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The Role and Scope of Comparative Effectiveness in Our Evolving Health Care System: Balancing Treatment Choices with Budget Reality

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Advances in medical technology have revolutionized how health care is delivered in the United States. Innovative medical device manufacturers have contributed significantly to improved patient outcomes, their quality of life, and how physicians practice medicine. Consider how scopes moved many invasive, high-risk inpatient procedures to non-invasive, lower-risk outpatient procedures. But these innovations come at a price. Makers of traditional medical devices and combination products (sophisticated technologies combining medical devices with drugs or biologics) spend millions upon millions of dollars annually to research, develop and ultimately market these new treatment options (pharmaceutical and biotech companies are, of course, also part of this equation). Physicians and consumers alike are faced with an array of studies and promises of improved patient outcomes resulting from their use of such technologies.

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The U.S. Food and Drug Administration (''FDA'') does not require comparative studies to determine that a medical device is safe and effective for its intended use. And the Centers for Medicare & Medicaid Services (''CMS'') does not require comparative studies to determine that a medical device is reasonable and medically necessary to treat Medicare patients. It should come as no surprise, therefore, that there is limited empirical evidence comparing new technologies with those on the market, or comparisons of alternative treatments, which, as will be discussed below, are not always easy to identify.

Both the government and industry have debated the concept and merits of comparative effectiveness research for more than 20 years, but have made only relatively small-scale forays into this arena. Now, with the continued rise in healthcare costs in the U.S., due in no small part to costly new treatment options (with most fingers pointing towards pharmaceutical manufacturers), policy-makers are more closely examining the idea of comparative effectiveness research, and it seems almost inevitable that a much more robust government-sponsored comparative effectiveness research and implementation regime will become a reality. Exactly what that reality may look like and when it will take shape remains an open question.

Comparative Effectiveness—What Is It?

The term ''comparative effectiveness'' itself is open to various interpretations, although most people agree that it captures a certain core concept. Comparative effectiveness represents a comparison of ''the effectiveness of two or more health care services or treatments,'' as it ''compares outcomes resulting from different treat-

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ments or services, and provides information about the relative effectiveness of treatments.''[1] It has also been defined as a ''rigorous evaluation of the impact of different options that are available for treating a given medical condition for a particular set of patients,''[2] or an evaluation and comparison of ''the clinical effect of alternative medical treatments.''[3]

The specific details surrounding comparative effectiveness research can be much more contentious and open to debate. For instance, how should effectiveness be measured, by the effect in routine clinical practice, or under optimal conditions? Also, should costs be included in such research? If so, should those costs be reported separately from effectiveness results, or should a ''cost-effectiveness ratio'' be the goal of such research?[4]

Why Comparative Effectiveness?

Regardless of the exact definition of comparative effectiveness, there is relative consensus among stakeholders that providing more and better quality medical evidence concerning treatment, prevention, and management of health conditions allows patients, providers, and health insurers to make more informed decisions about medical treatments.[5] As AdvaMed, a trade association for the medical device industry, has stated, comparative effectiveness is one ''tool to improve clinical outcomes and promote access to quality care.''[6]

Underlying and intermingled with much of the discussion of clinical comparative effectiveness is cost. Health care costs have risen dramatically and now account for approximately sixteen percent of the U.S. Gross Domestic Product.[7] The upward trend shows no signs of slowing, and policy-makers continue to grapple with how to address the issue.

Sen. Max Baucus (D-Mont.), a leading proponent of comparative effectiveness, has stated, ''more evidence on what works and doesn't work can lead to better health care decisions and thus to improved quality of care, improved efficiency, and ultimately to the potential for cost savings throughout the health system.''[8] The Congressional Research Service has also concluded that using comparative effectiveness information would help to use limited resources effectively and efficiently, which will become ''even more necessary as resources become more limited, variation in medical practice patterns persist, and the rate of health care spending continues to rise.''[9] Finally, the Congressional Budget Office has speculated that ''over the long term, the combination of additional information and revised incentives would tend to reduce spending for health care below currently projected levels, potentially to a substantial degree.''[10]

The inclusion of cost-effectiveness as a component of comparative effectiveness research would likely have a larger effect on medical treatment and practice than analysis of only the comparative clinical effectiveness of various treatments, ''primarily because the results would sometimes highlight that benefits were small relative to the incremental costs.''[11] Yet there is substantial debate about whether cost should be included at all in any comparative effectiveness assessment, or whether the realization of cost savings from better clinical information alone is as far as any cost consideration should go.

When one considers the real budget constraints our health care system faces, it seems very reasonable to recognize and acknowledge that cost is a factor and needs to be considered. To be consistent, however, with other federal policy and law designed to eliminate cost considerations from medical decision making (e.g., Federal Anti-kickback statute and Stark Self Referral laws), then there is no place for cost effectiveness in the comparative effectiveness equation. To put it simply, if we do not want physicians' medical judgment to be clouded or driven by financial considerations in the Anti-kickback or Stark sense, then the federal government, whether by legislation or regulation, should not be permitted to impose or influence physicians' treatment decisions through comparative cost effectiveness considerations. Consistency, however, is not a strong suit of our federal government, and particularly CMS. Over the years, CMS has, in several instances, utilized its regulatory discretion to limit payments for new technologies to those made for existing ''comparable'' technologies. To challenge these decisions, one has to succeed in convincing CMS that two or more technologies are not truly ''comparable.''

There remains, therefore, an uneasy tension between the dual goals of purely improving clinical outcomes and realizing costs savings from comparative effectiveness research. The goals of better clinical outcomes and costs savings may be compatible on a large scale. Applying a comparative effectiveness model that integrates cost effectiveness on a patient-by-patient basis may prove challenging. Many members of Congress place a premium on the physician-patient relationship and believe, appropriately so, that medical decisions and treatment options are very personal ones that should be made between a physician and the patient. Seemingly aware of this dynamic, the Congressional Budget Office has stated, ''better information about the costs, risks, and benefits of different treatment options, combined with new incentives reflecting the information, could eventually alter the way in which medicine

[1] ''Comparative Clinical Effectiveness and Cost-Effectiveness Research: Background, History, and Overview,'' Congressional Research Service (October 15, 2007), 4.

[2] ''Research on the Comparative Effectiveness of Medical Treatments,'' Congressional Budget Office (December 2007), 3.

[3] Floor Statement of Sen. Max Baucus (D-Mont.) Regarding Introduction of The Comparative Effectiveness Research Act of 2008 (August 1, 2008).

[4] CRS, ''Comparative Clinical Effectiveness and Cost-Effectiveness Research: Background, History, and Overview,'' 4.

[5] Floor Statement of Sen. Max Baucus.

[6] AdvaMed, ''Comparative Effectiveness Legislation,'' (March 2008).

[7] CBO, ''Research on the Comparative Effectiveness of Medical Treatments,'' 1.

[8] Sen. Max Baucus, ''Comparative Effectiveness Research Act of 2008'' (August 1, 2008).

[9] CRS, ''Comparative Clinical Effectiveness and Cost-Effectiveness Research: Background, History, and Overview,'' 1.

[10] CBO, ''Research on the Comparative Effectiveness of Medical Treatments,'' 28.

[11] *Id* at 26.

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is practiced and yield lower health care spending without having adverse effects on health.''[12]

However, at times the goals may be mutually exclusive. Comparative effectiveness research very well may lead to instances of cost/benefit analyses of treatments that many people are uncomfortable with, and raises numerous troubling questions. For instance, at what point does a proven incremental health benefit justify a vastly increased cost? In an era of fixed resources and increasingly tight domestic budgets, does that benefit justify spending those resources in such a fashion? And who makes those decisions—patients, physicians, private health insurers or the federal government?

There also exists the question of why the profile of the comparative effectiveness debate has risen to a level never seen before. The concept has been in existence for more than two decades, but only recently has there been so much focus on it. Is it a pure desire for improved clinical outcomes that is engaging policymakers, or is money the real driving force?

History of Comparative Effectiveness Debate

The history of the comparative effectiveness debate demonstrates that both Congress and industry are unwilling to accept cost-based definitions of comparative effectiveness. CMS and its predecessor agency were rebuffed in previous efforts to inject cost-effectiveness determinations into the Medicare process. Recently, the pressure to implement more comparative effectiveness research has come from Congress, which seems determined to keep cost factors out of the research itself, at the same time that it promotes comparative effectiveness research as a driver for cost savings in the national health care system.

Agency Initiatives

Debate about comparative effectiveness, or versions of it, is not new, and its history is very much intertwined with debate about the cost of health care. The Health Care Financing Administration (HCFA), the predecessor agency to CMS, was the first federal entity to highlight the issue of cost-effectiveness in health care coverage determinations. In 1989 it issued a proposed rule that outlined cost-effectiveness as a key component of the coverage process. The rule would have included cost-effectiveness as a factor in determining whether a treatment was reasonable and necessary.[13] However, the rule was never finalized, as HCFA received so much opposition from industry in particular, that it withdrew the rule and never re-issued it.[14]

Despite HCFA's withdrawal of the 1989 proposed rule, in the late 1990s, a congressionally-mandated report was issued showing that HCFA used comparability to alternative services as one of three coverage criteria, demonstrating that cost was in fact a central element in its coverage and payment analyses.[15] The report stated in part:

> Comparability is an additional criterion which allows for refining coverage/payment decision in cases where services are found to be more costly, but no more effective than the closely related alternatives. When such a finding is made, the service may be covered and paid at the rate of the lower cost alternative, or limited to specific patients or conditions for which it has been found more effective than the alternative services. The objective of this criterion is to assure value for the Medicare program and its beneficiaries.[16]

It is worth noting that this report flowed from the National Emphysema Treatment Trial or NETT, which was designed to compare lung volume reduction surgery (''LVRS'') to pulmonary rehabilitation. The NETT was the byproduct of HCFA's national non-coverage decision of LVRS. The agency enlisted the National Institutes of Health to conduct the multi-centered trial to compare LVRS to pulmonary rehabilitation. There were several questions and challenges raised about the study design. In fact, one medical center's Institutional Review Board did not approve of the study, questioning the ethics of randomizing late-stage emphysema patients to LVRS or pulmonary rehabilitation without the opportunity for cross-over for the surgery, when a qualified LVRS candidate needed to first ''max out'' on pulmonary rehabilitation. This experience illustrates that defining comparable treatment options is no easy task. Even NIH decisions on this front have not gone unchallenged.

Then, in 2000, HCFA published a notice of intent to publish a proposed rule on the topic. The notice stated that such a rule would be intended to clarify the definition of ''reasonable and necessary'' to require that new treatments provide ''added value.''[17] Yet again, HCFA never published such a proposed rule.[18]

Despite past indications that CMS would like to include cost considerations into coverage and payment analyses, currently, as a practical matter, Medicare will cover any treatment or procedure that has net medical benefits, *i.e.* ''benefits that outweigh the risks of the procedure—regardless of its cost or its effectiveness relative to alternative therapies.''[19] In fact, Medicare is ''effectively precluded from taking costs 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.''[20]

While CMS has used comparative clinical effectiveness research on a limited basis in making certain Medicare coverage determinations, *e.g.*, not to cover lumbar artificial disc replacement,[21] CMS's coverage guidance specifically states that ''cost effectiveness is not a factor CMS considers in making national coverage determinations,'' and that ''cost is not a factor in our review or determination to cover a particular tech-

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[12] *Id* at 1-2.

[13] *Id* at 31.

[14] Michael M. Gaba, ''Developing Integrated Product Approval and Reimbursement Strategies in the Absence of Clear Rules,'' Medical Device & Diagnostic Industry Magazine, (September 1999).

[15] *Id*.

[16] Donna E. Shalala, HHS, ''Lung Volume Reduction Surgery and Medicare Coverage Policy: Implications of Recently Published Evidence'' (report to Congress, 1998), 7.

[17] CBO, ''Research on the Comparative Effectiveness of Medical Treatments,'' 31.

[18] Rolf Rosenkranz, ''Baucus Plans Comparative Effectiveness Reforms,'' InsideHealthPolicy.com (January 8, 2008).

[19] CBO, ''Research on the Comparative Effectiveness of Medical Treatments,'' 32.

[20] *Id.* at 29.

[21] ''Baucus Plans Comparative Effectiveness Reforms.''

nology.''[22] While it may be true that CMS does not factor cost considerations into *coverage* determinations, i.e., answering the question will it pay, it is not precluded from taking into account cost for *payment* determinations, i.e., answering the question how much it will pay. Establishing a relatively low payment level will produce a *de facto* non-coverage determination.

According to The Medicare Payment Advisory Commission (''MedPAC''), an independent Congressional agency established to advise the U.S. Congress on issues affecting the Medicare program, ''there is not enough credible, empirically-based comparative effectiveness information available to patients, providers, and payers to make informed treatment decisions.''[23] Yet this state of affairs is due in no small part to the fact that there has been very limited demand for such research from the Medicare program, which remains the single largest and most influential payor of health care services.

Congressional Initiatives

Since 2000, CMS has not made large-scale public efforts to include comparative effectiveness analyses in their coverage or payment determinations. Yet Congress has picked up the mantle, and has increasingly become a driving force for change and implementation of comparative effectiveness research. In contrast to HCFA's efforts, however, Congress has shied away from introducing cost into any comparative effective analysis, and has dictated that CMS do the same.

As part of the 2003 Medicare Modernization Act (''MMA''), Congress authorized the Agency for Health Care Research and Quality (''AHRQ'') to spend up to $50 million in 2004, and additional amounts in future years to conduct and support research on ''outcomes, comparative clinical effectiveness, and appropriateness of health care items and services'' for Medicare and Medicaid.[24] Actual funding appropriated under that authority has averaged approximately $15 million per year.[25] At the same time, Congress prohibited CMS from using comparative effectiveness data to withhold coverage for a prescription drug.[26]

Congressional interest in comparative effectiveness has increased dramatically over the past several years, as Congress sees such research as a means to both identify the most effective treatments, and to reduce health care costs.[27] For instance, in the spring of 2007, Sen. Baucus introduced a Medicare Part D price negotiation bill would have required the Department of Health and Human Services (''HHS'') to develop a prioritized list of comparative effectiveness studies.[28] In May of last year, Reps. Tom Allen (D-Maine) and Jo Ann Emerson (R-Mo.) introduced the bipartisan Enhanced Health Care Value for All Act of 2007 (H.R. 2184), which authorizes $3 billion for comparative effectiveness research and established a public-private funding mechanism for comparative effectiveness research, to be overseen by an independent advisory board.[29] The House-passed Children's Health and Medicare Protection (CHAMP) Act would have established a public-private funding mechanism for comparative effectiveness research funded by a trust fund and overseen by an independent commission. This provision was not included in the House and Senate-passed Children's Health Insurance Program Reauthorization Act of 2007, which the President vetoed. Also, in June of 2007, the House Ways and Means Subcommittee on Health held a hearing on comparative effectiveness. Despite all of this congressional activity, there was no definitive movement on comparative effectiveness research in 2007.

Baucus has continued to push hard to establish a comparative effectiveness regime. He introduced legislation early in the spring of 2008 that would do so, although he very quickly withdrew the bill because of jurisdictional problems.[30] Following a July 17 Senate Finance Committee hearing, Baucus re-introduced The Comparative Effectiveness Research Act of 2008 (S. 3408) with modifications on July 31, 2008. This legislation has served as the basis for much of the current debate over comparative effectiveness.

According to the senator, the legislation ''would create a new entity responsible for generating better information on the effectiveness of health care treatments.''[31] The Health Care Comparative Effectiveness Research Institute would be a nonprofit corporation dedicated to researching the clinical comparative effectiveness of health care treatments including pharmaceuticals, medical devices, and surgical procedures without considering cost or health plan design factors.[32] However, it would also include an expert methodology committee that would be responsible for studying whether comparative effectiveness research should incorporate cost or health plan design.[33] The Institute would receive its funding through a combination of general revenues, the Medicare Trust Fund, and fees assessed to health insurance plans.[34]

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[22] CRS, ''Comparative Clinical Effectiveness and Cost-Effectiveness Research: Background, History, and Overview.''

[23] CRS, ''Comparative Clinical Effectiveness and Cost-Effectiveness Research: Background, History, and Overview,'' 1-2.

[24] Medicare Modernization Act, § 1013, Research Outcomes of Health care Items and Services, (2003)

[25] CBO, ''Research on the Comparative Effectiveness of Medical Treatments,'' 10.

[26] Medicare Modernization Act, § 1013.

[27] AdvaMed, ''Comparative Effectiveness Legislation.''

[28] CRS, ''Comparative Clinical Effectiveness and Cost-Effectiveness Research: Background, History, and Overview,'' 2-3.

[29] ''Comparative Effectiveness Legislation''; CRS, ''Comparative Clinical Effectiveness and Cost-Effectiveness Research: Background, History, and Overview,'' 2-3.

[30] Rolf Rosenkranz, ''Senate's Comparative Effectiveness Bill Lacked Tax Focus,'' InsideHealthPolicy.com (April 4, 2008).

[31] Floor Statement of Sen. Max Baucus.

[32] Amy Lotven, ''Baucus Drops Comparative Effectiveness Bill Funded Through Private/Public Partnership,'' InsideHealthPolicy.com (August 1, 2008); BNA *Medical Devices Law & Industry Report*, ''Senators Propose Nonprofit Institute Created to Study Comparative Effectiveness'' (2 MELR 524, 8/13/08).

[33] BNA, ''Senators Propose Nonprofit Institute Created to Study Comparative Effectiveness.''

[34] ''Baucus Drops Comparative Effectiveness Bill Funded Through Private/Public Partnership.''

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A medical device industry group has cautioned that any comparative effectiveness regime must take into consideration the unique role that medical technologies would have in such research and highlight the differences that exist between drugs and medical devices.

Baucus stated that ''doctors and patients need reliable, unbiased information about the effectiveness of treatments to determine the best care possible . . . this bill will advance the process of reviewing and producing valuable information and making it available to health care providers, and to all Americans.'' Sen. Kent Conrad (D-N.D.), the co-sponsor of the legislation further stated that doing more comparative effectiveness research will allow ''patients and their doctors [to] make better decisions on treatment—meaning we could lower costs and improve health care outcomes.''[35] Implicit in such statements is that while Congress is unwilling to insert cost considerations into comparative effectiveness research now, research supporters point to cost savings, and not pure clinical outcomes, as a driving force for initiating large scale research now, as health care costs are skyrocketing.

Medical Industry Reaction

While industry has been largely supportive of comparative effectiveness research in principle, it remains concerned about its implementation and implications in practice. It is natural to support initiatives that will give physicians better information with which to make medical decisions. It is more difficult to support initiatives that pit one technology against another with cost potentially being a key factor. It remains unclear who among the stakeholders will bear the economic cost of conducting this additional research. What is clear is that the medical device industry will bear the burden of carrying its investment costs until such additional data support appropriate coverage and reimbursement. And of course its R&D investments may never be recouped if the new technology is shown to be less effective than existing treatments and/or to not meet a real or perceived cost/benefit standard either now or in the future.

The Pharmaceutical Research and Manufacturers of America (''PhRMA'') has stated that it ''supports the development and use of high-quality evidence, including comparative clinical effectiveness evidence, for healthcare decision-making.''[36] PhRMA has also created a set of principles to ''establish a framework to help ensure government-supported health outcomes research, including research on comparative effectiveness, meets patients' needs and supports improvements in medical care.''[37]

The Biotechnology Industry Association (''BIO'') also ''strongly supports efforts to increase the availability of accurate, scientific evidence to inform clinical decision-making . . . . When appropriately applied, comparative effectiveness information is a valuable tool that, together with a variety of other types of medical evidence, can contribute to improving health care delivery.''

Yet, ''BIO is concerned that comparative effectiveness information may be used strictly as a means to contain costs, rather than deliver health care value by improving patient health outcomes.''[38] To that end, BIO also has developed its own set of principles on comparative effectiveness research.[39] BIO has also cautioned that ''care must be used to make sure that there is a common understanding of what is meant by the term comparative effectiveness,'' and that ''any comparative effectiveness study can be useful to inform the clinical judgment and individual needs in medical decision-making as long as the limitations of each study are known.''[40]

AdvaMed has stated that it 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, including non-treatment as a potential option.''[41]

AdvaMed's principles regarding comparative effectiveness include that only clinical effectiveness, and not cost-effectiveness be considered in any study, that Congress should explicitly prohibit using comparative effectiveness to deny individuals Medicare coverage, and that device manufacturers, along with other stakeholders, be included in discussions regarding comparative effectiveness policies.[42]

AdvaMed has commented on Baucus's legislation, stating that it was pleased that the bill would not authorize cost-effectiveness studies, adding, ''As Congress considers comparative effectiveness legislation, we believe safeguards should be included to ensure that the final determination of what treatment option works best for each patient should be made by individuals and their physicians.''[43] Similarly, the Medical Device Manufacturers Association (''MDMA'') has stated that

[35] BNA, ''Senators Propose Nonprofit Institute Created to Study Comparative Effectiveness.''

[36] ''PhRMA Statement on Comparative Effectiveness Bill'' (March 5, 2008).

[37] ''Health Outcomes Research: Principles for Government-Supported Health Outcomes Research on Medical Technologies and Services,'' PhRMA, available at http://www.phrma.org/health_outcomes_research.

[38] ''Comparative Effectiveness: Supporting Patient-Centered Care to Improve Health Outcomes,'' Biotechnology Industry Organization, available at http://bio.org/healthcare/compeffective/main.asp?p=yes.

[39] *See* Ted Buckley, Ph.D, ''The Complexities of Comparative Effectiveness'' (2007).

[40] ''BIO Challenges Comparative Effectiveness Application in White Paper,'' FDALegislativeWatch (November 21, 2007).

[41] ''Government-Funded Comparative Effectiveness Research,'' AdvaMed (October 24, 2007).

[42] ''BIO Challenges Comparative Effectiveness Application in White Paper.''

[43] BNA, ''Senators Propose Nonprofit Institute Created to Study Comparative Effectiveness.''

it will ''advocate the point that comparative effectiveness research should be truly about effectiveness and not about cost.''[44]

The device industry's support of comparative effectiveness research has been more qualified than that of the pharmaceutical or biotechnology industry, as the nature of devices makes comparative effectiveness studies somewhat challenging to apply to such products. [45] In contrast to individual drugs which remain on the market, unchanged, for long periods of time, devices are often developed in a short-turnaround, iterative fashion.[46] To that end, AdvaMed's President &CEO Steve Ubl has cautioned that it is ''essential that research recognize the unique iterative nature of device innovation when establishing research priorities and conducting studies.''[47] MDMA has also cautioned that any comparative effectiveness regime ''take into consideration the unique role that medical technologies would have in comparative effectiveness research and [] highlight the significant differences that exist between drugs and devices.'' [48]

Insurance Industry Reaction

In contrast, the private insurance industry has been extremely supportive of comparative effectiveness research, and has not shied away from expressing its support for the idea, based largely on cost considerations. For instance, the Blue Cross and Blue Shield Association has stated, ''To improve tomorrow's healthcare coverage we need to change the incentives in today's healthcare system.'' Comparative effectiveness research ''will empower patients and providers by providing information on quality and value, and improve safety and affordability of healthcare for everyone.''[49]

The Pharmaceutical Care Management Association believes that ''comparing the clinical effectiveness of competing drug therapies is an important tool in promoting value-based purchasing.''[50] Finally, America's Health Insurance Plans has indicated ''support for including cost considerations in comparative effectiveness research.''[51]

The Future of Comparative Effectiveness

Access to affordable health care remains a premier concern for Americans, regardless of their political persuasion. It is right up there with the price of gasoline as our top domestic priority. So regardless of who wins the presidential election, now only weeks away, we can and should expect comparative effectiveness legislation to be a key component of any health care policy debate during the 111th Congress. With Democrats expected to gain seats in both the House and Senate, Finance Committee Chairman Baucus likely will feel emboldened to press ahead with his comparative effectiveness legislation.

With the insurance industry in full support of head-to-head clinical trials envisioned by comparative effectiveness purists, the pharmaceutical, medical device, and biotech industries will need to be savvy in their advocacy to continue to support the overarching goal of comparative effectiveness research, i.e., to produce more insightful medical data, leading to higher quality affordable care for more Americans, while guarding against the infiltration of cost-effectiveness into the comparative effectiveness equation.

Our health care policy-makers need to be sensitive to the proper balance when pursuing the comparative effectiveness program. Controlling health care costs is a laudable and necessary goal—but it should not be done at the expense of dampening the innovative and entrepreneurial spirit represented by the medical device industry and its brethren in the pharmaceutical and biotech worlds.

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[44] ''Comparative Effectiveness Legislation Reintroduced,'' MDMA Update, (August 2008).

[45] ''BIO Challenges Comparative Effectiveness Application in White Paper.''

[46] *Id*.

[47] ''Baucus Drops Comparative Effectiveness Bill Funded Through Private/Public Partnership.''

[48] MDMA, ''Comparative Effectiveness Legislation Reintroduced.''

[49] BNA, ''Senators Propose Nonprofit Institute Created to Study Comparative Effectiveness.''

[50] ''Baucus Drops Comparative Effectiveness Bill Funded Through Private/Public Partnership.''

[51] BNA, ''Senators Propose Nonprofit Institute Created to Study Comparative Effectiveness.''

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