Testimony
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Statement of

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Introduction

Good morning, Mr. Chairman and Members of the Committee. I am very pleased to be here today to discuss the important issues of how we can facilitate, sustain, and promote health care innovation while we ensure that we have a health care system that is affordable. As my testimony will indicate, I believe that the work of the Agency for Healthcare Research and Quality (AHRQ) is critical to achieving these goals and complements the important work of the National Institutes of Health (NIH) and the Food and Drug Administration (FDA) and supports decision-making by the Centers for Medicare and Medicaid Services (CMS).

AHRQ's Role

Let me begin with a few words about where AHRQ fits within the Department of Health and Human Services. The basic and biomedical research supported by the NIH serves as the foundation for many of the advances in the prevention, diagnosis, and management of disease and impairment. Its work greatly expands the realm of possible public health and clinical interventions. While the Centers for Disease Control and Prevention (CDC) takes the lead on public health, community-based interventions often led by state and local health departments or public service media campaigns to improve health, AHRQ focuses on the role of clinical care and the health care delivery system.

AHRQ's mission is to improve the effectiveness, quality, safety, and efficiency of healthcare services that patients receive. What is unique about our mission is that it encompasses both the evaluation of the

effectiveness and quality of clinical services and the most effective and efficient ways to organize, manage, and safely deliver those services. As the Institute of Medicine report *To Err Is Human* made clear, this dual focus – on services and systems – is critical to improving health care.

AHRQ contributes to efforts to speed the diffusion of effective medical breakthroughs. Our research can extend the findings of biomedical research to populations not included in clinical trials, evaluate the effectiveness and cost-effectiveness of interventions to determine which populations benefit most, and develop effective strategies to facilitate their rapid adoption. We also facilitate adoption of new knowledge by putting into perspective the available scientific evidence so that clinicians can better assess the importance of recent breakthroughs.

In the area of drugs and devices that have received FDA approval, AHRQ focuses on their effectiveness (especially in comparison to existing options) and cost-effectiveness. We complement FDA's focus on the safety of drugs, biologics, and devices, with our focus on their safe use in daily practice. In the context of this hearing, this role is especially important. The harm that can result from inappropriate use of otherwise safe drugs, biologics, and devices is not only a tragedy for the patients involved but adds to health care inflation through the costs involved in attempting to repair the damage and related increases in medical liability expenditures. As a result, I am delighted to report that Dr. McClellan and I are developing an increasingly strong partnership between FDA and AHRQ in these areas.

However, innovations in health care are not limited to drugs and devices but may also include new surgical procedures, new applications of existing technology, information technology or communications

advances. Moreover, while some of these innovations offer unprecedented breakthroughs for some patients they may also result in unintended harm if not used appropriately. AHRQ's role, then, is to provide the best evidence regarding how to match specific services to patients' needs and preferences to promote the best possible outcomes.

Finally, we serve as a science partner for efforts by the Centers for Medicare and Medicaid Services to improve the effectiveness, quality, and safety of services they support and improve the ability of beneficiaries to make more informed health care choices. Prior to our 1999 reauthorization, we were required by law to make recommendations to CMS on coverage decisions. Today, upon request, we undertake technology assessments and other research activities to objectively synthesize all existing evidence on the effectiveness of medical interventions under consideration for coverage by CMS. We do not make recommendations.

Health Care Innovation and Health Care Costs

Mr. Chairman, America has a track record for health care innovation that is the envy of the world. The Administration and Congress in partnership have done much to accelerate and sustain that record through their commitment to biomedical and health care research. As a result, the pace of innovation has accelerated, the number of scientific journals and published research studies is exploding, and reports of scientific breakthroughs appear almost daily.

Many of these developments offer the potential for greatly improving the quality of life for patients; in

other cases the improvements are marginal at best. In some cases, innovation leads to the same or even higher quality of care at significantly lower costs while other innovation is cost increasing. The underlying challenge, therefore, is to effectively sort through the increasing array of clinical care options to develop objective scientific information so that those who make decisions – policymakers, systems managers, insurers, purchasers, clinicians, or patients – can make informed choices. The ultimate goal is to ensure that they can get real value for their health care dollar. Each of us may make different decisions as we weigh the evidence. My Agency's role is not to make those judgments. It is to develop and synthesize the evidence regarding health care interventions so that, whether you favor the current insurance-based system or favor a more consumer-driven model of health care decisionmaking, objective credible scientific information – on effectiveness, cost-effectiveness, and benefits (including down-stream cost savings) – is available to inform those decisions.

The need for such information has never been more compelling. Moreover, the resurgence of health care cost inflation at a time of increasingly constrained resources, both in the public and private sector, will only accelerate the demand for proof that we are getting real value for the health care dollars that we spend. Because our research focuses on both the effectiveness and cost-effectiveness of health care services as well as ways to improve the effectiveness, efficiency, and safety of the ways we deliver and use health care services, AHRQ is uniquely positioned to develop this type of scientific evidence.

How AHRQ Can Help

Let me suggest five broad areas in which AHRQ can assist in sorting through the array of new health care

innovation and help to speed the adoption of effective interventions.

First, AHRQ research identifies what is effective and cost-effective in daily practice.

Experience suggests that new drugs, technologies, and medical or surgical interventions are seldom equally effective for all types of patients. Will a breakthrough for the treatment of arthritis, tested in clinical trials with patients who only have that affliction, work as well in patients who not only have arthritis but are also taking medications for diabetes, congestive heart failure, and hypertension? Or how well does it work in patients whose racial, ethnic, and demographic characteristics differ from those in the clinical trial? Consider two examples from our research, one demonstrating the value of using the low-cost option; the other demonstrating the value of investing in much more expensive pharmaceuticals.

The first example, treatment of otitis media (middle ear infection), is the most frequent reason for administering antibiotics to children. Over-prescribing increases the chance for adverse reactions, leads to the development of bacterial resistance, and increases expenditures. AHRQ supported researchers found that the use of the less expensive generic antibiotics resulted in the same or lower failure rates. They concluded conservatively that substituting low cost antibiotics for only half of the expensive antibiotic prescriptions would have saved Medicaid nearly $400,000. This research has led to the development of guidelines by the American Academy of Pediatrics recommending less-expensive antibiotics and to a metric used to accredit health plans.

By contrast, in some cases, costly new interventions can reduce the long-term use of other health care resources. AHRQ research demonstrated that new, more costly anti-retroviral therapy for treating AIDS

patients is both effective and cost-effective. The increased expenditures for those drugs are much less than the savings in inpatient, outpatient, and emergency room costs. Overall annual costs per patient were reduced from $20,300 to $18,300. If extrapolated to the approximately 335,000 adults receiving care for HIV infection in 1996, over $500 million will be saved in HIV related healthcare.

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

Great opportunities for improving health, developed through biomedical research, are easily lost if physicians and patients are unable to make the best use of the knowledge in everyday care. These wasted opportunities are apparent daily in the under use of effective interventions and continued reliance upon outmoded approaches to patient care, which in turn contributes to the ever-increasing cost of care and avoidable loss of lives. By conducting and supporting research that focuses on their effective use, and working with clinicians and health care organizations to assure that this information is accessible when decisions are made, AHRQ ensures that Americans reap the full rewards of basic research and medical innovation.

For example, NIH-supported research identified the potential of warfarin, a blood thinner, to reduce the risk of stroke in patients with atrial fibrillation. But physicians seldom prescribed warfarin for their patients. AHRQ-supported researchers concluded that warfarin was effective in daily practice, identified the reasons that physicians were reluctant to use warfarin, and developed a program of providing warfarin that would have an expected annual net savings of $1.45 million per 100,000 people aged 65 years or older, of whom 6,000 would be expected to have atrial fibrillation. Using this knowledge, Medicare Peer

Review Organizations implemented projects to increase anticoagulation, and 28 projects in 20 states had a 58-71% increase, with a projection of 1,285 strokes prevented. The findings of this AHRQ funded study were influential in the development of guidelines by the American College of Physicians, American Heart Association, American College of Chest Physicians, and the Joint Council of Vascular Surgeons. Based on this work, United HealthCare has included use of anticoagulation therapy for patients with atrial fibrillation in the profiling of its 262,000 physicians.

Third, AHRQ facilitates the use of Evidence-Based Medicine.

In recent years AHRQ has focused increased attention on the development of technology and tools to facilitate the use of evidence-based medicine. For example, each year tens of thousands of patients, who go to an emergency department worried that their chest pain is being caused by a heart attack, are inappropriately sent home, inappropriately hospitalized, or suffer because of delay in treatment due to an inconclusive electrocardiogram (EKG). These delayed or missed diagnoses have serious implications for patient survival or impairment rates, hospital costs and subsequent malpractice lawsuits. An increasing number of EKGs are now equipped with special software developed by AHRQ research that improves diagnosis by predicting the likelihood of whether chest pain is the result of a heart attack. The software could prevent 200,000 unnecessary hospitalizations and more than 100,000 coronary care unit admissions a year and save roughly $728 million a year in hospital costs if implemented in half of the hospitals nationally. Soon-to-be-published research estimates that improved accuracy of diagnosis that results from use of this predictive tool could reduce malpractice costs nationally by $1.2 billion per year.

Approximately 600,000, or 15 percent, of the 4 million Americans who develop pneumonia each year are

hospitalized. Because of the lack of evidence-based admission criteria and the tendency to overestimate the risk of death, many low-risk patients who could be safely treated outside the hospital are admitted for inpatient care. An easy-to-use method developed by AHRQ-supported researchers accurately predicts which pneumonia patients can be safely treated at home, which costs 10 to 15 times less than hospital care for pneumonia. The findings from this study also suggest that hospitals could reduce pneumonia hospital stays in many cases by 1 day without adversely affecting patient health. Criteria were developed to assist physicians with determining when patients could be discharged safely.

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

With Medicaid pharmaceutical costs increasing 20% per year, States are considering and implementing a variety of cost containment strategies. An example of how our past research can be helpful to today's decisionmakers involves a study of an initiative by a New England legislature to limit Medicaid reimbursement to three prescriptions per month. AHRQ concluded that the strategy back-fired. Increases in utilization costs were 17 times greater than the savings in drug expenditures. The result was that the state abolished the prescription cap, and another 9 states have also changed their policies based on this research.

AHRQ research has also demonstrated that 85% of women with pelvic inflammatory disease, the leading cause of infertility, can be safely and effectively treated as outpatients, and developed an evidence-based approach to identify which nursing home patients require hospitalization for possible pneumonia and which can be treated at the nursing home. This approach not only saves the cost of a hospitalization but

also helps frail, elderly patients avoid the risks of experiencing additional hospital complications.

Fifth, AHRQ's role in speeding the pace of evaluation of health care innovation.

AHRQ's 1999 reauthorization directed us to serve as a science partner for public and private sector efforts to improve quality and urged us to continue our efforts, begun in the mid1990s, to speed the pace of the evaluation of health care innovations.

One of the critical roadblocks to coverage of innovative interventions is the lack of solid scientific evidence regarding their effectiveness, especially in comparison with existing interventions. While the FDA determines that a drug, biologic, or device is safe and that it has an impact when compared to placebo, those making coverage decisions, including clinicians and patients, still need more information regarding its relative effectiveness and relative costs. Similarly, promising biomedical research breakthroughs face a similar test. This is often frustrating for those whose creativity leads to the development of promising new technologies as they come to realize that passing FDA scrutiny is only part of the journey toward seeing their innovation in widespread use.

While these constraints are not of AHRQ's making – and are certainly not unique to the public sector; the private sector takes technology assessment seriously as well – we have begun, and will continue, our efforts to facilitate the speed of this process. For example, when Medicare asked us to evaluate the effectiveness of lung-volume reduction surgery, we concluded that there was insufficient evidence to reach a determination at that time. But we pointed out to Medicare the potential for developing the evidence through an innovative process of conditional coverage – in which Medicare would pay for the

procedure in selected institutions, provided the surgeons and patients agreed to the collection of outcomes data. This resulted in a partnership between Medicare, the National Heart Lung and Blood Institute, and AHRQ to assess the procedure. As a result of this study, we now know which patients are likely to benefit, and very importantly, a subgroup of patients who experienced increased mortality as a result of the procedure were identified so that avoidable and unintended deaths can be reduced.

Similarly, AHRQ has revamped its ability to provide Medicare with much more timely scientific advice, in as little as two weeks for brief assessments of the volume of available evidence to full-scale technology assessments that might take a year. These time frames reflect as significant improvement in our ability to serve Medicare more effectively.

There are at least two other ways in which we can serve as a science partner for private sector innovation. First, most technology assessments conclude that there is a lack of credible scientific studies from which to judge whether a technology is effective or ineffective. We are prepared to work with industry trade associations to assist their members, who have products moving to the end of the FDA review process, to better understand the types of studies that will be needed to assess the effectiveness of their products. This simple step would make a significant contribution to facilitating timely assessment of health care innovation.

Second, in future years, as existing patient safety grants end, we will want to expand our focus on human factors research. As one wag commented, human factors research helps us to "idiot proof our technology." More accurately, this research helps us to develop controls for our technologies so that they

remain easy to program even by a harried, stressed, distracted, sleep-deprived health care professional. One example is the infusion pumps, used to administer fluids to patients through their veins, that are often involved in patient safety adverse events. Human factors research would help us to understand approaches for reducing inadvertent errors in programming these pumps. As we expand our support for human factors research within our patient safety portfolio we will want to work with industry to ensure that we are targeting the critical questions that will improve the safety and quality of the products they design in the future. By ensuring that this type of critical information in the public domain, we can be a science partner for their efforts to develop even more effective and safe health care technologies.

AHRQ's New Direction

Mr. Chairman, before concluding, I would like to say just a few words about the future direction of AHRQ. As you know, I have been serving as Acting Director since March, 2002 and Director now for five months. During that time, our senior staff and I have undertaken a top to bottom review of our procedures and processes to determine how we can better fulfill the mandate of our 1999 reauthorization legislation to serve as a science partner for public and private sector efforts to improve quality.

We are determined to make AHRQ a "problem solving" agency. This entails a greater focus on "implementation research" that is designed to develop strategies for overcoming barriers to the adoption of clinical interventions that are both effective and cost-effective. We need to be more pro-active in closing the gap between what we know is effective and cost-effective in health care and what is done in daily practice.

We have developed closer linkages, at every stage of the research process, between the ultimate customers of our work and researchers, to ensure that we are addressing their highest priority challenges. In the public sector, we are beginning to work more closely than ever before with Medicare, Medicaid, the Community Health Centers, the Federal Employee Health Benefit Program, and the Departments of Defense and Veterans Affairs.

We also will be giving greater priority to identifying strategies for eliminating waste, assuring that evidence-based information is current, bringing our health care infrastructure, especially information technology, into the 20th century, redesigning workflow so that health care professionals can work more efficiently and effectively, and evaluating our financial and other incentives to ensure that we encourage safe, high quality care.

Conclusion

Mr. Chairman, in conclusion, let me note that one study demonstrated that the time frame from the approval of a research grant that ultimately yields useful findings to the widespread diffusion and adoption of those results was at least 17 years. That time frame is unacceptable. AHRQ is committed to playing its role in developing the scientific evidence for identifying effective interventions sooner and increasing the pace of their diffusion.

This concludes my formal testimony. I will be happy to respond to any questions.