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THE EVIDENCE GAP

British Balance Gain Against the Cost of the Latest Drugs

By GARDINER HARRIS

RUISLIP, England — When Bruce Hardy's kidney cancer spread to his lung, his doctor recommended an expensive new pill from Pfizer. But Mr. Hardy is British, and the British health authorities refused to buy the medicine. His wife has been distraught.

"Everybody should be allowed to have as much life as they can," Joy Hardy said in the couple's modest home outside London.

If the Hardys lived in the United States or just about any European country other than Britain, Mr. Hardy would most likely get the drug, although he might have to pay part of the cost. A clinical trial showed that the pill, called Sutent, delays cancer progression for six months at an estimated treatment cost of $54,000.

But at that price, Mr. Hardy's life is not worth prolonging, according to a British government agency, the National Institute for Health and Clinical Excellence. The institute, known as NICE, has decided that Britain, except in rare cases, can afford only £15,000, or about $22,750, to save six months of a citizen's life.

British authorities, after a storm of protest, are reconsidering their decision on the cancer drug and others.

For years, Britain was almost alone in using evidence of cost-effectiveness to decide what to pay for. But skyrocketing prices for drugs and medical devices have led a growing number of countries to ask the hardest of questions: How much is life worth? For many, NICE has the answer.

Top health officials in Austria, Brazil, Colombia and Thailand said in interviews that NICE now strongly influences their policies.

"All the middle-income countries — in Eastern Europe, Central and South America, the Middle East and all over Asia — are aware of NICE and are thinking about setting up something similar," said Dr. Andreas Seiter, a senior health specialist at the World Bank.

Even in the United States, rising costs have led some in Congress to propose an institute that would compare the effectiveness of new medical technologies, although the proposals so far would not allow for price considerations. At the present rate of growth, medical costs will increase to 25 percent of the nation's gross domestic product in 2025 from 16 percent, with half of the increase coming from new drugs and devices, according to the Congressional Budget Office.

To arrest this trend, the United States needs to adopt at least some of NICE's methods, said Dr. Mark McClellan and Dr. Sean Tunis, who served earlier in the Bush administration as, respectively, administrator and chief medical officer of the Center for Medicare and Medicaid Services. Dr. Tunis said he spent a lot of time in government "learning about NICE and trying to adopt the processes and mechanisms they used, and we just couldn't."

That's because the idea of using price to determine which drugs or devices Medicare or Medicaid provides has provoked fierce protests. But Dr. McClellan said the American government would soon have no choice.

Drug and device makers, which once routinely denounced the British for questioning product prices, have begun quietly slashing prices in Britain to gain NICE's coveted approval, especially because other nations are following the institute's lead. Companies have said that they will consult with NICE to help determine which experimental compounds enter the final stage of clinical trials, so the British agency's officials will soon influence which drugs enter the market in the United States.

The British government created NICE a decade ago to ensure that every pound spent buys as many years of good-quality life as possible, but the agency is increasingly rejecting expensive treatments. The denials have led to debate over what is to blame: company prices or the health institute's math.

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Drug company executives who were interviewed uniformly promised to cooperate with NICE, but industry advocates were not so kind. Robert Goldberg, vice president of the Center for Medicine in the Public Interest, an advocacy group financed by drug makers, likened Dr. Rawlins and his institute to terrorists and said their decisions were morally indefensible.

Developing a Method

It all started with Viagra.

Pfizer's introduction of the drug in 1998 panicked British health officials, who feared it would wreck the government's health budget. So they placed restrictions on its use. Pfizer sued, claiming the government's decision was arbitrary. To defend itself against similar claims, the government needed a standard method of rationing. The following year, NICE opened.

Asked whether he thought the institute would succeed, Frank Dobson, the Labor health minister at the time, famously said, "Probably not, but it's worth a bloody good try."

Britain's National Health Service provides 95 percent of the nation's care from an annual budget, so paying for costly treatments means less money for, say, sick children. Before NICE, hospitals and clinics often came to different decisions about which drugs to buy, creating geographic disparities in care that led to outrage. (Such disparities are common in the United States, even for federal Medicare patients.)

Now, any drug or device approved by the institute must be offered to patients. The institute has also written hundreds of treatment guidelines in hopes of improving, and making more consistent, basic medical care.

The institute has analyzed the cost-effectiveness of surgical operations, cancer screening tests and medical devices. For example, it found that drug-coated cardiac stents were worth only $450 more than bare-metal ones. In the United States, stent price differences are often far wider.

Five years ago, the British health institute recommended more emergency room CT scans of patients suffering from head trauma — forcing hospitals to buy more machines.

But the decisions that get the most attention are those involving new drugs. Any drug that provides an extra six months of good-quality life for £10,000 — about $15,150 — or less is automatically approved, while those that give six months for $22,750 or less might get approved. More expensive medicines have been approved only rarely. The spending limits represent the health institute's best guess for how much the nation can afford.

After consulting a citizens group, the institute decided that the nation should spend the same amount saving or improving the life of a 75-year-old smoker as it would a 5-year-old.

'Muddling Through'

The institute's decision-making process involves a series of independent assessments, consultations with manufacturers, committee meetings, comment periods for outsiders and appeals that, taken together, Dr. Rawlins described as "procedural justice," or "muddling through elegantly." While the institute provides advice, decisions are made by one of three committees made up of doctors, nurses and economists from outside the government.

Transparency recently became a high priority, but gaps in the idea of openness remain. At the institute's first public decision-making appraisal meeting in September, staff members handed a reporter a stack of documents, only to snatch them back moments later. The committee's chairman, Dr. David Barnett, was so intent on keeping the meeting brief that he told a committee member: "This must be the last question. It must be relevant. Otherwise, you will feel my wrath."

To analyze the value of the drug that Mr. Hardy, the kidney cancer patient, wanted, and the value of three other kidney cancer medicines, the British institute hired a university group that considered how many months the drugs delayed cancer's progress.

Firestorm of Protest

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The academics got drug prices and calculated the costs of administering them and treating their side effects. Not one of the drugs came close to being worth their expense, the group suggested. In a preliminary ruling in August, a committee from NICE agreed.

The decision caused a firestorm. Twenty-six prominent British oncologists wrote a letter to The Sunday Times saying that the institute assessed cancer treatments poorly and that patients were remortgaging their homes to buy drugs freely available in other countries.

Given that fewer than 6,000 people per year in England and Wales are diagnosed with kidney cancer, "Why put ourselves through so much heartache for very little money?" Andrew Dillon, the institute's chief executive, asked in a September interview. "The answer is that if we don't apply the same criteria even to small groups of patients, there's little value to what we do at all."

Dr. Sikora, who helped organize the August protest, predicted in a September interview that the institute would buckle under political pressure.

Flooded with anguished comments, the institute beat a hasty retreat. A preliminary consultation posted Nov. 5 said that the institute would instruct its appraisal committees to consider approving highly expensive life-saving drugs for terminal illnesses affecting fewer than 7,000 patients per year — a policy that seems tailor-made for Sutent and the three other kidney cancer drugs.

Negotiations with companies on possible discounts are continuing, and a committee is scheduled on Jan. 14 to make public this nascent compromise.

NICE has stood fast in other areas, though, rejecting Kineret for rheumatoid arthritis and Avonex for multiple sclerosis. In 2001, NICE ruled that Aricept and two other drugs used to treat Alzheimer's disease were worth their costs only if patients' conditions had increased from mild to moderate severity.

The analysis put a value on patients' improved thinking skills, and possible savings from delayed entry into nursing homes. Instead of pills, the institute suggested more counseling.

Advocates for patients with Alzheimer's disease called the decision heartless.

Dr. Rawlins said he was frustrated that his institute had been censured instead of the drug company executives who set sky-high prices. Take the case of Celgene, the maker of Revlimid, a drug for multiple myeloma, a bone-marrow cancer, that in a preliminary ruling on Oct. 28 the institute said was too costly.

Celgene's first big seller was thalidomide, a decades-old medicine now used as a cancer treatment, which is so cheap to manufacture that a company in Brazil sells it for pennies a pill.

Celgene initially spent very little on research and priced each pill in 1998 at $6. As the drug's popularity against cancer grew, the company raised the price 30-fold to about $180 per pill, or $66,000 per year. The price increases reflected the medicine's value, company executives said.

In 2005, the company introduced Revlimid, a derivative of thalidomide that is supposed to be less toxic, but may be no more effective. Celgene priced it at about $260 per pill, or $94,000 per year.

Offering Discounts

Private and public insurers in the United States must pay whatever Celgene and other makers of unique cancer medicines decide to charge, so prices are soaring. Spending on cancer drugs and other such specialty medicines rose 9 percent last year and now represents 24 percent of the nation's drug bill, according to Health Strategies Group, a New Jersey consulting company. Drug expenses in 2006 grew faster than any other part of the nation's health bill except home care.

But because of the institute, Britain's National Health Service has been among the first to balk at paying such prices, which has led many companies to offer the British discounts unavailable almost anywhere else.

Johnson & Johnson, for instance, agreed to charge for Velcade, another drug for multiple myeloma, only if tests showed it was effective in a particular patient. Novartis agreed to give free injections of Lucentis, a drug for age-related macular degeneration, if patients needed more than 14 shots. Dr. Rawlins said these deals were constructed by drug makers to hide from other countries the discounts offered in Britain.

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“It’s a good deal for us, but I can’t see that it will work in the long run because I can’t see that others countries will be so dim as to not notice it,” Dr. Rawlins said.

A more prudent bureaucrat would never make such a remark. Dr. Rawlins said that he delighted in controversy, “although I’ll admit that it doesn’t always work out.” He wears thick glasses and fine suits whose pockets are stuffed with nicotine gum packages that rattle as he walks. He laughs easily, plays the piano and viola, and moves effortlessly between politics and medicine.

His criticisms of the pharmaceutical industry have sharpened.

“I want them to produce new drugs for conditions we really need treatments for, but I loathe their marketing practices, which corrupt doctors in a dreadful way,” said Dr. Rawlins, who until recently practiced general medicine and for years was chairman of the British version of the Food and Drug Administration. “And I’m very conscious that the prices the pharmaceutical industry charges are what they think the market will bear.”

In 10 years, the health institute’s budget has grown to $50 million from $13 million, and it is scheduled to rise to $142 million in four years. NICE has 270 employees, who include doctors, economists and pharmacists.

Worldwide Impact

Agencies like NICE are popping up across the globe. Dr. Leonardo Cubillos, Colombia’s national director of insurance, said that Colombia was using British methods to choose drugs for a national health insurance package.

Membership in an international group of drug and device assessment agencies grew to 45 last year from 8 in 1992. The British institute has created a consulting group to advise foreign governments.

Much of the reason for this proliferation of agencies is that, while prescription drugs represent just 10.3 percent of overall medical spending in the United States, that share is 17 percent on average in industrialized countries.

As spending on drugs soared in many nations — often haphazardly — overall health often showed little improvement. So international aid agencies are advising governments to adopt British assessments and deliberations to improve their public’s health while lowering costs, and officials are listening — a trend that is likely to accelerate during the present global economic slowdown.

The health institutes in both Britain and Germany may soon suggest prices for drugs, a strategy intended to deflect political pressure back on the companies and shorten negotiations that now often take months.

“We have been told that the price is the price, but the worm is turning now,” Dr. Barnett said.

Company executives acknowledge that they are increasingly acceding to British demands to slash prices.

But the most pressing question for the industry is what influence the British institute will have in the United States. The United States already spends more than twice as much per capita on health care as the average of other industrialized nations, while getting generally poorer health outcomes.

Michael O. Leavitt, the Bush administration’s secretary of health and human services, said in a September speech that, at its present growth rate, health care spending “could potentially drag our nation into a financial crisis that makes our major subprime mortgage crisis look like a warm summer rain.”

And while there is fierce disagreement about how and whether to control drug and device expenses as part of a broader reform of the health system, many say some cost controls are inevitable. At a September device industry conference in Washington, a seminar on the issue was standing-room only and half of the questioners mentioned NICE.

John R. Dwyer Jr., a Washington lawyer who represents device makers, said that many in the industry have believed that major changes to control costs in the federal Medicare program were inevitable, and “people see NICE as the only workable paradigm.”

Meanwhile, Mr. Hardy waits. In recent weeks his growing tumor has pressed on a nerve that governs his voice. He can barely speak and is increasingly out of breath. The Hardys are hoping that in January NICE will approve the use of Sutent, allowing Mr. Hardy

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"It's hard to know that there is something out there that could help but they're saying you can't have it because of cost," said Ms. Hardy, who now speaks for her husband of 45 years. "What price is life?"