Britain: Breast cancer patient's legal challenge highlights rationing of health care

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Ann Marie Rogers, a 54-year-old breast cancer patient and mother of two, went to the Court of Appeal this week as part of her fight to receive the drug Herceptin free of charge under the National Health Service (NHS).

Last month, Rogers lost her legal case challenging a decision by the Swindon Primary Care Trust (PCT) to deny her the treatment. At that time, the High Court ruled that the Swindon PCT did not contravene government policy or act unlawfully when it refused to fund her treatment for early stage breast cancer with the drug.

Mr. Justice Bean said there were different opinions on whether or not to prescribe Herceptin to patients with early stage breast cancer. "The court's task is not to say which policy is better, but to decide whether Swindon's policy is arbitrary or irrational and thus unlawful," he said. "Accordingly, despite my sympathy with Ms. Rogers' plight, I must dismiss the claim for judicial review."

Rogers described the decision as a "death sentence." She has already borrowed £5,000 for three treatments of Herceptin, but said she cannot afford to pay for further treatments. The High Court ruled that the PCT should continue providing the drug until March 31, or until the Court of Appeal gave its judgment. On March 29 the Court of Appeal said it would make its ruling "as soon as reasonably possible."

The Rogers case says much about the state of health care in the twenty-first century. Under the profit system, the fruits of science and technology and their revolutionary implications for medical treatments and cures are sacrificed at the altar of profit, in the name of "cost effectiveness" and "value for money."

Herceptin (the brand name for the drug Trastuzumab) targets the HER-2 protein, which can fuel the growth of breast tumours. It has been licensed since 2002 in Britain for use in women with advanced breast cancer, where the disease has spread within the breast or to another organ. But it is awaiting license for treatment of early stage breast cancer.

In Britain, more women die of breast cancer than any other form of cancer.

Rogers' case has highlighted the plight of other breast cancer sufferers across the UK. Another early stage breast cancer patient, Elisabeth Cooke, a 59-year-old mother of two from Bristol, England, is also appealing to the High Court in an attempt to overturn an NHS decision not to give her the drug. Her case has been adjourned pending the outcome of Rogers' appeal.

The Swindon PCT denied that its decision was based on cost factors. It said it could not prescribe the drug as it had not been approved as a treatment and its safety and benefits had not been checked. But media debate has largely focused on why it is not economically possible to prescribe the drug.

There is growing evidence that Herceptin is effective in treating early stage breast cancer. Lawyers in the Rogers case produced recent evidence from the United States showing that the drug more than halved the chances of the aggressive HER-2 form of breast cancer returning.

Following treatment trials, the New England Journal of Medicine in October described Herceptin as "revolutionary" and "maybe even a cure" for breast cancer.

In November, the North Stoke PCT in England reversed a decision denying access to the drug to Elaine Barber, a 41-year-old mother of four. The PCT had argued that the drug's efficacy was unproven and, on that basis, it was too expensive to fund its use.

The PCT changed its position when Health Secretary Patricia Hewitt called on the trust to let Barber receive treatment. This action avoided Barber pursuing a High Court challenge to the original decision.

Upon allowing Barber to be treated, the North Stoke PCT issued a statement in which it all but admitted that its original decision had been based on the cost of the drug. Mike Ridley, the chief executive, said, "The introduction of any new expensive treatment inevitably provokes a review of the PCT's investment priorities, especially as we work to recover from our financial deficit. There is no contingency budget in this financial year for the prescribing of adjuvant Herceptin."

Several other PCTs in Britain have prescribed the drug to patients, but these decisions have only followed public protests.

In February, the PCT in mid- and west-Wales agreed to provide Herceptin under the NHS to women in the early stages of the disease, following protests by Julie Davies and other breast cancer patients. Another breast cancer patient in Wales, Jayne Sullivan, recently held a week-long sit-in in the National Assembly foyer to draw attention to the issue. Sullivan explained: "There is only a short window of opportunity—a few weeks after chemotherapy—when Herceptin can be used. While officials delay and talk, women's lives are being put at risk."

Earlier this month, doctors in Jersey were given the go-ahead to prescribe Herceptin whenever they think it necessary. But the Jersey Health Department has set aside just £300,000 to pay for it, meaning it is effectively rationed.

On March 11, it was announced that primary care trusts in Norfolk would allow surgeons at Norfolk and Norwich University Hospital to offer the drug. Once again, a restrictive criterion has been applied to the distribution of the drug.

Patients must test positive for the HER-2 receptor. But only 20 percent of women with breast cancer will test positive, according to research.

Further criteria require that a patient's tumour be 10mm or more in size, and that the patient has completed both surgical treatment and chemotherapy. (Chemotherapy generally takes up to six months after diagnosis to complete). Herceptin must be started within six months of chemotherapy.

In a number of other countries with public health service provision, Herceptin is already being made available for early stage breast cancer. This is the case in Germany, France, Spain, the Netherlands, Slovenia, the US and four provinces in Canada.

In Britain, drugs can be issued as standard only once they have been licensed and given approval for the NHS by the National Institute for Health and Clinical Excellence (NICE). This body was established by the Labour government in 1999 with a remit to offer advice on drugs and clinical best practice for the NHS. However, its main criterion for assessing a drug is whether it offers "value for money."

In her study of the privatisation of health care in the UK, entitled *NHS PLC*, Allyson M. Pollock points out that when NICE was formed, "A large part of its aim was to try to limit the growth of the NHS drugs bill by submitting the sales-oriented claims of the pharmaceutical firms to independent and objective assessment."

But, Pollock continues, "NICE appeared to be quickly 'captured' by the pharmaceutical industry, which was in any case represented on NICE's governing body. NICE's first attempt to discourage the use of a drug, Relenza, which its expert assessors found to have too little therapeutic benefit, was reversed, and NICE also shied away from evaluating the cost effectiveness of drugs it did approve."

In February 2002, NICE finally ruled that the multiple sclerosis drug beta interferon should not be prescribed to new patients, as it was too expensive. In its provisional ruling in July 2000, NICE said that the drug's "modest clinical benefit appears to be outweighed by its very high cost."

Other drugs rationed in Britain include Temozolomide, used for treating brain tumours. Last month, Tom Dargavel, a patient at Singleton Hospital in Wales, was told that the drug was not available, despite the fact that it was saving the lives of brain tumour patients in Germany and the US.

NICE initially rejected the use of Temozolomide, whilst stating that no final decision had been made. The NICE preliminary recommendation appraisal committee said that the drug should not be widely used for the treatment of the aggressive form of brain cancer known as high-grade glioma, with which Dargavel has been diagnosed. This is despite expert advice estimating that Temozolomide alone could potentially benefit 800 patients a year in the UK.

Professor Roy Rampling, a UK expert in brain tumours, said drugs like Temozolomide were "the biggest breakthrough in treating brain tumours in 30 years," and were "standard care in many other developed countries." Rampling is a signatory to a letter sent to Health Secretary Patricia Hewitt demanding that NICE withdraw its recommendation and allow the drug to be available under the NHS.

Due to the controversy over Herceptin, NICE has implemented a new review procedure, but it is expected to take some time before the drug will be finally recommended. Other cancer-fighting drugs such as Avastin, Erbitux, Gleevec, Rituxan and Tarceva are also increasingly deemed too expensive and are not currently widely prescribed.