access to care, particularly for vulnerable Americans who are reliant on public systems to get basic care for chronic health conditions, such as mental illnesses. Mental Health America is particularly concerned with how these trends will impact the Medicaid program as well as the public mental health system in this country.

As these deliberations continue to unfold, Mental Health America offers the following comments for the Committee's consideration:

Promoting patient/consumer inclusion: The current comparative clinical effectiveness proposals seek to influence and reform health care delivery in the best interest of the patient. However, these efforts often lack a balanced representation of the very stakeholders for whom these decision will be most important, patients/consumers. Decision makers must recognize the importance of including patients/consumers as partners at every stage of comparative clinical effectiveness efforts including: research design, review, evaluation and governing bodies that make decisions about how to apply evidence in practice and policy. The process to evaluate and develop evidence-based interventions, treatments and policies should be transparent and open to the public and include all stakeholders in the decision making process. Consumers and families should have active and meaningful roles on review, evaluation and governing bodies that make decisions about how to apply evidence in practice and policy. In addition, clear and complete research findings should be communicated to consumers and families, and tools and practices should be developed to aid consumers in how to use such information in their dialogue with caregivers.

Preserving access to individualized care: Scientific and practical evidence can aid in determining what is the best intervention to optimize an individual's care, but such evidence alone cannot guarantee the right choice for every individual. Therefore, it is important that reimbursement and coverage policies re-

flect the need for individualized care and maintain flexibility for clinicians and individuals to access a range of treatments and services. In addition, it is important to advocate for wider investment in practical clinical trials and other research methods that generate evidence applicable to real-world treatment settings.

Promoting quality health care first: The underlying motivation of these initiatives is cost containment rather than improving quality of care. Safety and optimal treatment for the individual should be the overriding goal of any comparative clinical effectiveness approach. Treatment costs are relevant to the discussion but must be weighed in the system context—total care costs for an individual across services and settings—rather than as unit costs. In the context of clinical decision making, cost should be evaluated by providers and consumers after a careful weighing and discussion of benefits and risks and a dialogue that emphasizes choice across a range of therapeutic options. Mental Health America opposes processes and policies that emanate solely from cost containment objectives. Moreover, our organization opposes the misuse of the concept of evidence or the findings from comparative clinical effectiveness initiatives as a justification for denial of coverage, reimbursement or access to care except in areas where significant safety concerns are identified.

Identifying and addressing gaps in research: The boundaries of scientific research are stretching and revealing new understanding and options for treating many chronic illnesses, including mental health conditions. Even as emerging science gives us information about how and why mental illnesses affect individuals, and about genetic biomarkers that may better guide treatment choices, it also reveals the absence of universally effective treatments and practices and the limitations to the current body of scientific evidence in mental health. We believe there are limitations of clinical research design—particularly the "gold standard" of randomized controlled trials—which do not effectively measure important outcomes, such as quality of life, employment, relationships, and the impact of side effects of different treatments. Realities of the individual consumer (age, gender, ethnicity, co-occurring disorders, and treatment goals and preferences) often are not captured as part of this research. Mental Health America supports the role of all levels of evidence—including randomized clinical trials, quasi-experimental studies, observational studies and expert consensus—in creating the evidence base for an intervention or service.

Our abovementioned comments mirror those to which we have submitted to Oregon's Drug Effectiveness Review Project and the Agency for Healthcare Research and Quality's Effective Health Care program. Attached are two documents that Mental Health America submitted to Oregon's Drug Effectiveness Review Project which include comments to their reports on atypical antipsychotics and second generation antidepressants. These documents illustrate in further detail the concerns we have in using comparative clinical effectiveness approaches and caution state leaders regarding the limitations of applying this information to public policy decision making.

We hope you take into consideration our views and thank you again for this opportunity to comment.

Attachment A

NMHA Comments on the

Draft Drug Class Review for Atypical Antipsychotic Drugs—**Update 1**

March 14, 2006

Thank you for the opportunity to respond to the draft drug class review on pharmacologic treatments for atypical antipsychotic (AAP) medications. We appreciate that you have continued to update and review your conclusions. We commend DERP for its inclusion of the CATIE study in this review and we are most pleased to see that you chose to include information about limitations of the research and addressed some of our previous concerns.

However, the review still highlights the desperate need for better research on both the efficacy and the effectiveness of these medications and points to the ongoing necessity for caution when states and private companies develop pharmacy policies based on limited information. On page 13, the review acknowledges that "quality of the evidence on effectiveness is a key component, but not the only component,

in making decisions about clinical policies." NMHA continues to encourage the Oregon Center to communicate to its participating agencies and on its website that the Drug Effectiveness Review Project needs to be used within a larger context of policy decision-making. Below NMHA has additional questions and comments about the review.

Overall Inadequate Research

As with previous reviews of atypical antipsychotic medications, this review found that the research is generally inadequate to draw appropriate conclusions about which atypical antipsychotic medications work for different individuals. Comments from the CATIE principle investigator Dr. Jeffrey Lieberman reinforce this notion. During the National Institutes of Mental Health (NIMH) briefing on September 26, 2005, Dr. Lieberman stated, "The outcomes show that Schizophrenia patient choices must be individualized. What works for one individual may not work for another."

Furthermore, the CATIE data is presently incomplete. Only Phase 1 data has been released. Further analysis and more detailed evaluation of study findings are forthcoming. It is important to note that CATIE study researchers and NIMH Director Dr. Thomas Insel have said that it would be counterproductive for anyone to use this data to reduce access and that it would be "premature to change public policy on the basis of this study."

This lack of data makes it very difficult for policymakers, researchers, and others to draw any conclusions about the comparative effectiveness of these medications. We strongly urge DERP to clarify in its review that a general lack of evidence about differences does not mean that there are no differences between the medications.

On page 18, the DERP review reports that only 3 effectiveness trials were identified and reviewed for comparative effectiveness and short term adverse events of AAPs in patients with Schizophrenia. Yet in the review, it states that the results of effectiveness studies are more applicable to the "average" patient than results from highly selected populations in efficacy studies. The review states, "The remainder of the direct evidence comes from efficacy trails, which include narrowly defined patient populations, and are not conducted within the context of a care system with the typical range of co-interventions and/or co-morbidities, and a small number of studies with observational designs. The generalizability of the findings of the efficacy studies to broader groups of patients and setting is limited." We are very concerned by this finding, especially because it limits stakeholders' abilities to use the review for policymaking decisions. We encourage DERP to make a call for more research within the review and to offer reasons why this lack of data is important for policymakers.

In addition, on page 20, the DERP review states, "There is very limited evidence regarding AAPs used for the treatment of schizophrenia in subgroup populations." We are very concerned about the lack of research focused on differences in responses by people of different genders, race and ethnicity. Again, we encourage DERP to use this review to call for more research in this area and to look at other sources of information that addresses this important issue.

Adverse Events

We noted the review did find that patients appeared to have significant differences in tolerability of side effects and other adverse events. This is a critically important area, and is believed to be strongly linked with patients continuing with certain medications. We strongly recommend highlighting this finding in the introduction as well as conclusion of the report.

Finally, the information organized is one piece in a complex puzzle of making healthcare decisions. As state policymakers face difficult choices in an environment of increasing healthcare costs, we are concerned that this information will become political cover for establishing policies that will harm the health of vulnerable citizens. We recommend that the following guidance be shared with participating agencies and be featured prominently in the reviews and in your cover letters:

- Please note that the information organized in the drug class reviews is an important part of making decisions about the effectiveness of this class of medications, but it should not be the sole source of making such decisions. The Oregon Center recommends that treatment guidelines, clinical experience, and consumer input be also included in any pharmacy management programs.
- The Oregon Center urges participating agencies to work with consumer and provider groups to assess what medications work best in clinical practice, and to ensure that adequate choices are available in participating agency's pharmacy programs. All pharmacy policies should be voluntary to provide flexibility to the physician and the patient.

- All pharmacy policies should contain several choices of medications to accommodate different responses to medications, including different adverse responses or differing responses based on gender, race, or ethnicity.

Attachment B

NMHA Comments on the Draft Drug Class Review for **Second Generation Antidepressants**

July 19, 2006

On behalf of the National Mental Health Association (NMHA), thank you for the opportunity to respond to your draft drug class review on pharmacologic treatments for second generation antidepressants.

We applaud the Drug Effectiveness Review Project (DERP) for acknowledging on page 5 that, "The tremendous volume and large variability in the quality of evidence to support use of these products makes it difficult for clinicians and decision makers to make evidence-based decisions." This acknowledgment supports our concern of the limitations of the scope and power of existing scientific research. Below NMHA has additional comments about the review.

Effectiveness studies are lacking

We note that the report comments on the limited number of studies that review effectiveness of the compared medications. While we recognize this general weakness in scientific research, we are surprised that DERP then concludes that it can comment on the comparative effectiveness of these medications. Based on the fact that an inadequate sample of such studies is presented in the report, we urge DERP to comment prominently that such conclusions cannot be drawn based on the available evidence.

Furthermore, of particular concern is the dearth of research on quality of life measures as stated on page 16, "Quality of life and functional capacity were rarely assessed, and if they were, they were considered only as a second outcome." These measures greatly impact a patient's satisfaction with and adherence to a particular medication and should be weighed equally to measures of efficacy and symptom reduction. By including these measures, patients, physicians, payers and decision makers will receive a more accurate picture of how effective or ineffective a particular medication is.

Limited data on subgroups

The conclusions that were drawn from this report are generalized to subgroups which were not included in many of the studies that were reviewed. For example on page 28, the review states, "We did not find any evidence that one group has a greater benefit from an individual drug than another." Yet we noticed that very little research focused on differences in responses by people of different genders or racial and ethnic minorities and for people with co morbid health conditions.

Furthermore, the report acknowledges on page 17 that, "Most studies received a fair rating for internal validity. The generalizability of the results was hard to determine and might often be limited."

While we appreciate DERP's recognition of this issue, these conclusions affirm what we know exists in the scientific research today. Given this lack of data, however, we call on DERP to prominently note that conclusions about response to second generation antidepressants among subgroups is "inconclusive" rather than the current conclusion that evidence shows "no differences." Again, this clarification will highlight that the evidence base is insufficient to allow conclusions to be drawn that emphasize the need for individualized care choices.

The information about scientific evidence that DERP presents in this report is one piece in a complex puzzle of informing and improving healthcare decisions. While NMHA is committed to promoting high quality mental health care that is informed by the best scientific evidence available, we continue to be concerned at the local application of reports similar to DERP's as a rationale for limiting choice of care to one or two agents, or requiring that individual's fail on the preferred (cheapest) medication before being allowed to choose from more (possibly) therapeutically appropriate choices.

- As DERP prepares the final report, we urge you to feature prominently the following key messages:

- Clarify that the information organized in this report is one component in making decisions about the effectiveness of second-generation antidepressants; it should not be the sole source of making such decisions on a clinical or policymaking level.
- Urge private and public policymakers and payers to work with consumer and provider groups to incorporate scientific evidence with knowledge from clinical practice and from patient viewpoints and values.

- Make prominent the message that evidence that no significant differences exist within this class of medications does NOT imply that:
  - All medications are identical
  - None of the medications are efficacious in treating depression.
  - Call for more research in primary care populations, for subgroups, and for effectiveness research for treatment of depression that includes measure of functionality and patient preference.
  - Clearly state that current evidence on second-generation antidepressants does not provide clear justification for policies that limit choice of medication because existing evidence affirms that different therapies are efficacious for different individuals.

NMHA continues to encourage the Oregon Center to communicate with its participating agencies and on its website that the DERP needs to be used within a larger context of policy decision-making.

If you have any questions, please contact Jennifer Bright, Vice President for state policy.

Statement of the National Alliance on Mental Illness, Arlington, Virginia

Chairman Stark and Congressman Camp, on behalf of the National Alliance on Mental Illness (NAMI) I am pleased to offer the following statement on strategies for increasing information comparative clinical effectiveness. As the nation's largest organization representing people with serious mental illness and their families—210,000 members and 1,200 affiliates in all 50 states—I am pleased to offer our views on this important issue.

NAMI feels strongly that comparative effectiveness research can serve as an important source of information that contributes to both medical care decision-making between patients and providers, as well as decisions about coverage and reimbursement. In addition to such research, expert clinical guideline development, review of patient registries and existing claims and utilization data, health services research, disease management strategies, and e-health initiatives all have a role in supporting better real-time decisions with a focus on the individual patient/consumer.

NAMI is a member of the National Working Group on Evidence-Based Healthcare, a coalition of patient and chronic disease advocacy organizations that is working to ensure that comparative effectiveness research plays the most appropriate role in our health care system. NAMI concurs that the focus of comparative effectiveness research must be on health conditions and chronic illness broadly, rather than narrowly focused on particular healthcare technology. This will allow a more useful analysis of all available approaches and a comparison of risks *and* benefits that will be most relevant and useful to the end user—patients and their families. It is also important that updates of such research must be frequent to ensure that new evidence is rapidly disseminated to clinicians and patients/consumers.

NAMI would like to commend the Agency for Healthcare Research and Quality (AHRQ) for its pursuit of transparent and inclusive processes to prioritize, conduct and disseminate the findings from its systematic reviews in the Effective Healthcare program. NAMI, along with many of our colleagues in the National Working Group on Evidence-Based Healthcare, have participated in public forums, offered comments on priority setting, key questions for the reviews, and draft reviews and participated in review of dissemination materials from the Eisenberg Center. These interactions have been positive and we have seen efforts to incorporate recommendations and concerns into final products.

It should be noted however that this positive experience with AHRQ is in contrast to NAMI's experience with other organizations involved in such work, such as the Drug Effectiveness Review Project (DERP) and Consumers' Union. While the DERP's processes have recently improved, the organization has been resistant to wider transparency and inclusive processes that incorporates meaningful input from patient advocacy groups. This has been coupled with an absence of focus on methods

of dissemination that promote dialogue with all stakeholders to ensure a balanced consideration of issues related to implementation in policy decision-making.

DERP reviews in turn have been used to inform the work of Consumers' Union's Best Buy Drugs program, which seeks to inform consumers—principally by their own definition consumers without health coverage or with high pharmaceutical costs—about both comparative clinical effectiveness and cost-effectiveness. The Consumers' Union program too often portrays choices for consumers in an overly-simplistic and potentially misleading way. While there are disclaimers on the site that consumers should not discontinue medications and that individual's response to medications will vary, the notion of identifying "best buys" leads to a conclusion that there is a choice that will fit the majority of the audience.

In fact, there is overwhelming evidence that in the case of medications to treat mental illness, individual response to medications will vary based on age, gender, race/ethnicity, health status, co-occurring health conditions—details which are absent from the Best Buy literature. Further, NAMI is extremely concerned about the lack of inclusion of chronic disease and patient advocacy organizations in the development of Best Buy products. Such exclusion—even omitting public comment periods that could ensure relevance to their audience—is misguided in an environment where all stakeholder opinions must given consideration.

As with our colleagues in the National Working Group on Evidence-Based Healthcare, NAMI offers no specific recommendation on where an entity conducting comparative effectiveness research should be placed, we do urge policymakers to avoid seeking to reinvent processes or organizational entities. Instead, it is important to emphasize the need for an inclusive and broadly-representative partnership between government, private entities, providers, as well as patients and their families.

NAMI also has concerns about any entity that places payor and private-stakeholder entities in leadership roles without adequate balance from clinical and chronic disease and patient representation. It is critical that the voice of Americans living with chronic diseases and their families have meaningful and varied representation on government bodies, advisory groups and other mechanisms to assure a diverse voice. This is in contrast to current bodies organized around evidence-based medicine in which a select few organizations are representing the global consumer perspective.

NAMI shares the views of the National Working Group on Evidence-Based Healthcare Working Group in urging that cost-effectiveness NOT be part of any review of comparative clinical effectiveness. The consideration of cost factors can sometimes be important to inform clinical and consumer decision-making. However, this analysis of cost-effectiveness must be separate and subsequent to analysis of clinical value. This is a necessary separation to emphasize the focus on quality of healthcare rather than cost first. Cost-effectiveness analysis is even more complex and controversial in terms of reflecting stakeholder values, thus potentially further politicizing any conduct of comparative effectiveness analysis.

NAMI agrees strongly that there is tremendous risk in comparative effectiveness research being used as a blunt policy instrument for cost control. It is troubling that groups as respected as the Congressional Budget Office (CBO) have articulated the misguided notion that such research can provide a simplistic and objective decision about the best choices of therapeutic interventions for every individual. Restrictions on patient and clinician choice of therapies in state Medicaid programs and in Medicare Part D drug plans demonstrate the potential for inappropriate application of comparative effectiveness research to coverage decisions, particularly for high-cost chronic health conditions. These approaches fail to recognize and support individualized care decisions and imply "population based" solutions to complex individual health conditions.

NAMI shares the view of the National Working Group on Evidence-Based Healthcare that comparative effectiveness research is only as good as the measures and populations that are included in the research being compared and synthesized. Its applicability to a specific individual or a particular circumstance may be significantly limited. Within a cost containment framework, studies that demonstrate similar average outcomes on a limited number of targets can provide a rationale for limiting treatment choices. In reality, differences between people in their response to treatment and multifaceted outcomes that often accompany the management of chronic illnesses confound this logic.

NAMI is encouraged that you and your colleagues in Congress, including Representative Tom Allen, are open to suggestions about how to ensure that HR 1184 incorporates protections to ensure patients and consumers have access to all options for care. We share his view that comparative effectiveness research be an informant rather than a driver of healthcare decisions. Full participation of patients and fami-

lies in every aspect of comparative effectiveness research is critically important and consistent with the historical tenets of evidence-based medicine that balance research, clinical expertise with patient perspectives and preferences.

Thank you for the opportunity to share NAMI's views on this important issue.

Statement of Pharmaceutical Research and Manufactures of America

The Pharmaceutical Research and Manufacturers of America (PhRMA) appreciates the opportunity to comment on comparative effectiveness research and its role in improving the health care patients receive. PhRMA supports the development and use of high quality evidence, including comparative effectiveness evidence, for health care decision-making. Development of high quality evidence can support physicians' and patients' treatment decisions, consumers' decisions about health plans and benefit designs, and health plans' policy decisions. Proposals for expanding government-supported comparative effectiveness research should be structured to promote better patient health rather than to deny or delay patients' access to beneficial care, as occurs in Europe and Australia.

PhRMA has previously issued principles on evidence-based medicine and health outcomes research (attached), which encompass comparative effectiveness research. Consistent with these principles, programs for government-supported research should:

- Recognize and support the central role of the physician and patient in treatment decision-making;
- Provide information to support good decision-making; government or quasi-governmental organizations supporting comparative effectiveness research should not make coverage recommendations or decisions;
- Improve quality of patient care by identifying and supporting approaches to making better use of the evidence we already have about what works in health care;
- Support research to close evidence gaps across the health care system, including care management, health benefit and delivery designs, and the full range of treatments;
- Encourage pluralistic approaches that provide for multiple organizations to generate and evaluate evidence in patient-centered, clinically sensitive ways;
- Reflect emerging use of genomic, health information technology, and other advances ("personalized medicine") to tailor treatment decisions;
- Draw on a full range of evidence, including evidence on patient reported outcomes and consider both direct benefits and broader indirect benefits that are important to society, such as quality of life, patient functionality and economic productivity;
- Utilize open, transparent, patient-centered processes for setting research priorities, conducting research, and applying and communicating findings; and
- Ensure effective, balanced communication of results, including disclosure of the limitations of the findings.

PhRMA recognizes the value of expanding the amount of available evidence for health care decision-making. We also believe research on how to make better use of the evidence we already have about what works in health care needs to be an equally prominent part of any new effort's agenda. This latter type of work likely has the greatest potential to improve both outcomes and efficiency. For instance:

- A National Institutes of Health official has pointed out that if all heart patients were treated according to current guidelines, heart disease would no longer be the nation's number one killer.[1]
- Physician organizations have pointed out that there are treatments known to effectively control diabetes, yet many patients do not receive them.[2]
- A 2007 study in the journal *Health Affairs* estimates that if all patients with hypertension were treated to guideline, 89,000 premature deaths and 420,000 hospitalizations could be avoided annually—in addition to the 86,000 pre-

[1] Statement by Dr. Claude Lenfant, Director National Heart, Blood and Lung Institute. *Dateline NBC.* 21 May 2001.

[2] Agency for Health Care Quality and Research. Closing the Quality Gap: Diabetes Care Strategies. April 2004.

mature deaths and 8333,000 hospitalizations for heart attack and stroke already avoided.[3]

Research that determines how to close these and many other known gaps between what we already know and the care patients receive is a priority that needs to be included in any new health research initiative.

As part of this integrated approach, programs for comparative effectiveness research should include research to develop comparative evidence on care management approaches and benefit designs that ensure delivery of high quality care, rather than being limited to treatments and services. This broad agenda is defined in current statute (Sec. 1013 of the Medicare Modernization Act) but has yet to be fully implemented. The importance of pursuing this portion of the agenda is evident in recent reports of forward-looking employers who have achieved better health outcomes and savings by modifying their health benefit designs in ways that promote access to treatment for several chronic conditions, rather than by restricting access.[4] Likewise, academic studies have pointed to the importance of benefit design in determining health outcomes and costs.[5]

In addition, as the Committee considers expanding the government's role in comparative effectiveness research, it should ensure that the research questions that are relevant to patients, physicians and other health care providers are given a high priority. Having an open, patient-centered process for setting research goals and allowing patient and provider voices to be heard will ensure that comparative research benefits patients and providers.

PhRMA and our member companies are engaged in a number of activities to strengthen the field of comparative effectiveness research and enhance the evidence base. However, we also believe more can be done to strengthen the field of comparative effectiveness research and strengthen our health care evidence base.

While supporting steps to expand evidence on comparative effectiveness, we also recognize that this type of evidence can be misapplied as a blunt cost control tool through "one size fits all" coverage or payment policies. Physician and patient experience, a growing body of research, and the emerging science of molecular medicine all show why one size almost never fits all in medicine. Comparative effectiveness research should be used in ways that reflect differences in patient response to treatment and differences in individual clinical needs and preferences, and enable physicians to tailor treatment for the individual based on best available evidence.

Some proposals for creating a new comparative effectiveness research entity have pointed to the example of governments in other developed countries that use comparative and cost-effectiveness information. Experience with the use of comparative—and cost-effectiveness evidence in these countries illustrates the way it can lead to patient access restrictions on important medical advances. In the United Kingdom and Australia, patients face very significant restrictions on access to treatments based on the use of rigid comparative- and cost-effectiveness standards to establish centralized coverage policies. Patients who have diseases such as cancer, Alzheimer's disease, diabetes, osteoporosis, blindness, and rare diseases, have faced government-imposed access restrictions. These access barriers illustrate one of the major challenges of centralized government approaches to generating and using comparative and cost-effectiveness research, and the strengths of more pluralistic approaches.

The range of different proposals for government comparative research illustrates some of the important, unresolved issues in this area. Important issues to be addressed include clarifying the definition and goals of comparative effectiveness research; defining the scope of government-supported comparative effectiveness research; establishing patient-centered approaches to research priority-setting and communication; developing research methods to support high quality comparative effectiveness research; and understanding the relationship between comparative effectiveness research, personalized medicine, and health information technology.

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[3] D. Cutler, et al. **The Value Of Antihypertensive Drugs: A Perspective On Medical Innovation** *Health Affairs*, January/February 2007; 26(1): 97–110.

[4] Milt Freudenheim. To Save Later, Employers Offer Free Drugs Now, *The New York Times,* 21 February 2007.

[5] A. Chandra, Harvard University, et al., "Patient Cost-Sharing, Hospitalization Offsets, and the Design of Optimal Health Insurance for the Elderly," NBER Working Paper Series, Working Paper 12972, March 2007.

PhRMA looks forward to working with policy makers to address these issues and advance the field of comparative effectiveness research.

Statement of Society of General Internal Medicine

Mr. Chairman and Members of the Subcommittee:

Thank you, Mr. Chairman, for calling this hearing to address the issues surrounding comparative clinical effectiveness for improving healthcare and thereby the health of Americans. Your long record of fighting for the best possible health care for the American people is well-known and deeply appreciated by all of us who share your passion for improving a system that everyone in America knows has great strengths and very deep flaws.

We are testifying today on behalf of the Society of General Internal Medicine (SGIM), an organization comprised of approximately 3,000 academic general internists throughout the United States. SGIM exists to promote improved patient care, research, and education in primary care and general internal medicine. Our members are specialists in adult medicine, treating patients who often present with complex, multiple diseases—some chronic, some acute—in a healthcare system that sometimes works against the provision of the highest quality care.

As an organization, we are especially sensitive to the needs of minority and underserved populations, who suffer the most from inadequate access to quality care and the needless health consequences resulting from leaving otherwise minor conditions untreated.

We understand that comparative clinical effectiveness research will not cure all the ills of the health care system. However, we believe that such the development of the methods, individuals, and capacity to do such research and to translate its findings into practice will very significantly contribute to improving the quality of health care in this country. Moreover, the implementation of the results of such research could ultimately result in reductions in the costs of care, thereby allowing much needed improvements in access to care for underserved Americans.

As you know, Mr. Chairman, the FY08 Budget Resolution includes a provision authorizing the committees of jurisdiction in the House and Senate to establish a deficit neutral trust fund for comparative effectiveness research (CER) in healthcare. Because members of SGIM are leaders in the fields of clinical and health services research that form the basis for CER, because SGIM members are the leaders of the AHRQ and NIH research training programs that will need to produce those who will make such a national CER initiative possible, and because SGIM members are on the front line of delivering primary care, we fully expect they will play a major role in the development of this emerging sphere of research and its translation into clinical practice.

As the Subcommittee prepares to address this critical issue, SGIM would like to offer comments on a variety of aspects of the legislation you are developing, including (a) the location of the research infrastructure within the existing governmental health care structure, (b) the methods to assure that the research priorities chosen as well as the conduct and dissemination of the research that is undertaken are held to the highest scientific standards, free of political or other undue influence, (c) the sources of funding for this initiative, and (d) the substantive areas that need to be addressed to maximize the impact of this research.

No Need to Reinvent the Wheel

SGIM believes that the prioritization and governance of the conduct of comparative clinical effectiveness research is fundamentally a Federal Governmental responsibility. The federal responsibility for assuring that the provision of healthcare throughout the United States is of the highest quality should be unquestioned. No outside entity—whether for profit or non-profit—can demonstrate the strength, the independence, the commitment to all citizens' health, and the degree of acceptance that the Federal Government can. To "outsource" such a responsibility would call into question the seriousness of the commitment and could create a series of undermining unintended consequences.

Within the Federal Government, SGIM believes strongly that the Agency for Healthcare Research and Quality (AHRQ) is the natural home for any newly-developed CER program. Placing the program into an existing governmental agency saves both time and money during the initial—and crucial—implementation phase. CER is an important component of translational research. AHRQ's role in the De-

partment of Health and Human Services (HHS) is facilitating the translation of medical evidence into practice, which it accomplishes, in part, through its Evidence-Based Practice Centers, as well as through collaborations with the Food and Drug Administration (FDA) and the Centers for Medicare and Medicaid Services (CMS). AHRQ's role in leading the development and implementation of health information technology (HIT) to support the translation of such efforts into improved access and to further quality improvement and patient safety also would leverage its being the home for CER. Understandably and importantly, the national healthcare industry outside of HHS looks to AHRQ as the fair and committed leader and partner to fulfilling this translational role.

In addition, because AHRQ's authorizing statute already contains the mandate to address issues related to health disparities, locating the CER program in that Agency assures these critical issues will be addressed in any approved research and that they will be reported in the peer-reviewed scientific journal articles that result from that research.

Assuring an Objective and Independent Process

Ultimately, comparative clinical effectiveness is about the provision of quality health care. But, we would be naïve not to acknowledge that there are financial implications for the government, for private industry, for physicians, and for patients involved in nearly every decision that would be made in this field. For this reason, it is imperative that this research be undertaken under the most transparent, ethical and objective conditions possible.

First, the decision about what research to do—and not do—must be based on scientific standards that are widely recognized and accepted. Priority setting by AHRQ must be a public process in which all stakeholders—individuals and organizations—have the opportunity to make their case for what they believe to be the appropriate priorities. But the decisions on those priorities should be made by an objective advisory committee of career experts from within the government and nationally-recognized authorities outside the government with no conflicts of interest that could raise questions concerning the objectivity of the decisions made.

Second, the conduct of the research must be held to the highest ethical standards. SGIM believes that this research is best conducted at academic health centers and other similar institutions throughout the United States. Specific grant awards should be chosen by well-established practices by peer-review panels operating within the confines of the priority-setting described above. Research and researchers should be reviewed periodically by career AHRQ employees to assure the adherence to the high ethical standards.

Finally, it is critically important that the results of this objective research be made available and broadly disseminated to the American people and to the health care community in a timely and accurate manner. Therefore, concrete provisions should be included in the legislation to assure that no future Congressional Committee, no Executive Branch employee, and no Administration is able to delay or prevent the publication or dissemination of the results of this research.

Sources of Funding

As the Subcommittee delves into this initiative, it will be obligated to consider the source from which the resources to make it a reality will come. This question is, to an extent, a subset of the issue described above, as the sources of funding used can have a significant impact on the objectivity and independence of the project.

There is no question that Medicare Trust Fund money should and will be an important contributor to this effort. Medicare (and for that matter, Medicaid) stand to benefit greatly from the improvements in clinical effectiveness that will result from this concentrated research effort and it is reasonable that these funds will contribute to the investment needed to launch this initiative.

However, it is also undeniable that the private health insurance industry will also benefit from learning what medical procedures, processes, and products have the highest clinical utility for patients. Clearly, treating or curing people faster results in long-term cost savings that will inure to the benefit of the insurance industry. It follows that they should be active participants in making the investments that lead to the needed research.

The Subcommittee is uniquely positioned to devise a formula that will result in both the public sector and the private sector contributing to this initiative. It is important, however, that any formula used is broad-based and does not tie dollars invested to any specific research. To do otherwise would generate questions related to the independence of the research effort, specifically as it relates to the funding.

That would undercut the arms-length relationship that will be crucial for establishing the program's integrity.

The Needs for a Successful Comparative Clinical Effectiveness Research Initiative

Merely suggesting that there should be a stronger national effort in comparative clinical research, that it should be handled according to the highest scientific standards through AHRQ, and that it should be funded broadly will not lead to a successful, high impact, and sustained result. For the success of this potentially transforming healthcare initiative, it is critical that the Subcommittee be specific in identifying those issues that are currently not being addressed through existing research mechanisms.

To do this, SGIM recommends that the subcommittee create a six-part research program by statute to address the specific unmet needs of comparative clinical effectiveness research as called for in the Budget Resolution:

1. Capacity to Develop Reports Based on Current Knowledge

There is an almost unlimited amount of recent research, funded by the National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), AHRQ, and others, that has already been done that can provide the raw material to set in motion quickly research that will add significantly to our knowledge base of the comparative effectiveness of clinical treatments.

SGIM recommends that AHRQ use the infrastructure established by Section 1013 of the Medicare Modernization Act (MMA), but utilize not less than $25 million in the first year (with amounts growing each year after that) to expand the existing capacity beyond the current limited research that has been conducted as a result of the modest effort of the MMA. Such expansion would provide the wide range of data needed to leverage optimally current information to result in a measurable improvement in care.

The goal of this effort would be the production of a minimum of 80–100 reports yearly on a range of important healthcare issues with decision support for implementation.

2. Capacity to Develop New Understanding of Effective Care Based on Ongoing Care

While SGIM believes it is important to obtain the maximum benefit from existing research, we also believe in developing new understanding about effectiveness based on on-going care. Specifically, we would use, in part, the existing infrastructure of the Centers for Education and Research on Therapeutics (CERTs) and the Developing Evidence to Inform Decisions about Effectiveness (DeCIDE) Network for this purpose.

At the same time, we recommend the creation of additional capacity to develop new information on the effectiveness of treatments through the use of existing and developing public and private sector electronic medical records (EMR) systems. This would not create new databases, but would leave control of health records and data with the owners of the data—a distributive model. With greater emphasis being placed on EMRs, it is important that any CER program be positioned to capture data on EMRs for maximum benefit.

The objective of this effort would be to create methods and capacity to do research cheaper and faster (e.g., 6–18 month projects instead of multi-year multimillion dollar research) that takes advantage of the increased use of EMRs and HIT for assessing the outcomes of new and existing interventions for which full scale clinical trials are not necessary. It is anticipated that not less than $50 million could be expended on this effort in the first year, with the available funds growing each year thereafter.

3. Accelerating the Translation of New Information into Practice and Routine Healthcare Delivery

As indicated above, SGIM does not believe it is necessary or wise to reinvent the wheel in the implementation of this effort. We believe it is possible to use the existing infrastructure of networks including Accelerating Change and Transformation in Organizations and Networks (ACTION), the Primary Care Practice-based Research Networks (PBRNs), and AHRQ's Innovations Clearinghouse. These networks would be ideal for translating new information into practice and routine healthcare delivery, something that currently is lacking in our health care system.

The goal of this aspect of the program would be to expand the number of AHRQ's "learning collaboratives" that link cutting edge providers and health

plans with those seeking to emulate the national leaders in adoption of health information technology, patient safety, and quality improvement. In addition, it should be a stated objective of the legislation to create specific implementation roadmaps for proven interventions and to expand support for training and implementation teams. Not less than $50 million should be set aside in the first year to meet these important objectives, with the amount growing each year thereafter.

4. Demonstrate Approaches that Improve Efficiency and Reduce Waste

Currently, AHRQ provides very limited support for organizational redesign to improve efficiency by comprehensively addressing the structure and management of healthcare settings, as well as processes of care. SGIM recommends that this initiative be increased to not less than $40 million in initial year funding, with the available funding levels growing in each subsequent year.

The goal of this program is to use demonstrated and proven approaches for increasing the efficiency with which care is organized and delivered rather than the obtrusive traditional cost containment measures that often generate negative unintended consequences. We expect that this will generate patient and provider support for needed expansion of healthcare coverage in the context of limited resources.

In addition, we expect that this will create support for such models of improved efficiency being adopted by healthcare systems, clinics, and academic health centers that otherwise would be hesitant to risk redesign of their systems.

5. Increase Transparency on Value to Support Consumer Choice

AHRQ presently plays a number of key roles related to quality and value, including serving as the chair of the Ambulatory Quality Alliance (AQA) and the co-chair of the joint AQA–Hospital Quality Alliance Steering Committee, a leading role with the Quality Demonstration projects, and chair of the Quality Interagency Coordination (QuIC) Task Force of all Federal Departments and agencies with an interest in healthcare quality. In addition, it operates many public-private partnerships. Thus, it would be reasonable and practical for AHRQ to undertake the development of systems specifically designed to measure and report on healthcare performance. We would anticipate a need for not less than $30 million in the first year of this undertaking, with the funding growing substantially in subsequent years.

The first goal is for AHRQ to establish valid and robust methods to measure and report the quality of healthcare performance and to support transparency, accountability, and rewards that are fair and accurate, something that is currently very much in question and undermining trust in, and ultimately, the positive impact of, such efforts.

The second goal is to create sufficient capacity to assist in the implementation of such methods, including the use of voluntary, consensus-based standard-setting intended to harmonize measures across Federal agencies and across the entire healthcare industry.

6. Research and Research Training to Support Remaking Healthcare

SGIM believes that AHRQ can reasonably use not less than $75 million in the first year (with growing outyear funding) to apply existing approaches to funding peer-reviewed, investigator initiated research, research training, and career development to expand greatly the ability to address the wide and crucial needs for basic research in healthcare delivery, the development of new methods, and demonstrations of innovative approaches to improve healthcare, to train badly needed new researchers in this area, and to establish, support and retain early researchers' career development.

The very specific goal of this initiative is to establish the capacity for new innovative research and a cadre of researchers nationally that would be positioned to apply the innovations developed by biomedical researchers to improve the efficiency and effectiveness of healthcare delivery and, ultimately, to improve the health of our citizens with maximal efficiency.

SGIM estimates that the total first year funding for the six initiatives discussed above should not be less than $270 million. We also believe that the goal should be to grow this funding to not less than $1.0 billion per year at the earliest possible date. We would support the Subcommittee devising a mechanism to assure that the funds available are not artificially limited through binding statutory provisions that prevent fully addressing the need. Given that 17 percent of the Gross Domestic Product (GDP) is spent on health care, this is an

exceedingly modest proposal designed to elevate comparative clinical effectiveness research closer to its appropriate level within a well managed health care system.

Conclusion

This Congress has an enormous task, and an enormous opportunity, before it in addressing the shortcomings of the healthcare system. Forty-seven million Americans, including nine million children, are struggling without health insurance. Hospitals and physicians are subject to annual reduction proposals in Medicare reimbursement rates. States are feeling the strain of a Medicaid system that often treats the poorest people in the most expensive manner possible—in emergency departments.

In the face of these seemingly intractable problems, comparative clinical effectiveness is a research field whose time clearly has come. It will not solve everything that is wrong with the healthcare system. But, it is a strong, serious, positive step that this Congress and Administration can take together to improve the quality and the availability of healthcare for all Americans.

The Society for General Internal Medicine is a long-time advocate for the funding of such research and training for such research, with the ultimate objective of improving healthcare and health. Our mission is to promote improved patient care, research, and education in primary care—a mission that is core to every action and position we take. We are pleased and proud to participate in the debate over this important initiative and look forward to working closely with you, Mr. Chairman, and the other Members of the Subcommittee in the days and months ahead to help bring this proposal to fruition.

Thank you.