



Testimony of
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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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