

Background

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Comparative Effectiveness in Health Care Reform: Lessons from Abroad

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President Barack Obama has proposed the creation of an Institute for Comparative Effectiveness as a key component of an ambitious health care reform.¹ The institute would have the authority to make official determinations of the clinical effectiveness and cost-effectiveness of medical treatments, procedures, drugs, and medical devices.

President Obama's initial nominee as Secretary of Health and Human Services (HHS), former Senator Tom Daschle (D-SD), has likewise proposed the creation of a supremely powerful Federal Health Board, which would have similar authority to make decisions that would be binding on health plans and providers financed by federal taxpayers, and potentially on private health insurance coverage.² While Senator Daschle has withdrawn his name from Senate consideration, the concept of such a board or institute is strongly indicative of the Obama Administration's policy orientation toward centralized health policy decision-making.

The U.S. House of Representatives has just passed the \$850 billion American Recovery and Reinvestment Act (H.R. 1), the so-called economic stimulus bill, which would establish a Federal Coordinating Council for Comparative Effectiveness Research. The bill would provide \$1.1 billion for the new council and delegate spending authority to the HHS Secretary to investigate the effectiveness of different drugs and medical devices.³ The Senate version of the economic stimulus package contains a similar provision.

Of course, there is no reason why private-sector or government officials should not have access to the best

Talking Points

- Today, in virtually every country, health care is heavily influenced by government policy that fosters a professional monopoly of supply and strict top-down regulation.
- President Barack Obama has proposed the creation of an Institute for Comparative Effectiveness would mean more government control of private medical decisions.
- The idea that government is intrinsically superior to a spontaneous and free market is groundless. American policymakers who believe the health care systems in many European countries to be ideal should learn about citizens of the United Kingdom being denied the medicines they need.
- It is clear from the British experience and other international examples that a comparative effectiveness strategy that relies on central planning and coercion would be counterproductive and also would lead to cost constraints that could worsen patients' medical conditions and damage the quality of their lives.

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information on what works and what doesn't. Nor is there any reason why such scientific evaluations should not be widely available to doctors and patients alike. But studies of the comparative effectiveness of medical devices, drugs, and technology should be conducted primarily within the private sector, and there should be no government monopoly over either the research or the distribution of information. The key issue is the personal freedom of patients to be able to choose the health care that, in the professional judgment of their doctors, best serves their personal needs.

Focus on Medical Technology. Technology, in particular, can be expensive. Over the past 20 years, health technology assessment (HTA)—the synthetic coordination of information assessing medicines and treatments—has become increasingly popular with policymakers and legislators around the world. Advocates of HTA invariably believe that such an approach has the capacity to provide decision-makers in the public and private sectors with objective information on the value of medical technologies, devices, and medicines. Driven by concerned perceptions of “unproven technology,” “spiralling costs” and “increasing consumer expectations,” its proponents aim to produce synthesized research information that they believe sheds light on the effects and costs of various forms of health technology.

Such an approach, however, would guarantee the incremental advance of government control of private medical decisions. While formally touted as an instrument of efficiency and effectiveness, it

would distort scientific research in the service of political or budgetary objectives while denying individual freedom of choice. In that sense, this approach would serve as a propaganda tool designed to legitimize anti-consumerist rationing.

Comparative Effectiveness in Health Care: How It Started

The intellectual roots of effectiveness research can be traced back to mid-18th century Scotland and the “arithmetical medicine” practiced by the graduates of the Edinburgh medical school. It was there that James Lind famously undertook a controlled trial of six separate treatments for scurvy.⁴ During the 1830s, Pierre Louis developed the *méthode numérique* in Paris, whereby he demonstrated that phlebotomy did not actually improve the survival rates of patients suffering from pneumonia.

At the beginning of the 20th century, Ernest Codman, an American physician, founded what is today known as “outcomes management” in patient care. Shunned by established institutions, he set up his own unit, the End Result Hospital. In line with his teachings and the findings from this unit, end results were made public in a privately published book, *A Study in Hospital Efficiency*.⁵ Of 337 patients discharged from the hospital between 1911 and 1916, Codman recorded and publicized 123 errors.

In England, the 1930s saw the development of health services research. In a world increasingly obsessed with egalitarian uniformity, J. A. Glover found a tenfold variation in tonsillectomy.⁶ Subse-

1. For a brief discussion of the Obama proposal, see Robert E. Moffit and Nina Owcharenko, “The Obama Health Plan: More Power to Washington,” Heritage Foundation *Background* No. 2197, October 15, 2008, at <http://www.heritage.org/research/healthcare/bg2197.cfm>.
2. For a brief discussion of Daschle's proposed Federal Health Board, see Senator Tom Daschle, with Scott S. Greenberger and Jeanne M. Lambrew, *Critical: What We Can Do About the Health Care Crisis* (New York: Thomas Dunne Books, 2008). See also Robert E. Moffit, “How a Federal Health Board Will Cancel Private Coverage and Care,” Heritage Foundation *WebMemo* No. 2155, December 4, 2008, at <http://www.heritage.org/research/healthcare/wm2155.cfm>.
3. The provision is included in Title IX of Subtitle B of the American Recovery and Reinvestment Act of 2009. According to the report language accompanying the House bill, “By knowing what works best and presenting this information more broadly to patients and health care professionals, those items, procedures, and interventions that are most effective to prevent, control and treat health conditions will be utilized, while those that are found to be less effective and in some cases, more expensive, will no longer be prescribed.”
4. Stephen R. Brown, *Scurvy: How a Surgeon, a Mariner, and a Gentleman Solved the Greatest Medical Mystery of the Age of Sail* (New York: St. Martin's Press, 2003).
5. Ernest A. Codman, *A Study in Hospital Efficiency* (Boston, Mass.: Privately printed, 1916).

quently, following several decades of socialized health care in the United Kingdom, the 1970s and 1980s witnessed the release of a range of studies that highlighted wide geographical variations in general medical admissions including operations such as appendectomy, caesarean section, cholecystectomy, hysterectomy, tonsillectomy, and prostatectomy.⁷ Such variations not only demonstrated the inequities of the National Health Service (NHS), but also raised questions about the probity and cost-effectiveness of many of its treatments.

Following the publication of Archie Cochrane's *Effectiveness and Efficiency: Random Reflections on Health Services*⁸ in the United States, researchers demonstrated large variations in the rates of prostatectomy for patients with benign prostatic hyperplasia.⁹ This work and others suggested that such variations "meant either under-provision in some places and/or over-provision (and possibly ineffective treatment) in others."¹⁰ While "comparative effectiveness" builds on skepticism, the investigation of variations, randomized control trials, and cost-benefit analysis, its reviews purport to be systematic. As such, they attempt to go beyond the more narrative-based reviews that used to dominate the typical review article in medical literature.

Comparative Effectiveness: The Rationale

In recent decades, health care has advanced in significant ways. Across the developed world, not only has medical knowledge progressed, but investment in equipment and drugs has delivered unprecedented gains. Treatments are safer and more effective than ever before. Quality of life and life expectancy have been enhanced. Alongside aging

populations has come the world of ever-increasing consumer expectations.

The rapid growth of medical knowledge and technology means it is much harder for doctors and other health care providers to keep up to date. Indeed, the problem of information and practice transference is rendered almost impossible by the fact that health care is now a highly statist and corporatist venture. Today, there is no such thing as a free market in health care, and many of the problems popularly associated with it are in fact the result of state failure.

Today, in virtually every country in the world, health care is heavily influenced by government policy and fosters professional monopoly of supply and strict top-down regulation.¹¹ While there is nothing inherent in health care that guarantees such an outcome, governments, either actively or passively, grant special legislative favor to interest groups when it comes to people's medical treatments and insurance.

The idea that government is intrinsically a superior agent, over and above a spontaneous and free market, is groundless. As David Friedman, a professor of law at Santa Clara University in California, has argued, both the notion of market failure in health economics and its popularity with most opinion leaders have arisen because many health policy analysts "interpret the problem in terms of fairness rather than efficiency."¹² This almost unconscious adherence to the notion of market failure in health care is rooted in:

the error of judging a system by the comparison between its outcome and the best out-

6. J. A. Glover, "The Incidence of Tonsillectomy in School Children," *Proceedings of the Royal Society of Medicine*, Vol. XXXI (1938), pp. 1219–1236.
7. D. Sanders, A. Coulter, K. McPherson, *Variations in Hospital Admission Rates: A Review of the Literature* (London: King Edward's Hospital Fund for London, 1989), p. 31.
8. Archie Cochrane, *Effectiveness and Efficiency: Random Reflections on Health Services* (Leeds: Nuffield Provincial Hospitals Trust, 1972).
9. J. E. Wennberg, A. G. Mulley, D. Hanley, *et al.*, "An Assessment of Prostatectomy for Benign Urinary Tract Obstruction: Geographic Variations and the Evaluation of Medical Care Outcomes," *JAMA*, Vol. 259, No. 20 (1988), pp. 3027–3030.
10. Andrew Stevens, Ruairidh Milne, and Amanda Burls, "Health Technology Assessment: History and Demand," *Journal of Public Health Medicine*, Vol. 25, No. 2 (1998), p. 99.
11. Brian Micklethwait, "How and How Not to Demonopolise Medicine," *Political Notes* No. 56, Libertarian Alliance, London, 1991.

come that can be described, rather than judging it by a comparison between its outcome and the outcome that would actually be produced by the best alternative system available. If, as seems likely, all possible sets of institutions fall short of producing perfect outcomes, then a policy of comparing observed outcomes to ideal ones will reject any existing system.... The question we should ask, and try to answer, is not what outcome would be ideal but what outcome we can expect from each of various alternative sets of institutions, and which, from that limited set of alternatives, we prefer.... My conclusion is that there is no good reason to expect government involvement in the medical market, either the extensive involvement that now exists or the still more extensive involvement that many advocated, to produce desirable results.¹³

Curiously, it is within the context of government control and anti-competitive corporatism that new and innovative medical treatments are met with initiatives for even more rationing by government officials, as well as other highly regulated players including private medical insurers. In recent years, many countries have introduced comparative effectiveness or HTA programs, ostensibly to improve their decision-making and their allocation of relatively scarce medical resources. In reality, many politicians and officials have done so not least because they are trying to get themselves off the hook of past promises they made concerning the provision of comprehensive, unlimited, or, as in the case of the United Kingdom, seemingly “free” health care at the point of service.

Since extensive government intervention has distorted health care markets and has made it impossible for individuals to determine a clear and

transparent value of the costs and benefits of health care technology through a normally functioning price system, the proponents of comparative effectiveness, or health technology assessment, have instead resorted to a predictably pseudoscientific methodology to give their bureaucratic determinations a sheen of objectivity. As with other forms of centralized government planning, the practitioners of these bureaucratic arts attempt to capture and mathematically profile and model their assessments; in assessing health technology, they seek “to compare and prioritize new technologies based on different units that aggregate... benefits.”¹⁴

In a study of HTA for the Stockholm Network, a prominent European think tank, research has focused on these assessments in terms of the value of human life:

In HTA, the dominant aggregate natural unit is called quality-adjusted life years (QALYs). Generally, QALYs factor in both the quantity and the quality of life generated by new health care interventions. It is the arithmetic calculation of life expectancy and a measure of the quality of the remaining life years.... To date QALYs are the preferred indicator of HTAs calculations, although one may find additional tools in use by HTA bodies such as HRQoL (“health related quality of life,” which considers physical function, social function, cognitive function, distress, pain: in brief, anything to do with quality of life), DALYs (“disability life adjusted years”—of life lost due to premature mortality in the population and the years lost due to disability for incidents of the studied health condition), and healthy-year equivalents (HYEs).¹⁵

Despite the pretense of scientific objectivity, this type of health technology assessment is nothing of the sort. It is designed primarily to provide policy-

12. David Friedman, “Should Medicine Be a Commodity? An Economist’s Perspective,” *Philosophy and Medicine: Rights to Health Care*, Vol. 38 (1991), at http://www.davidfriedman.com/Academic/Medicine_Commodity/Medicine_Commodity.html (January 29, 2009).

13. *Ibid.*

14. Meir P. Pugatch and Francesca Fikai, “A Healthy Market? An Introduction to Health Technology Assessment,” Stockholm Network, London, 2007, p. 5.

15. *Ibid.*

makers with a legitimizing rubric by which they can mimic a few elements of the market and therefore deploy a degree of fake economic rationality in justifying their decisions. In this way, practitioners of HTA attempt to balance the requirement to provide innovative health care technologies with ham-fisted efforts at controlling the costs of those technologies.

Consider the quality of human life and lifespan. The use of QALYs is pseudoscience. It is nothing more than a tool for central planning that attempts to objectify what is inherently subjective. The limited attempts to capture accurately the various “units of healthcare benefit” mean that there is an inevitable gulf between the theoretical underpinnings of QALYs and the actual behavior of ordinary people. Moreover, the artificial prioritization of so-called cost-based considerations by practitioners of health technology assessment is invariably made at the expense of other considerations. As Dr. Meir Pugatch and Francesca Fikai of the Stockholm Network note, “Thus, a decision to prioritize a less therapeutically effective medicine because of cost-based considerations over an effective, but more expensive, medicine could lead to some serious political, social and moral dilemmas.”¹⁶

Not only is this type of health technology assessment methodologically flawed: It is incompatible with personal freedom and contradicts the subjective choices of genuine economic agents. When deployed at the national level through the power of a government agency, it is inevitably subject to additional political pressures. Indeed, in 2009, it is clear that national organizations that conduct these assessments—such as the National Institute for Health and Clinical Excellence in the United Kingdom or the Institute for Quality and Efficiency in Health Care in Germany—are in the business of rationing health care technologies so that they mesh with the politically fixed budgetary allocations of the national government.

Today, it is clear that the political economy of these government bodies means that their structures, processes, and pseudoscientific constructs have a significant and detrimental impact on the

practice of, and even the public discourse on, health care. Far from reflecting scientific rationality and economics, health technology assessments often reflect either politically driven social judgments of the decision-makers in these agencies or, worse, a thinly veiled attempt to accommodate whatever political pressures happen to be momentarily dominant.

How Comparative Effectiveness Works in Europe

According to the International Network of Agencies for Health Technology Assessments (INAHTA),¹⁷ many industrialized countries have bodies that are charged with health technology assessments or comparative effectiveness studies. Despite this, the evolution of these bodies and their responsibilities at the national decision-making level has been far from uniform.

For example, some of these bodies have an advisory role. They make reimbursements or pricing recommendations to a national or regional governing body, as is the case in Denmark. Others have a more explicit regulatory role. They are accountable to government ministers and are responsible for listing and pricing medicines and devices. This is the case in France, Germany, and the United Kingdom.

The United Kingdom. The experience of the United Kingdom in making the difficult decisions about what kind of health care technologies, devices, drugs, and medical treatments and procedures should be favored in Britain’s National Health Service has been cited favorably by Senator Daschle.

The NHS was established in 1948. It is a single-payer health care system, directly administered by the British government, funded through taxation, and provided mainly by public-sector institutions. Because the NHS is a fully nationalized entity, the central government specifies the capital and current budgets of its regional health authorities and determines the expenditure on drugs by controlling the budgets given to each general practitioner. Overall, NHS health care is rationed through long waiting lists and, in some cases, omission of various treatments.¹⁸

16. *Ibid.*, p. 6.

17. See INAHTA home page at <http://www.inahta.org> (January 30, 2009).

For the British government, the practice of HTA facilitates rationing by delay. It is a tool that aims to ensure that expensive new technologies are initially provided only in hospitals that have the technical capacity to evaluate them. While the NHS Research and Development Health Technology Assessment Programme is funded by the Department of Health and, according to its criteria, researches the costs, effectiveness, and impact of health technologies, the Medicines and Healthcare Products Regulatory Agency (MHRA) ensures that drugs and devices are safe.¹⁹

In 1999, the government went a step further and set up the National Institute of Health and Clinical Excellence (NICE).²⁰ At its heart is the Centre for Health Technology Evaluation that issues formal guidance on the use of new and existing medicines based on rigid and proscriptive “economic” and clinical formulas. With the NHS obliged to adhere to NICE’s pronouncements, criticism of NICE has been ceaseless, particularly from various patient organizations.

NICE is a controversial body. It has tried repeatedly to stop breast cancer patients from receiving the powerful breakthrough drug Herceptin and patients with Alzheimer’s disease from receiving the drug Aricept. The criteria by which this agency makes its decisions have been kept largely secret from the public. As is inevitable with any nationalized health care system, life-extending medicines such as those to treat renal cancers are refused on the grounds of limited resources and the need to make decisions based not on genuine market economics but on an artificial assessment of the benefit that may be gained by the patient and society “as a whole.”

In 2001, NICE deliberately restricted state-insured sufferers of multiple sclerosis from receiving the innovative medicine Beta Interferon. Claiming

that its relatively high price jeopardized the efficacy of the NHS, patients with the more severe forms of the disease were told that they would have to go on suffering in the name of politically defined equity.²¹

In more recent years, patients with painful and debilitating forms of rheumatoid arthritis have been informed by NICE that in many instances they will not be allowed to receive a sequential range of medicines that have often been proved to be of significant benefit. Instead, the institute decreed that “people will be prevented from trying a second anti-TNF treatment if the first does not work for their condition.”²²

Similarly, in August 2008, patients with kidney cancer continued to be denied effective treatments designed to prolong their lives, often by months or even a few years. The calculations used by NICE have been systematically disputed by clinical experts who are more concerned with patient welfare than with vote-seeking, but the institute has also come under fire for not involving doctors who are active on the front line of medicine: “With Sutent for instance, there was just one oncologist on the panel.”²³

In January 2009, patients with osteoporosis also fell foul of NICE. The institute declared that only a small minority of patients with this debilitating disease would receive the medicine Protelos, and even they would receive it only as an extreme last resort. While clinicians and osteoporosis support groups have pointed out that more than 70,000 hip fractures result in 13,000 premature deaths in the U.K. each year and that these otherwise avoidable episodes needlessly cost the NHS billions of pounds, not only are patients being denied necessary treatments, but taxpayers’ money is wasted.²⁴

Indeed, according to its annual reports and accounts, NICE is now spending more money on

18. Helen Evans, *Sixty Years On—Who Cares for the NHS?* (London: Institute of Economic Affairs, 2008), pp. 26–54.

19. See MHRA home page at <http://www.mhra.gov.uk> (January 30, 2009).

20. Pugatch and Ficai, “A Healthy Market? An Introduction to Health Technology Assessment,” p. 8.

21. “MS Research Urges End of NHS Bar on Drug,” *The Daily Telegraph*, June 19, 2001.

22. See press release, “NICE Limits Options for People with Rheumatoid Arthritis,” *Arthritis Cares*, London, July 21, 2008.

23. “Nasty Truth About NICE: It’s the Body that Rations NHS Drugs. But This Leading Cancer Specialist Says Its Decisions Are Deeply Flawed,” *The Daily Mail*, August 8, 2008.

communicating its decisions than would be spent if it allowed patients access to many of the medicines it is so busy denying them. The money that the institute now spends on public relations campaigns “could have paid for 5,000 Alzheimer’s sufferers to get £2.50-a-day drugs for a year,” according to *The Daily Mail*.²⁵

Devoid of a market and the language of price, this top-down system ironically ignores many of the societal costs associated with failure to treat severe illness, such as illness-related unemployment. Moreover, the fact that preventing access to more costly medicines may save money in the short term overlooks the costs for the future. If older medicines lead to more rapid deterioration of a condition, the effect could be a more expensive hospital or nursing home episode later.

Denmark. The Danish health care system is completely state-funded, with public provision of hospital beds representing more than 90 percent of the hospital sector. Under the Healthcare Act, citizens are covered for all or part of expenditures for treatment, including reimbursement for all pharmaceutical products listed with the Danish Medicines Agency. Therefore, there is no need for price regulation of drugs. With central and municipal government having significant control of the funding and provision of health care, the acquisition of new technology is left initially to the five regions that run the hospitals.

Denmark’s national HTA system was explicitly established on the basis of its making prioritized resource-allocation decisions. Carried out by the unit known as the Danish Centre for Evaluation and Health Technology Assessment (DACEHTA), it operates within the framework of the National Board of Health (NBH), itself a part of the Danish Ministry of Health.²⁶ In reality, this means that

“[t]he Ministry keeps a close watch on it in order to neutralize ‘expensive’ healthcare technologies, as their adoption results in requests for extra funding from the regions.”²⁷

France. In France, health care is a statutory right enshrined in the Constitution of the Fifth Republic. Unlike in Denmark or the United Kingdom, however, French health care is financed mainly by social insurance and delivered by a mixture of public and private providers. While two-thirds of French hospitals are state-owned, one-third are private, with half of the latter group being not-for-profit.

There have been various attempts in recent years to extend government control of health care costs. In 1991, the French government extended its Health Map system by which it controls the capital construction of all hospitals as well as their budgets, the purchase of medical equipment, the rates charged by private hospitals, the number of pharmacies per head, and even the price of drugs.²⁸

In 2005, the government went a stage further with the establishment of a centralized High Health Authority. While this body has had only a limited impact—and France continues to enjoy a comparatively higher diffusion rate for new technologies than is found in many other countries in Europe—it is nevertheless designed to stipulate the benefits of medicines and determine their price-reimbursement levels. As such, it is set to raise the focus on cost-containment and bring its decision-making under closer state control.

Germany. As in France, health care in Germany is financed primarily by social insurance and provided by a mixture of public and private providers. While all services are contracted instead of being provided directly by the government, more than 10 percent of Germans opt for full private medical insurance.²⁹ Providing a potent source of exit from

24. “NICE Decision to Block Osteoporosis Drug Access Was ‘Irrational,’” *The Daily Telegraph*, January 20, 2009.

25. “Drug Watchdog NICE ‘Spends More on “Spin” than Tests on New Treatments,’” *The Daily Mail*, September 10, 2008, at <http://www.dailymail.co.uk/health/article-1054049/Drug-watchdog-NICE-spends-spin-tests-new-treatments.html> (January 30, 2009).

26. See National Board of Health home page at <http://www.sst.dk> (January 30, 2009).

27. Meir P. Pugatch and Helen Davison, “A Healthy Market? Health Assessment Technology in Context,” Stockholm Network, London, 2007, p. 9.

28. Brian Abel-Smith and Elias Mossialos, “Cost Containment and Health Care Reform: A Study of the European Union,” London School of Economics and Political Science *Occasional Paper in Health Policy* No. 2, 1994, pp. 33–35.

the state, the regulated private sector puts pressure on the government to ensure that the sectoral differences in service do not become so wide that ever-larger numbers of young, high-income consumers defect by going private and delegitimizing a central pillar of the Bismarckian philosophy.

While the pressure to maintain some semblance of parity with the private sector meant that state spending rose dramatically for many years after the introduction of a formal reference pricing system in 1989, the strategic objective of the German Ministry of Health has been to reduce supply, particularly through the use of published positive and negative lists concerning medicines and treatments. Through these lists, pressure is applied to the statutory sick funds to control costs.³⁰

It is in this context that health technology assessment has played an ever-greater role in German health policy since the 1990s. In 1990, the Office of Technology Assessment at the German Parliament (TAB) was established, and in 2004, the government set up the Institute for Quality and Economic Efficiency in the Healthcare Sector (IQWiG).

Tasked with the central goal of efficiency, IQWiG investigates and stipulates which therapeutic and diagnostic services are appropriate.³¹ Disseminating its pronouncements to various self-governing bodies, its information is used concerning the coverage of technologies in the benefits catalogue. With such ventures being funded primarily by the German Ministry for Health and Social Affairs, assessment bodies can refuse a hospital's claim for reimbursement for the unauthorized use of new technology.

Lessons for American Policymakers

There is a pervasive European mythology: a widespread belief that American health care is rooted in the free market. In reality, much of American health care is a highly planned, regulated, and government-funded system. Through major entitlement and welfare programs such as Medicare and

Medicaid, which contribute to rapidly growing American health care costs, government takes a historically higher proportion of gross domestic product than does even the British NHS. Moreover, by virtue of the structure and financing of private-sector health insurance, there is little consumer control over health care dollars.

Nonetheless, the United States is not only a major consumer of health care services, but also the world's largest producer of medical technology. Investment in new medical technology is comparatively high, as is its rate of diffusion: "This is demonstrated by cross-national examinations of the comparative availability of selected medical technologies such as radiation therapy and open-heart surgery. Measured in units per million, the United States experiences levels of availability up to three times greater than in Canada and Germany."³²

During the presidential campaign, Barack Obama proposed an Institute for Comparative Effectiveness that would make formal recommendations on medical technologies, devices, and drugs. In Congress, champions of comprehensive overhaul of U.S. health care favor policies that would explicitly accelerate America's trajectory downward toward a European-style medical interventionism.

Fearing the impact of the rising costs of Medicare, Medicaid, and the highly regulated arrangements of the private insurance sector, many American legislators and other top policymakers are becoming attracted to the idea of a body that would make top-down pronouncements on the cost-effectiveness of new medical technologies. The idea of a statutorily created agency charged with system-wide cost containment and rationing of medical services and technologies is becoming surprisingly fashionable in Washington policy circles.

The implications of this trend are alarming for U.S. citizens, particularly when one considers that the technology a society uses reflects the wider and underlying incentive structures it adopts for using

29. Pugatch and Davison, "A Healthy Market? Health Assessment Technology in Context," p. 10.

30. *Ibid.*, p. 11.

31. *Ibid.*

32. "American Democracy and Health Care," *British Journal of Political Science*, Vol. 27, No. 4 (October 1997), p. 573.

it: “An incentive structure that encourages providers to trade off the costs and benefits of health care gives providers little incentive to use expensive technologies and thus researchers will have little incentive to create it.”³³

In the long term, a statist, centralized control of medical technology offers little if any regulatory benefit. Through its own logic, it not only stifles innovation, but also, in doing so, ends up precluding those very inventions that could turn out to be of immeasurable benefit to individuals and to society in general.

If comparative effectiveness and health technology assessment especially are to be useful, they must be generated primarily by the private sector on a competitive and non-coercive basis. In avoiding the imposition of a uniformity of rules that comes with government intervention, physicians and other medical professionals would and should remain free to pick and choose from the best practices and professional insights into the treatment of medical conditions as they see fit (with, of course, the informed consent of their patients).

It is only by returning health care to a genuinely patient-centered and consumer-driven health care marketplace that information, innovation, and best practice will permeate the complex array of health care arrangements in both the public and the private sectors. It is only through open competition and the economic discipline of the free market that real progress and productivity can be secured.

Therefore, in framing a policy on comparative effectiveness, America’s policymakers should be governed by four principles:

- **They should reject the statutory creation of a board, council, or institute that would centralize government control of patient access to drugs, devices, medical technologies, treatments, or procedures.** This is especially the case

if such an agency were to have the power to override the considered judgment of competing professional expertise, especially the professional judgment of a patient’s attending physician.

- **Comparative effectiveness research and health technology assessments should be undertaken primarily by the private sector.** While government can contribute to research efforts and promote the widespread availability of the best information, it must not exercise monopoly power over the conduct of research itself or the distribution of information.
- **Comparative effectiveness research should be patient-centered and supportive of quality and value, not focused simply on cost-containment.** In this respect, it should foster scientific advances, health information technology, and the emerging science of personalized medicine.
- **Comparative effectiveness research must move beyond randomized clinical trials and embrace practical clinical trials.** It should include observational data, and its methodologies should fully address issues such as the validity and applicability of findings.

Conclusion

As is clear from the British experience and other international examples, a comparative effectiveness strategy that relies on central planning and coercion would not only be counterproductive in the long run—because it would undermine the incentives for medical innovation—but would also lead to the imposition of cost constraints that would worsen patients’ medical conditions and damage the quality of their lives.

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33. Pugatch and Davison, “A Healthy Market? Health Assessment Technology in Context,” p. 16.