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Health Care: Drug, medical-device makers urge caution on 'comparative effectiveness' research

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When it comes to treating some common diseases, physicians have a dizzying array of treatment options at their disposal.

Take coronary artery disease: There's bypass surgery. There's medication. There's medical devices such as stents. Then there's drug-coated stents. And if a pill or device is involved, then there's the question of which brand or model to use?

It can be like standing in the cereal aisle at a supermarket. With so many choices, how's a doctor to decide what's best?

A new federal research priority is aiming to empower doctors, as well as patients and health-insurance companies, with better information for making these kinds of decisions.

The shift could have major implications for Minnesota's health-care and medical-device companies.

Comparative-effectiveness research attempts to compare different medical treatments side-by-side to determine which drugs or devices are most effective. To the surprise of many, that sort of information often isn't available to doctors.

"We know very little about the effectiveness of many treatments," said Jean Slutsky, director of the Center for Outcomes and Evidence at the Agency for Healthcare Research and Quality. Slutsky was among several speakers last week at the University of Minnesota, where officials from Medtronic, the Mayo Clinic, UnitedHealth Group and other firms grappled with what the policy might mean for Minnesota companies.

The U.S. Food and Drug Administration attempts to ensure drugs and medical devices are safe, but the agency makes no attempt to judge which treatments are most effective. Unlike Britain, the United States has no federal agency dedicated to evaluating the value of various medical treatments. That's left to physicians, who must sometimes make decisions without scientific evidence to support them.

The cost factor
As rising health-care costs strain both government and private business, federal officials are moving forward with the country's first major investment in comparative-effectiveness research.

They've got the support of health insurers and some patient-advocacy groups. But drug and device makers are urging caution, warning that the research, if not applied correctly, could put a damper on innovation.

For employers and health insurers, publicly funded comparative-effectiveness research could mean a treasure trove of new information for making coverage and reimbursement decisions.

A more focused effort to identify the most effective treatments, advocates say, will improve the quality of health care and potentially help limit wasteful spending, too.

"We really need to have a national discussion," said Carolyn Pare, CEO of the Buyer's Health Care Action Group, a coalition of employers pushing for changes in health care policy. "We need to be sure that the money we're paying for health care brings the best results. Right now, we operate under a system of 'do everything, no matter what,' and we just can't afford that."

In particular, some policymakers want to know if government programs are reimbursing for expensive treatments that

aren't proven to work as well as more affordable options.

The federal stimulus packaged signed by President Barack Obama in February included $1.1 billion for government-sponsored, comparativeeffectiveness research. The money has been divided among Health and Human Services, National Institutes of Health and the Agency for Healthcare Research and Quality, each of which will play a role in deciding how the money is spent.

While the government funding is unprecedented, the concept of comparative-effectiveness research isn't new. Hospitals, insurers and medical groups have done such comparisons for decades. But such comparisons are typically based on secondary research that relies on limited data from existing studies, often sponsored by the manufacturer, that only compare a single treatment to a placebo or control.

But a health care system that places greater value on treatment comparisons might raise the bar for new medical devices, requiring companies to retool and spend more on pre-market clinical studies.

"Rather than proving your product is safe and effective, which is essentially the FDA requirement, you're now going to have to establish that it's better than another therapy," said Ralph Hall, an attorney at Bakers & Daniels who specializes in health-care law and corporate compliance and teaches at the University of Minnesota law school.

"So that's going to require time, effort, money, to establish that superiority."

Companies that fail to establish such superiority will see their odds for a commercially successful product drop significantly, Hall said. But those who can provide evidence that their product is most effective will likely see an upside in faster adoption, he said.

It's a higher-risk, higher-reward environment, and in the venture capital world, that typically means fewer products.

Wise companies that have the resources will likely start designing more complex clinical studies that include comparisons to existing products, Hall said.

Medical-device companies have unique concerns because, unlike drug compounds, devices tend to evolve based on doctor feedback after the products are on the market, said Susan Alpert, chief regulatory officer for Medtronic. It is important that studies be conducted at the right time so that a negative comparison doesn't cause a device to be shelved before it reaches its prime, she said.

If payers' demand for comparisons restricts early devices from getting out of the gate, Alpert said, "that's not going to be good for innovation, or frankly for Minnesota."

The emerging emphasis on comparing treatments comes at a time when pharmaceutical companies are seeing a declining return on research and development spending, said Dr. Les Paul, vice president for clinical and scientific affairs for the National Pharmaceutical Council.

"We're trying to tackle more difficult and challenging targets, and now if you add the bar of comparative effectiveness, we don't know exactly what the impact will be on innovation," Paul said. He predicted one possible unintended consequence is less "marginal innovation," small changes made to products in order to compete with rivals that over time can add up to better products.

A report filed with the legislation says the research should not be "construed as mandates or clinical guidelines for payment, coverage, or treatment." However, it's likely that if the funding produces telling, high-quality results, it would be influential in setting both public and private reimbursement rates — and physicians would feel pressured to incorporate the findings into their decisions.

"We won't mandate it directly, but it will be indirect," Hall said. The research will be incorporated into practice guidelines from hospitals, professional groups and others. "How much freedom physicians will have to vary from that is an open question."

That idea has prompted political conservatives to blast the research effort as a gateway to government intrusion in health care. Other critics, including the Congressional Black Caucus and the Society for Women's Health Research raise concerns that the research will ignore treatment differences between races and genders.

Comparative effectiveness is also worrying advocates of personalized medicine, the emerging field that seeks to tailor medical treatments based on patients' personal makeup and genetic markers. Others say those concerns are overblown, and that the research can be designed to recognize some treatments might work best for certain people but not the broad population.

Mayo Clinic CEO Denis Cortese said comparative research alone won't improve health care unless physicians have access to the information at the point of care and health care consumers can be educated to understand more treatment is not always better treatment.

"That's a big hurdle," Cortese said. "Whatever happens here, if the doctors and the patients get together and don't like it, we're going to have a problem."