# British officials wrestle with cost of cancer drugs

#### Availability of drugs differs from country to country

By MARIA CHENG
AP MEDICAL WRITER

LONDON — In October, Rocky Fernandez was told he might not live to Christmas.

Suffering from kidney cancer that had spread to his lungs, his doctor wanted to prescribe him Sutent, a relatively new cancer drug. But Fernandez hit a roadblock.

The agency that tells the British government which treatments are worth paying for had decided last year that Sutent — at \$5,160 a month — was too costly to be offered free under the national health care system.

The decision on the Pfizer Inc. drug, and others, led to an outcry from thousands of British cancer patients and their doctors over the denial of costly drugs that don't cure but can prolong survival, if only for a few months. "Many people might not under-

stand why we want drugs that can only give you an extra three, six or 18 months," Fernandez said. "But for some families, that can make all the difference." Under fierce pressure, the Brit-

ish health authorities relented in February. Thanks to that reversal, and a personal plea by Fernandez to his hospital to cut through red tape, he recently took his first tablet of Sutent.

Had he been in the United States, Fernandez, 45, would likely have gotten the drug much sooner — though he might have had to pay for part of it depending on whether he had health insurance and what type of coverage.

"We consider Sutent to be an effective drug," said Dr. Len Lichtenfeld, deputy chief medical officer of the American Cancer Society. "If patients want it and doctors want to prescribe it, most (U.S.) programs will probably pay

Still, Lichtenfeld said neither system is perfect.

"If you want to talk about early access to an effective drug, being in the U.S. may be slightly better," he said. "But if you want to talk about the most people having the most access to drugs paid for by the government, you're better off

Such issues are also part of the health care reform debate in the United States — but they are approached gingerly. Congress recently approved a billion dollars to study the effectiveness of certain treatments and tests, but lawmakers refused to link the results of such research to payment policy. One possibility is that in the future, insurers might require higher copayments for treatments that are deemed less effective.

As more costly, life-extending drugs are developed, Britain's National Institute for Health and Clinical Excellence, or NICE, will likely face more tough decisions of its own. NICE acts as a kind of budgetary police, advising which treatments are a good buy; its recommendations are almost always adopted by the government.

When the institute first rejected Sutent, leading cancer doctors slammed the decision, while some patients mortgaged homes or dipped into pensions to pay for the drug on their own. In changing course earlier this

year, the institute decided that expensive treatments like Sutent would be approved under certain conditions: Such drugs had to extend life by at least three months and be used for illnesses that affect fewer than 7,000 new patients a year. That means the government is willing to pay to extend lives of those suffering from some rare diseases, but not for more common ones. That criterion offers a builtin protection for the government's limited health budget.

One of NICE's most contentious criteria is how much should be paid per each added year of a patient's survival. The general threshold calls for not spending more than \$44,235 per year of

As NICE chairman Michael Rawlins puts it: "We have a finite pot of money."

He said the institute recognized the significance of prolonging life, and noted that NICE had sometimes approved treatments costing up to \$70,775 per year of life added.

But Rawlins said that the government wouldn't be able to afford



The Associated Press IN THIS UNDATED image, Rocky Fernandez is seen at Wembley fire station in London. With more new, pricey cancer drugs on the market, the British health system is struggling to make tough decisions about how much to pay to extend a terminal patient's life. Thanks to lobbying from Fernandez and other kidney cancer patients,

the health agency reversed itself

the high cost of a drug that adds

recently and agreed to swallow

a few months of survival.

such expensive medicines if they were for more common conditions like breast cancer or heart disease, since the cost would be astronomi-

Health economist Julien Le Grand of London's School of Economics worries that NICE's authority is being undermined by constant challenges to its deci-

We should have a consistent rule that says what will be funded (by the government) and what won't. It shouldn't be a question of who shouts the loudest," he said.

Some doctors say Britain, which spends about \$13 billion a year on all drugs including cancer drugs, needs to loosen the purse strings. France, for example, spends 10 times more on new cancer drugs · defined loosely as having been on the market for less than five years — than Britain.

According to Britain's department of health, Britain spends about \$112 per person on cancer care each year. In comparison, both France and Germany spend more than \$177 per person. In

Cancer Partners UK.

Sikora acknowledged that amid the financial meltdown, boosting budgets is probably unrealistic. "We do need a rationing system because in a lot of cases, there just isn't the money."

a refund if a drug doesn't work.

Janssen-Cilag, offered reimbursemade similar offers for some of their cancer drugs.

patient, who has campaigned for years with two other patients to get access to Velcade, says the drug strategies show the government has listened to patients' concerns. In her own case, she says that without Velcade, "I would be

the last seven years.

"We are far behind the U.K. when it comes to deciding what will be paid for by the government in health care," Lichtenfeld said. "For us, cost-effectiveness doesn't enter into the discussion. Maybe it should."

On the Net: and Clinical Excellence: www.nice.org.uk/

the U.S., direct medical costs for cancer care are about \$295 per person, according to the National Institutes of Health — almost three times what Britain spends.

"My colleagues in Paris can use drugs freely, but I can't do it here because they haven't been approved (for government payment)," said Dr. Karl Sikora, an oncologist and medical director of

To get cheaper drugs, Britain has cut deals with pharmaceutical firms that either offer a discount or

When NICE decided that Velcade, a treatment for the blood cancer multiple myeloma, wasn't worth the cost, its Belgian maker, ment if it failed in certain patients. Other companies, including Roche AG and GlaxoSmithKline, have

Jacky Pickles, a blood cancer

All health systems will eventually be forced to make hard decisions about which patients to spend money on, experts say. "These new cancer drugs are incredibly expensive, and the risks and benefits need to be weighed carefully," Lichtenfeld said. A recent report in the New England Journal of Medicine found that Medicare's spending on cancer drugs has jumped 267 percent in

National Institute for Health

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#### **HEALTH & FITNESS • 9**

#### **Weekend Doctor**

By DR. THOMAS F. VAIL

Excess weight can cause foot pain. However, it's tough to lose weight when your feet hurt.

Being overweight or obese changes the way your foot functions. Force on your foot increases, your steps are shorter, your feet angle out more and flattening of the foot increases.

Studies have shown that overweight patients experience more heel pain, tendonitis, arthritis, ball-of-foot pain, fractures and sprains in their feet and ankles than patients at a normal weight.

So what do you do if foot pain from excess weight prevents you from exercising?

Reducing foot pain will allow you to exercise in comfort, helping you lose weight safely and improving your health.

Foot orthotics can minimize abnormal force on the feet and are often used to treat and prevent foot problems for those carrying excess weight and/or trying to lose weight.

A firm, controlling foot orthotic can support the forces caused by extra weight and provide shock absorption to decrease the stress on your joints and prevent arthritis. The best orthotics are those that conform closely to the

arch of the foot. Though prefabricated orthotics are available, they often do

not provide enough support to adequately relieve pain. People carrying excess weight are more likely to need custom orthotics for the best pain relief.

Other treatments for foot pain caused by excess weight include stretching, strengthening and anti-inflammatory If you are starting a weight loss program, be sure to talk to

your primary care physician, a registered dietician, and personal trainer or physical therapist to create the best exercise program for your needs. For more information on foot orthotics, talk to your podia-

Vail is with Advanced Footcare Clinic, Findlay. Questions for Blanchard Valley Health System doctors may be sent to weekend@thecourier.com, or to Weekend, The Courier, P.O. Box 609, Findlay, OH 45839-0609.

## Cyclists should pay attention to their bones

### They are prone to low bone density

By JEANNINE STEIN LOS ANGELES TIMES

Cyclists are no strangers to breaks and fractures, but Andrew Coggan could be forgiven for not expecting a hip fracture from a bike crash at age 30. He may have been less surprised than most of his peers though, having recently been diagnosed with low bone density.

For many cyclists, an injury like Coggan's is the first sign that bones are not as strong as they should be. Although cyclists are known for staying on top of their training for heart rate zones and pedal cadence, increasing research suggests they should also pay attention to their risk of thinning bones.

"Sometimes athletes in their late 20s and early 30s will come in for a femur or a hip fracture, and they'll be surprised because the fall was really not that bad," says Dr. Max Testa, a sports medicine physician at the Orthopedic Specialty Hospital in Salt Lake City who routinely treats elite cyclists. "But we'll look at the X-rays and see that there is some osteopenia (lower-than-normal bone density) there.

Many factors contribute to osteopenia or osteoporosis (very low bone mineral density) in cyclists, but one of the culprits is the nature of the exercise itself. Cycling is a low-impact sport that puts little mechanical load on the bones. That's great if you have joint problems, but it's the weight-bearing nature of exercise that signals bones to create more mass. Without such stress, bones don't get stronger, making them more prone to injury.

Avid cyclists, amateur and professional, seem to be especially at risk of bone injuries if they don't do any cross-training. (Swimmers may also be in danger, since that sport requires little mechanical loading as well.) The lower spine is a particularly susceptible area, because it gets almost no loading. The hips may get some from the action of pedaling.

Coggan, now a senior scientist and exercise physiologist at Washington University, St. Louis, had been cycling one to two hours a day for about 15 years when he crashed in 1989. "And I recall prior to that," he says, "when

I'd be chatting with a group of cyclists, I'd be ries. taking note of the fact that everybody had scars " from things like broken arms and broken col-

A recent study in the journal Medicine & Science in Sports & Exercise found that competitive male road cyclists had significantly lower bone mineral density in their spines than a control group of men who were moderately physically active while doing other recreational activities. They were also more likely to have osteopenia and osteoporosis than those in the control group, despite the fact that the cyclists had a greater calcium intake.

Another study, published in the journal Bone in 2002, found that male road cyclists had lower bone mineral density than male mountain bikers after adjusting for body weight and controlling for age. The difference there could be that mountain biking, with its bumps and jumps, perhaps provides more impact and stimulation for bone growth than does road

Young cyclists aren't immune.

"You don't achieve peak bone mass until your late 20s," says Debra Bemben, co-author of the more recent study and an associate professor in the health and exercise science department at the University of Oklahoma. "If cyclists are in their early 20s and they're not doing anything else for exercise that's going to load their spine and help them achieve peak bone mass, it may put them at risk if they fall, since they'll have a greater chance of fracture. This is a pretty important health issue."

Further, some hard-core cyclists may not be eating enough to offset what they burn when exercising, depriving their bodies of bonestrengthening nutrients such as calcium and vitamin D. Especially at risk are women who have disordered eating, menstrual disruptions and bone loss — known as the "female athlete triad."

"If there's a deficit in the energy balance," Bemben says, "then the body is not able to build things up, like bone."

That caloric shortfall could also trigger other physiological problems, such as hormone imbalances. For women this could mean lower estrogen levels; for men, lower testosterone levels. Bemben says estrogen and testosterone have protective effects on bones, slowing the rate of bone breakdown.

But hormones aren't only affected by calo-

"If people overexercise, that can suppress testosterone in men, as it can suppress estrogen in women," says Dr. Aurelia Nattiv, director of the Santa Monica-UCLA Osteoporosis Center, although studies have not always borne out the low testosterone-low bone density con-

"Too much of a good thing can cause negative effects on bone. We do see that sometimes not only do women lose their periods and have low levels of estrogen, but elite male runners can have low testosterone. So adequate hormonal balance is important." She adds that a family history of osteoporosis can contribute as well.

Even perspiration can be a factor, Bemben says.

"Cyclists may lose a lot of calcium in their sweat," she says. "Even if they're taking in amounts (of liquid) that are seemingly high for the average man, that might not be enough to balance what they're excreting."

Although the subject of bone density occasionally pops up on cycling message boards, it's not exactly a hot topic.

'Some people have no clue," Testa says. "They don't even know it's an issue." A dual energy X-ray absorptiometry (DXA) scan is most often used to test bone density, a noninvasive test that uses low levels of radiation. Testa adds, "Often people are surprised to find that their results are not ideal.

And though women are reminded (via the media or their physicians) to up their calcium intake to prevent osteoporosis, men usually don't get the same messages. Young male cyclists, especially, figure they're healthy and don't need to be concerned. Some sports medicine physicians, orthopedists and cycling coaches discuss the issue with patients, but Testa and others say more education may be

Coggan, still a competitive amateur cyclist, got another DXA scan a few weeks ago and the news wasn't great — he has osteopenia in his lumbar spine and osteoporosis in his hips. He says that while he does do weight training and runs occasionally, he knows he needs to focus his athletics more on health rather than performance.

"I have a couple more athletic goals I want to achieve," he says, "and then I may have to

### **Huge study boosts** disappointment on multivitamins

By LINDSEY TANNER AP MEDICAL WRITER

CHICAGO — The largest study ever of multivitamin use in older women found the pills did nothing to prevent common cancers or heart disease.

The eight-year study in 161,808 postmenopausal women echoes recent disappointing vitamin studies in men.

Millions of Americans spend billions of dollars on vitamins to boost their health. Research has focused on cancer and heart disease in particular because of evidence that diets full of vitamin-rich foods may protect against those illnesses. But that evidence doesn't necessarily mean pills are a good substitute.

The study's lead author, researcher Marian Neuhouser of the Fred Hutchinson Cancer Research Center in Seattle, offered this advice: "Get nutrients from food. Whole foods are better than dietary supplements," Neuhouser said.

The study appeared in the Archives of Internal Medicine.

Co-author Dr. JoAnn Manson said despite the disappointing results, the research doesn't mean multivitamins are useless.

For one thing, the data are observational, not the most rigorous kind of scientific research. And also, it's not clear if taking vitamins might help prevent cancers that take many years to develop, said Manson, chief of preventive medicine at Harvard's Brigham & Women's Hospital.

She said multivitamins may still be useful "as a form of insurance" for people with poor eating habits.

Vail

The study involved an analysis of data on women in their 50s and up who participated in longrunning government studies on postmenopausal women. Almost 42 percent of the women said they used multivitamins regularly.

After about eight years, roughly equal numbers of vitamin users and nonusers developed common cancers, heart attacks and other cardiovascular problems. Overall, there were 9,619 cases of cancer, including cancers of the breast, lung, ovary, colon and stomach; and 8,751 cardiovascular ailments including heart attacks and strokes. In addition, 9,865 women died, also at similar rates in multivitamin users and nonusers.

Alice Lichtenstein, a Tufts University nutrition professor who was not involved in the research, said the study is important because it involved so many women.

"All the evidence keeps pointing in the same direction," Lichtenstein said.

Eric Jacobs, an American Cancer Society epidemiologist, said while his group doesn't advise vitamins to prevent cancer, it does recommend maintaining a healthy weight and eating at least five servings of fruits and vegetables daily while limiting red meat. Similar habits are also thought to help reduce heart disease risks.

On the Net: Archives: www.archinternmed.com American Cancer Society: www.cancer.org

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