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## Life or death rations

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**THE grape-sized lump Bronwyn Wells first felt in her left breast was so big, she thought it had to be a cyst because she "couldn't believe a cancer could get that big that quickly". Knowing her scans had been clear eight months earlier and feeling no great sense of urgency, Wells, then aged 41, waited three weeks before she saw her GP. The doctor agreed: probably a cyst. But she referred her to a breast clinic, where the news darkened.**

A day of tests that included a mammogram, ultrasound examination, needle biopsy and core biopsy made it clear she had breast cancer. Not only that, but it was HER-2 positive, which means it was fast-growing and aggressive.

A lumpectomy failed to remove all the growth and Wells had a full mastectomy, followed by chemotherapy and then treatment with the breast cancer drug Herceptin, a medicine her doctors had been reluctant to tell her about because of its cost: \$60,000 for a one-year course.

"My reaction was, if this is going to save my life, I don't care how much it costs," Wells says. She raised the money to pay for the first three doses, each of which costs \$3000 and lasts for three weeks, before luck intervened. The Howard government put the drug on the Pharmaceutical Benefits Scheme from October 1, 2006, for the treatment of early stage breast cancer, at an estimated cost of \$470million from 2006-07 to 2009-10 for the 2000 patients a year affected.

"I was absolutely delighted," says Wells, who eventually returned to her legal career in December 2007 after taking two years off work to fight her illness. "The financial impact of something like breast cancer is enormous."

Wells is one of the lucky ones. The inevitable limit on healthcare funds coupled with an almost limitless demand means a decision to help patients with one type of disease inevitably results in some other patients missing out.

Often the health system has to make decisions about targeting its funds in a way that will yield the biggest health benefits, a principle reflected in recent contentious recommendations to reduce access to free mammography screening for women aged under 45 and over 75, in order to increase screening of women in the target age group of 50-69 who are deemed most at risk. The move, proposed in a recently released evaluation of the BreastScreen Australia program, triggered consternation among breast cancer patient groups.

But there are plenty of other expensive drugs, to say nothing of procedures, devices or even entire allied health professions, all clamouring for taxpayer support through the PBS or Medicare.

Federal Health Minister Nicola Roxon acknowledged the strain on the budget will only worsen, saying in a speech this week that keeping to "business as usual" would send health and aged-care costs soaring from 9 per cent of gross domestic product now to 12.4 per cent by 2033, though still below the present US share of about 16 per cent. "These are numbers to turn any treasurer pale," she said.

Drug costs play no small part in these rising costs. Avastin, a drug used to treat bowel cancer, the second most common malignancy in Australia, was added to the PBS from July 1 at a cost of \$310.7m over four years. A little more than 1700 patients a year are expected to benefit.

In many cases cancer drugs are not cures but instead improve survival chances or delay death. The question the health system is having to face is: how much extra life should a drug allow a dying patient in order to deserve public funding?

The kidney cancer drug Sutent, which was added to the PBS in May at a cost of \$131m, extends progression-free survival by about 11 months, while another bowel cancer drug, Erbitux, has been repeatedly knocked back for PBS funding partly because its benefit is much less, about five months of

extra life, despite its cost being about \$72,000 a patient a year, similar to Avastin.

Lloyd Sansom rejects the notion that Australia rations health care, but acknowledges choices of what treatments to fund are driven by evidence of which work best. He chairs the Pharmaceutical Benefits Advisory Committee, the body that advises the federal government on whether a new drug should be PBS-listed.

Sansom says the PBAC aims to "purchase health outcomes rather than purchase products", and one of the ways it does this is by applying a statistical tool called the quality-adjusted life year, or QALY.

The QALY takes into account the quality as well as quantity of additional life gained, adjusting the rating for a drug's effectiveness by also considering its side-effects, and allows the overall benefit to be compared with the cost.

The QALY has been taken up with particular enthusiasm in Britain, where the National Institute of Health and Clinical Excellence sets the maximum acceptable price tag to buy one extra year of healthy life at pound stg. 20,000-pound stg. 30,000 (\$37,000-\$56,000).

Sansom says the view for many years in Australia has been that setting an absolute ceiling is "almost impossible". The equivalent figure here works out at between \$30,000 and \$40,000, although that is fluid and the PBAC has recommended drugs for approval that cost as much as \$55,000 per QALY and rejected others with figures as low as \$30,000, bearing in mind other factors.

Sansom acknowledges the cost of many modern drugs, particularly those for cancer, which can often range between \$25,000 and \$50,000 a year for each patient, will become more of an issue as the population ages and health budgets come under increasing pressure.

"If we had infinite money, if money was not a barrier to anything, we'd say 'of course it's been registered, and the risk benefit for this drug has been acceptable'," Sansom tells Focus. "That's utopian ... you have to make judgments. PBAC members know that whenever we say no (to a drug application), some people are likely to be disaffected by that decision.

"Every PBAC member, when I put things to the vote, you can see that they know at the back of their minds that this decision is going to affect someone. But of course a publicly funded system cannot exist on that individual context basis. It's got to be a population basis. That's what makes it work."

All these new medicines promise to push up still further the percentage of health spending that occurs in the last year or so of a person's life, a figure that according to some estimates is already close to 50 per cent.

Sansom says there is "an interesting debate internationally" about expensive drugs that promise small, but to the individual undoubtedly significant and priceless, improvements in terms of survival.

"Do people value their life more at the end of their life than at any other stage? Should we pay more towards end-of-life drugs?" Sansom asks. "Should we spend \$200m on a drug that gives a median extension of life by three weeks, or should we recommend that that \$200m be spent on palliative care services? That's not an answer for PBAC to make, that's an answer for society to make, through its governance and through the democracy in which it operates."

But some health experts are concerned that our mechanisms for allocating resources, including decisions as to which drugs get PBS access, are too prone to politicised pressures.

In some cases, they feel this results in popular causes such as breast cancer getting a disproportionate share of public sympathy, while patients with less photogenic or more stigmatised conditions receive less attention.

A paper published last year by public health experts at the University of Sydney analysed 43 television news reports about breast cancer broadcast in Sydney between October 2005 and August 2006, when Herceptin won PBS listing, and found the majority (54 per cent) characterised the issue as desperately sick women being denied lifesaving treatment by a callous government.

Not one of the reports challenged the price being asked by the drug company concerned, and most implied Herceptin was a wonder drug, even though the study cited scientific evidence suggesting the drug might reduce a woman's risk of dying by just 1.8 per cent in a two-year period, meaning one life would be saved for every 55 women treated.

"With limited healthcare budgets, significant expenditure in one area holds implications for reduced expenditure in others," said the study, published in the *Journal of the Royal Society of Medicine*.

"In cases where public policy is influenced by emotive media accounts, legitimate questions arise of why those who are lucky enough or manipulative enough to attract media attention (are) thought to have a special claim on resources."

Sansom bristles at any suggestion that the PBAC's 2006 decision on Herceptin represented a caving-in to public or political pressure.

Instead, he points to the committee's initial rejection for subsidy, also in 2006, of the Australian-invented cervical cancer vaccine Gardasil, in the face of extremely positive publicity about the vaccine and the likelihood that it would save lives. Gardasil was approved later that year after its maker, CSL, agreed to drop the price.

But patient groups such as Breast Cancer Network Australia are confident the pressure they applied in 2006 won the day, just as they think it did five years earlier, when a special program was set up by the Howard government in the face of a popular campaign to give women with late-stage breast cancer access to the drug.

In the late 1990s the PBAC thrice rejected applications to subsidise Herceptin, which led to the government bypassing the PBAC system altogether. The special program is still running and costs \$166m over four years.

Cancer expert David Goldstein, president of the Clinical Oncology Society of Australia, says the system for approving PBS drugs is "reasonably democratic" and while there is "some margin for public pressure", the 2001 creation of a special scheme for Herceptin was now seen as a mistake best not repeated.

But some other experts are less convinced that the health system is always so rational, despite Sansom's protestations to the contrary.

Simon Chapman, professor of public health at the University of Sydney and one of the authors of the study that examined media reporting of Herceptin, is about to publish a further paper on the coverage of bowel cancer. It finds bowel cancer seriously under-represented in news reports, accounting for just 4.1 per cent of all cancer news reports despite the disease causing 11.5 per cent of cancer deaths.

Tellingly, there were no reports of celebrity diagnoses, in contrast to the high-profile reporting of Kylie Minogue and Belinda Emmett's struggles with breast cancer.

Had the coverage been proportionate to the number of new cases every year, there would have been 127 reports on colorectal cancer, in contrast to the 39 that were in fact broadcast on Sydney's five free-to-air networks between May 2005 and May 2008.

Chapman says purchasing decisions in Australia are mostly rational compared with most other countries, but the Herceptin experience shows "that the system is still very vulnerable to interest groups promoting tragic case studies and trying to push governments into a corner".

"Very few people want to get down to saying, 'Will it be worth putting all this money into giving people an extra three or four months of life?', which is unfortunately often what's involved," Chapman tells *Focus*.

"Pharmaceutical companies are very adept at funding patient groups ... which become very grateful and are very potent in making the case for greater (drug availability).

"I'm not surprised to hear any regulator saying that's not taken into account, because such people wouldn't be very long in their jobs if they did. But you only have to look at the way (Coalition health minister) Tony Abbott went from trying to resist the policy, to being knocked over by the effectiveness of the patients' campaign."