

a memo from the medical review team's leader, highlighting the team's struggle to determine whether this drug provided any clinically important benefit and whether that benefit outweighed the harms. "Ordinarily," the memo said, "a marginally clinically significant treatment effect would not preclude an approval of a product. However, the ability to approve such a product would then focus even more on the safety profile. . . . In the case of ramelteon, there are several issues in the safety profile of concern," including frequent symptomatic side effects and possible hyperprolactinemia. The sense that the FDA's decision was a close call was not communicated in the label.

To its credit, the FDA has recognized problems with drug labels. In 2006, it revised the label design, adding a "highlights" section to emphasize the drug's indications and warnings. It also issued guidance about reporting trial results in the label, emphasizing the importance of effectiveness data. Yet the data presentations for the approval studies referred to in the labels for Lunesta and Rozerem, which were updated in 2009 and 2008, re-

spectively, are substantively unchanged.

The FDA has not issued new guidance about its drug-review documents. A standardized executive summary of the reviews would be a substantial improvement. These summaries should include data tables of the main results of the phase 3 trials, highlight reviewers' uncertainties, and note whether approval was conditional on a post-approval study.

Toward this goal, we conducted a pilot test, funded by the Robert Wood Johnson Foundation's Pioneer Portfolio, in which FDA reviewers created "Prescription Drug Facts Boxes,"⁵ featuring a data table of benefits and harms. Recently, the FDA's Risk Advisory Committee recommended that the FDA adopt these boxes as the standard for their communications. FDA leadership is deciding whether and how to use the boxes in reviews, labels, or both.

Whatever approach the agency adopts, it needs a better way of communicating drug information to clinicians. We don't need to wait for new comparative-effectiveness results in order to improve practice. We need to better disseminate what is already known.

No potential conflict of interest relevant to this article was reported.

The views expressed in this article are those of the authors and do not necessarily reflect those of the Department of Veterans Affairs or the U.S. government.

From the Dartmouth Institute for Health Policy and Clinical Practice, Hanover, NH; and the VA Outcomes Group, VA Medical Center, White River Junction, VT.

This article (10.1056/NEJMp0907708) was published on October 21, 2009, at NEJM.org.

1. Drugs@FDA. Approval history of NDA 021223: Zometa. Silver Spring, MD: Food and Drug Administration. (Accessed October 8, 2009, at http://www.accessdata.fda.gov/Scripts/cder/DrugsatFDA/index.cfm?fuseaction=Search.Label_ApprovalHistory#apphist.)
 2. Major P, Lortholary A, Hon J, et al. Zoledronic acid is superior to pamidronate in the treatment of hypercalcemia of malignancy: a pooled analysis of two randomized, controlled clinical trials. *J Clin Oncol* 2001;19:558-67.
 3. Drugs@FDA. Approval history of NDA 021476: Lunesta. Silver Spring, MD: Food and Drug Administration. (Accessed October 8, 2009, at http://www.accessdata.fda.gov/Scripts/cder/DrugsatFDA/index.cfm?fuseaction=Search.Label_ApprovalHistory#apphist.)
 4. Drugs@FDA. Approval history of NDA 021782: Rozerem. Silver Spring, MD: Food and Drug Administration. (Accessed October 8, 2009, at http://www.accessdata.fda.gov/Scripts/cder/DrugsatFDA/index.cfm?fuseaction=Search.Label_ApprovalHistory#apphist.)
 5. Schwartz LM, Woloshin S, Welch HG. Using a drug facts box to communicate drug benefits and harms: two randomized trials. *Ann Intern Med* 2009;150:516-27.
- Copyright © 2009 Massachusetts Medical Society.

Four Health Care Reforms for 2009

Victor R. Fuchs, Ph.D.

Prospects for the enactment of some reform look good, but comprehensive, sustainable reform of the health care system must wait for another day. Republican support for President Barack Obama's ambitious agenda is fading fast, if it ever existed. An imaginative, truly bipartisan approach that moves the

system away from employer-sponsored insurance — the Wyden-Bennett plan — has failed to gain any traction. Within the Democratic majority, sharp disagreements in each house, and between the House and Senate, do not augur well for coherent legislation, even if political compromises can be struck.

Disappointment with the reaction of some of the public and gridlock in Congress might lead to the abandonment of reform this year. With the need so great, and with so much effort having been put forth by so many people, that would be a crime. Almost everyone agrees that the present U.S. health care system is dysfunc-

tional: it is too costly, too incomplete in coverage, and too prone to avoidable lapses in quality of care. A true remedy would require major changes in the financing and organization of care; such changes currently have little support from either politicians or the public. But a start must be made.

Although comprehensive change is probably beyond reach this year, several specific reforms should and could be enacted: the creation of insurance exchanges, the elimination or limitation of the tax exemption of employer-sponsored health insurance, the appointment of an expert commission to devise changes to the way Medicare pays providers, and the provision of ensured funding for a quasi-independent institute for technology assessment. Each of these changes alone has a high probability of doing some good. Taken together, they reinforce each other and lay a foundation for further reforms.

Insurance exchanges that bring together insurance companies and potential buyers have lower administrative costs than does a system in which numerous sellers and buyers of insurance have to make separate deals. Exchanges are particularly valuable for individual buyers, for persons who are self-employed, and for small firms; they would also be an excellent alternative to employer-sponsored insurance. To succeed, the exchanges must attract large numbers of enrollees — healthy persons as well as sick persons — and must have risk-adjustment rules to protect insurance companies that enroll a disproportionate number of sick beneficiaries.

Insurance exchanges that attract large numbers of participants benefit from economies of scale, eliminate the cost of brokers, and

can offer a wide choice of insurance policies. From the point of view of insurance companies, a well-functioning exchange is beneficial because it permits them to add large numbers of customers at a relatively low cost. Alain Enthoven has pointed out that the Federal Employees Health Benefits Program is a kind of insurance exchange.¹ Although it is not called an insurance exchange, it works similarly to one, and it functions well for both government employees and the companies that insure them. The California Public Employees' Retirement System (CalPERS) performs a similar function for employees of California's state and local governments.

The revelation that top Goldman Sachs executives are given a tax-free \$40,000-per-year health insurance policy highlights what is arguably the most regressive feature of the entire federal tax code: the tax exemption of employer contributions to health insurance premiums. This exemption confers huge subsidies on high-income Americans and small or no subsidies on those with low incomes. There are three reasons that the exemption has this effect: first, the higher a person's marginal tax bracket, the larger the subsidy he or she receives; second, on average, higher-income workers tend to have more generous insurance policies; and third, the proportion of people who receive employer-sponsored insurance rises dramatically with family income, from approximately one in four among those with incomes under \$30,000 to more than four in five among those with incomes above \$75,000.² Elimination of the subsidy would not only make the tax system fairer, but it would also provide more than \$200 billion of additional

federal revenue annually. If Congress did nothing else for health care this year, this reform would accomplish a great deal.

Some observers believe that loss of the tax exemption would cause a large decrease in employer-sponsored insurance coverage. No one knows the extent or timing of this effect; it might occur quickly, or it might occur over the course of several years. Well-functioning insurance exchanges would ease the transition from employer-sponsored insurance; synergistically, the removal of the tax exemption would spur the growth of exchanges. Thus, these two reforms would reinforce each other. Sooner or later, the country must wean itself from employer-sponsored insurance if it is to achieve universal coverage with equitable and adequate financing and lower administrative costs.

Most observers are convinced that reform of Medicare's payment system for providers is a good place to start in reducing health care expenditures without jeopardizing the public's health. Not only does Medicare spending account for a significant portion of total health expenditures (approximately 20%), but changes that are initiated by Medicare are often adopted subsequently by private insurers. Expert advisors have recommended useful reforms in the past, but the pressure that special interest groups place on Congress usually blocks implementation. The United States needs an independent commission of physicians and other experts to devise payment reforms, including realignment of reimbursement rates to more accurately reflect the value of services, some bundling of payments to provide an incentive for efficient use of re-

sources, and new benefit designs. Recommendations should be submitted for Congressional approval, but they must be adopted or rejected as a package, rather than picked apart piece by piece. The latter approach provides maximal opportunity for lobbyists for special-interest groups to determine the outcome, whereas a congressional “yes” or “no” vote on a total reform package would allow the public interest to play a larger role.

Health care spending has grown 2.7% faster than the rest of the economy over the past 30 years, primarily as a result of new technology.³ Some of the new drugs, tests, and procedures have contributed to longer, high-quality lives. Many have not. Currently, there is no institution that has been established with the specific aim of evaluating the value of new technologies (or of new applications of older technologies). It is not feasible for individual physicians or physician groups to carry out the necessary analyses and disseminate findings throughout the health care community. To accomplish this task, Congress should create a quasi-independent institute for technology assess-

ment with steady, ensured funding, such as a fixed percentage of annual Medicare expenditures.⁴ The assessments performed by this institute will initially be particularly valuable to the expert commission that is charged with making Medicare payment methods more efficient and more equitable.

One omission from these recommended reforms is a proposal for dramatically increasing the number of insured Americans. I favor increased coverage and have advocated universal coverage, financed by a value-added tax that is dedicated to funding basic health care for all. To be sustainable, expanded coverage must be accompanied by adequate new revenues and by changes in the organization and delivery of care that will predictably lower costs. The proposals that are currently being considered for expanding coverage do not meet that test. Indeed, I believe the proposed expansion of employment-based insurance (through employer mandates) and the expansion of income-tested insurance such as Medicaid (through raising the income threshold for eligibility) are the wrong way to go. These

inefficient and inequitable methods contribute to our present problems and must eventually be replaced.

I believe that the four reforms proposed here have more chance of doing good than harm, will lower rather than increase the deficit, and will reinforce one another. Given the complexity of health care, that's the most that we can expect until comprehensive change in the financing and organization of care becomes politically possible.

No potential conflict of interest relevant to this article was reported.

From Stanford University, Stanford, CA.

This article (10.1056/NEJMp0907979) was published on October 7, 2009.

1. Enthoven AC. Building a health marketplace that works. *Health Affairs* blog, July 31, 2009. (Accessed September 9, 2009, at <http://healthaffairs.org/blog/2009/07/31/building-a-health-marketplace-that-works/>.)
2. Employee Benefits Research Institute estimates from the Current Population Survey. March 2009 supplement. Washington, DC: Employee Benefits Research Institute.
3. Pauly MV. Competition and new technology. *Health Aff (Millwood)* 2005;24:1523-35.
4. Emanuel EJ, Fuchs VR, Garber AM. Essential elements of a technology and outcomes assessment initiative. *JAMA* 2007;298:1323-5.

Copyright © 2009 Massachusetts Medical Society.

Implementing Evidence-Based Health Policy in Washington State

Gary M. Franklin, M.D., M.P.H., and Brian R. Budenholzer, M.D.

The Obama administration's infusion of stimulus funds into enhanced comparative-effectiveness research (CER) is in keeping with the conclusion of a recent Commonwealth Fund report that, of the top 15 ways of bringing health care costs under

control, CER promises the greatest short- and long-term savings.¹ In addition, the report notes, CER efforts are the most likely to reduce the out-of-pocket health care costs of ordinary households. To address the unsustainable increase in overall health care ex-

penditures — a matter made more urgent by the financial challenge of providing health care coverage for all citizens in the state — the Washington State legislature and successive governors Gary Locke and Chris Gregoire have, since 2003, en-