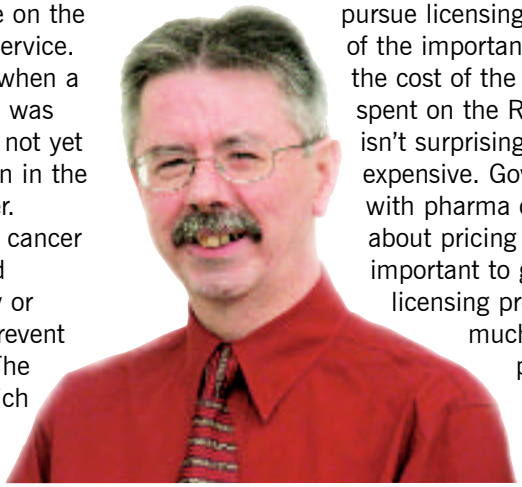
Speeding drug approvals

There's an interesting lobbying campaign going on in the UK at the moment in which a women's group is fighting for the cancer treatment drug Herceptin to be made more widely available on the country's National Health Service. The campaign was started when a woman from Stoke-on-Trent was informed that the drug was not yet approved for treating women in the early stages of breast cancer. Herceptin is given to breast cancer patients after they have had treatment with radiotherapy or chemotherapy in order to prevent cancer developing further. The proportion of women in which it is effective is about one in six.



Tom Mulligan

'No' for primary cancer care

The problem in the UK at the moment is that Herceptin is not licensed for treating primary breast cancer, it is licensed for treating people who have cancer for a second time. Herceptin is currently going through approval and licensing procedures. However, it may be 2007 before the drug is made widely available, and the campaigners claim that in the meantime this could lead to the deaths of thousands who could have been treated and saved. The UK government has ordered that all women diagnosed with early breast cancer should be tested to see if they can be treated with Herceptin and that there should be a 'fast-track' assessment of the drug which could speed up the approval process conducted by the UK's National Institute for Health and Clinical excellence (NICE). The manufacturer, Roche, is due to submit an application for the use of Herceptin in early cancer early next year. The UK government says it is determined to take action in getting Herceptin licensed.

There are several issues here. The obvious one is why is there a time lag in making available a drug that has been shown to be efficacious and is already available for early cancer treatment in a number of countries? Is it not possible for pharma companies to pursue licensing at an earlier stage? One of the important issues, of course, is the cost of the drug, but given the time spent on the R&D of a new drug it isn't surprising that the treatment is expensive. Governments can argue with pharma companies all they like about pricing but isn't it more important to get the approval and licensing procedure completed much more quickly than present systems, not just those in the UK, seem to allow?

Getting fast-track drug approvals

Another issue is fast-track approvals. If these are possible, why is there a 'normal' approval process that takes so long and what are the criteria for a drug to be fast-tracked? In the case under discussion, it is public pressure that has forced the fast-tracking of the drug, which is hardly an ideal situation.

The pharmaceutical industry obviously wants to have its products approved quickly, governments want to provide the best health care possible for the public, and agencies like NICE want to meet these goals too, though obviously with safety as a primary concern. With a product like Herceptin, which has been approved elsewhere already, it is difficult to understand the delay in approval for primary cancer treatment in the UK. Governments are meant to play the major role in setting the health care agenda and ensuring that the best treatments the pharmaceutical industry can produce, in particular those for unmet medical needs, get to the public as quickly as possible. It shouldn't need a public campaign to make this happen.

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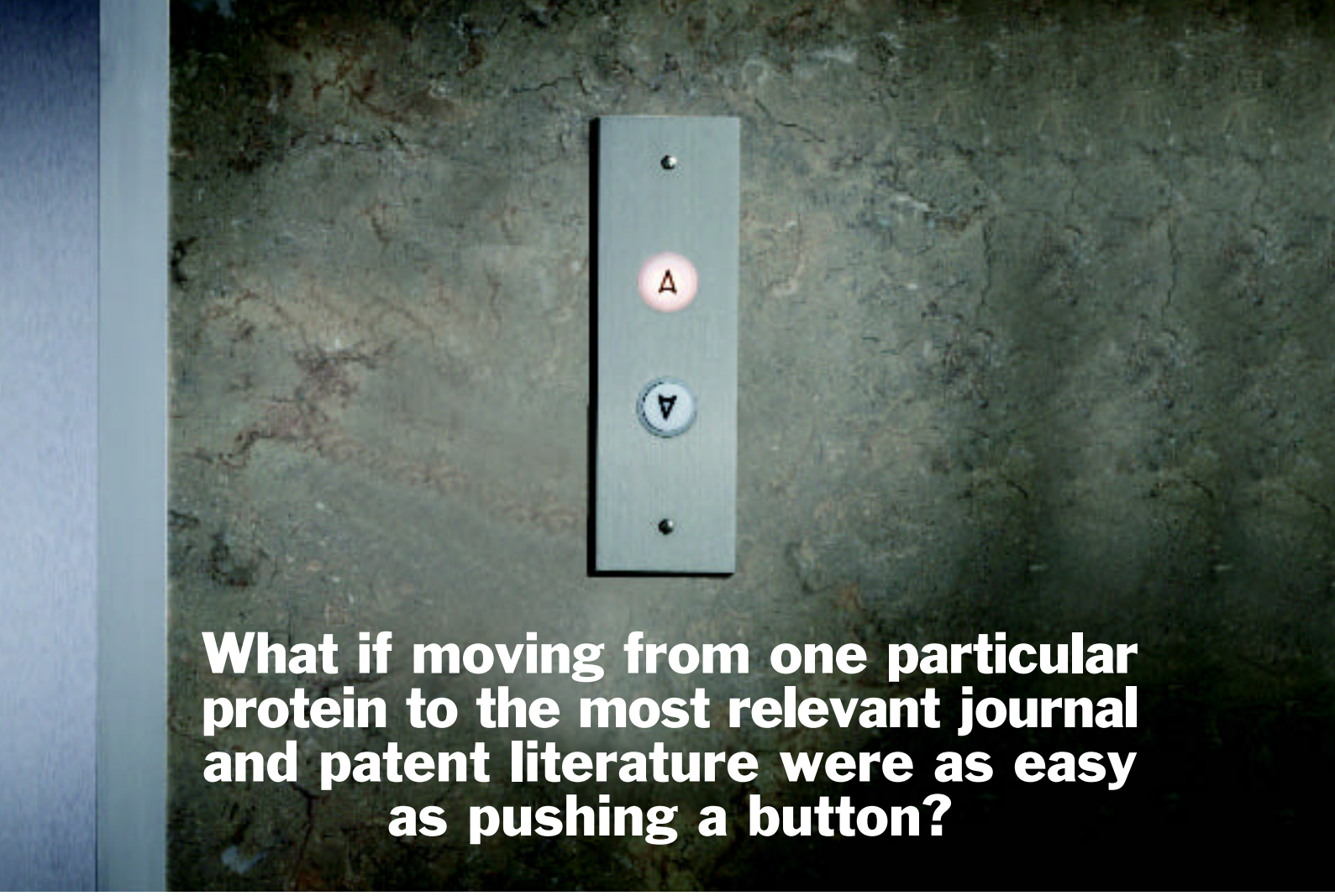
Editor – *sp*²



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