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## Health Law Surprise Is Page 1,617 Demanding Which Drugs Work

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Page 1,617 of the 2,400-page law signed by President Barack Obama this week -- the most sweeping change to U.S. health-care in 45 years -- sparked little of the debate surrounding the expansion of coverage to 32 million Americans or its tax on employees' "Cadillac" insurance plans.

Yet the 43-page measure tucked inside the bill may have a far greater effect on medical care.

The overhaul creates an institute, funded with \$500 million or more annually, to spur studies of which drugs, devices and medical procedures work best. The boost for comparative-effectiveness research, as the field is known among health experts, will increase scrutiny on treatments used by millions of Americans, including cholesterol drugs led by Pfizer Inc.'s Lipitor and heart stents from Medtronic Inc., said John Sullivan, an analyst at Leerink Swann & Co.

The findings may add scientific rigor to doctors' decisions sometimes influenced more by marketing, said Jeffrey Lerner of the ECRI Institute, a nonprofit that conducts such research. In a health overhaul attacked by critics as too pricey, it's one of the few measures with a chance to rein in U.S. medical spending that soared to \$2.5 trillion last year, Sullivan said.

Comparative effectiveness will probably be "a headwind for the health-care industry," the

Boston-based analyst said in a March 23 phone interview. "If research shows that less complex and maybe less expensive products and therapies work just as well, that is not good news" for the companies.

### Subsidize Coverage

The overhaul, the culmination of a yearlong battle between Democrats and Republicans, tightens restrictions on insurers, increases taxes on health-care companies and requires most Americans to get insured. The House voted March 21 to approve the bill, 219 to 212.

Congressional Republicans, who unanimously opposed the legislation, will campaign this fall on a promise to repeal it, said Kentucky Senator Mitch McConnell, the Senate GOP minority leader, after Obama's bill-signing. The law "cuts Medicare a half a trillion dollars, raises taxes by half a trillion dollars, and in all likelihood will drive the cost of insurance up," he said.

Comparative effectiveness is one of multiple tools in the law designed to pry savings from the system, said Peter Orszag, Obama's budget director, in a March 23 telephone interview. The legislation also experiments with new payment systems for doctors, penalizes hospitals with high readmission rates and creates an independent commission to decide which treatments Medicare should pay for, he said.

## **‘Lower-Cost System’**

“I don’t think there’s any one piece that, by itself, is the end-all-be-all” for slowing the growth in medical expenses, he said. “Together, they work to move toward a higher-quality, lower-cost system over time.”

The health bill’s funding builds upon \$1.1 billion approved by Congress last year for effectiveness research. The new legislation creates a nonprofit Patient-Centered Outcomes Research Institute and tasks it with setting a national agenda for the studies, as well as providing more money and disseminating results.

The institute will be run by a 19-member board of governors with three representatives of drug, device and diagnostic- testing companies as well as patient advocates, doctors and the National Institutes of Health. The U.S. Comptroller General, a presidential appointee, must name the board within six months.

Its funding will start at \$10 million this year and reach about \$500 million in 2013 when money from Medicare and a new insurer tax kicks in, according to an estimate from the Brookings Institution, a Washington-based research center. The budget may increase if insurance rolls grow, Brookings estimates.

## **Spending Doubled**

National health-care spending has more than doubled over the last 35 years as a share of the overall economy, the Congressional Budget Office said in a December 2007 report. Even so, the U.S. lags behind other countries in life-expectancy and infant mortality rates, said Douglas Elmendorf, the agency’s director, in testimony to Congress last March.

Studies suggest less than half of all medical care is backed up by adequate evidence of its effectiveness and “a substantial share” of spending “contributes little if anything to the overall health of the nation,” he said.

The health-care law focuses on studies that assess effectiveness rather than compare costs. It also bars Medicare, the U.S. government insurer for the elderly, from using the research as the sole grounds for denying reimbursement for medical products or procedures.

## **‘Substantial’ Savings**

Still, “the savings can be substantial if you’re drawing a clinical study conclusion that a generic drug works as well as a branded drug,” said Leerink Swann’s Sullivan, offering one example of research that may be done. Therapies used by large numbers of people are likely to be investigators’ first targets.

“You’re talking about saving not pennies on the dollar, but very substantial savings” if patients can replace a branded drug with a generic, he said.

Along with statins such as New York-based Pfizer’s Lipitor, Sullivan cited anti-inflammatory drugs that include Remicade, made by Johnson & Johnson of New Brunswick, New Jersey, and heart stents manufactured by Minneapolis-based Medtronic and Boston Scientific Corp. of Natick, Massachusetts.

The research is likely to spur consolidation among health-care companies, said Lerner, chief executive officer at the ECRI Institute based in Plymouth Meeting, Pennsylvania, which serves governments and hospital systems. Smaller manufacturers may not have the resources to rebut studies questioning a product’s value, he said by telephone.

## **Facing Competition**

“When you compete against other technologies, you’re going to have to demonstrate scientifically that you measure up and that takes time and money and sophistication,” Lerner said.

“The companies are now going to have to not just launch new products with marketing hype, but they’re going to have to demonstrate evidence of superior clinical effectiveness,” said Vivian Coates, an ECRI vice-president.

The fallout from a 2005 study of antipsychotic medications shows the most effective treatment doesn’t always win, said Robert Rosenheck, a psychiatry professor at Yale University School of Medicine in New Haven, Connecticut.

The U.S.-backed study found a 50-year-old drug that may cost about \$2.50 a day worked as well as newer medicines priced eight times higher, Rosenheck said. Sales of the next-generation antipsychotics, led by AstraZeneca Plc’s Seroquel, Eli Lilly & Co.’s Zyprexa and Johnson & Johnson’s Risperdal, nonetheless jumped 43 percent in four years to \$14.75 billion by 2009, according to IMS Health Inc., a collector of prescription-drug data based in Norwalk, Connecticut.

“The overwhelming weight of very aggressive marketing for 15 years shapes attitudes in ways that aren’t likely to be changed by research,” said Rosenheck, author of two antipsychotic comparison studies, in a telephone interview.

## **Active Marketing**

Comparative studies changed treatment of breast cancer, spurring doctors to end the routine removal of entire breasts after research found less drastic operations just as effective, Rosenheck said. “But those are mostly where

there was no private corporation actively marketing its perspective.”

Orszag, an economist trained at Princeton University in New Jersey and the London School of Economics, is a longtime proponent of comparative effectiveness.

Orszag grew frustrated as a scholar at the Brookings Institution when so much attention was paid to the rising cost of Social Security, he said in a May interview. Health care represented a far larger share of the nation’s economy, he said.

The budget chief eventually discovered the work of the Dartmouth Atlas of Health Care, a national study on regional variations on medical spending and outcomes in the U.S. Researchers at Dartmouth suggested \$700 billion may be saved annually by eliminating differences in the cost of similar procedures and foregoing treatments not proven to help patients.

## **‘Huge Efficiencies’**

“Huge efficiencies could be gained if we change the way we practice medicine,” Orszag said in May, when he argued for a government institute to gather more evidence. Republican critics argued throughout the yearlong overhaul battle that the concept was a stealth effort to deny health care to people who need it.

The overhaul’s support for comparative research, tied to Medicare and the insurer tax, is “unprecedented” and should help insulate the program from politics, said Daniel Mendelson, a health-care expert in the White House Office of Management and Budget under former President Bill Clinton.

The dedicated funding “shows the very, very deep commitment among members of Congress” to such studies, said Mendelson, now

chief executive officer at Avalere Health LLC, a Washington consulting firm with government and industry clients.

### **'Part of the Dialogue'**

Companies need to recognize that comparative research is “a permanent part of the dialogue,” he said.

Drugmakers, led by Pfizer, support the effort as “an important solution for better quality and ultimately better value in health-care,” said Randy Burkholder, an associate vice-president at PhRMA, the industry’s trade group in Washington, in a telephone interview. Device companies agree, said David Nexon, an executive vice-president for the industry’s AdvaMed trade group.

Device makers favor the legislation because it focuses on clinical effectiveness, rather than cost, and because manufacturers will be part of the decision-making, he said in a telephone interview. The research may speed use of technologies proven better than existing treatments, Nexon said.

“It takes about 17 years until a new technology is fully accepted as the dominant practice even for something that’s new and better,” he said  
March 23.

“If you’ve got something that’s really superior, having these studies validate that can really speed up the adoption of new practices.”

### **Volume and Value**

The research will have to overcome a payment system that rewards doctors for the volume of care done, rather than its value, said Devon Herrick, a health economist at the nonprofit National Center for Policy Analysis in Dallas.

“There’s really very little incentive for a physician or hospital to follow cost-effectiveness studies,” Herrick said. “Often what we consider to be waste, a hospital considers that revenue. Traditionally, doctors never had to know about the cost of the drugs they’re prescribing.

“Quite often what happens is you go to your doctor and they pull a free sample out of the pill cabinet,” Herrick said. “People like getting something for free, but they don’t know it’s the highest-price drug that the companies want to promote,” he said.