Future of US drug pricing is in doubt

The National Institutes of Health (NIH) has vowed to tighten up guidelines for collaborative projects (CRADAs) between the US government and private pharmaceutical companies by the end of this year. The new guidelines are likely to preclude exclusivity clauses in favour of the drug companies and to restrict the terms of business arrangements. The NIH alone currently has more than 100 CRADAs in process. The move follows mounting public concern over what is seen as a means of enhancing drug companies' profits at the expense of the US taxpayer, and was sparked off by the pricing of the drug Taxol.

This was approved by the Food and Drugs Administration in December 1992 for treating ovarian cancer, with which over 20000 American women are diagnosed every year.

Derived from the Pacific Yew tree, the drug was developed originally by the National Cancer Institute and handed over to Bristol-Myers Squibb for commercial development in January 1991 under the terms of a CRADA. These agreements were established by a 1986 act to expedite the delivery of new drugs to as many patients as possible. The act does not grant federal agencies the authority to regulate the prices charged for drugs, but the NIH asks its collaborators to sign a "reasonable pricing" clause. The vagueness of the wording is open to interpretation, but protest consumer groups and members of congress say that the

scale of pricing for Taxol, from $695.25 to $986.18 per cycle, contravene the clause. "It is the federal taxpayer who has taken all the real risks and who ought to have a return on the investment," says Steve Jennings, staff director of the subcommittee on regulation, business opportunities, and technology, which has convened a series of congressional hearings into the matter. By the end of 1992, the government had spent $39m and Bristol-Myers Squibb over $100m. Analysts forecast that the drug stands to make $800m or possibly more, as it is likely to be effective in several other forms of cancer.

Correction

London's specialist centres cut by half

The London Implementation Group is not proposing that the plastic surgery service at Bilericay Hospital should be moved nearer to London, as this article by Luisa Dilner said (26 June, pp 1709-10). The group suggests that because of its proposals to expand plastic surgery services at the Royal London Hospital the Bilericay unit should not be moved closer to London.

Mrs Bottomley defends doctors

Last week I reported that witnesses told a Commons select committee how complaints procedures in the NHS were widely perceived as being biased in favour of the medical profession at the expense of patients' interests. It is likely to be one of the issues put before the forthcoming review of NHS complaints procedures under Professor Alan White (BMJ 1993;307:1711). If doctors come to feel that his inquiry is targeted at them it may be that they will find an unexpected ally in Virginia Bottomley.

When subsequently the secretary of state for health appeared before the same committee she disclaimed doctor bashing and refused to rise to baited questions from MPs. At issue before the select committee or the ombudsman was whether there should be lay presence in the clinical complaints procedure, which at present entails adjudication by two independent consultants.

In a written submission the Department of Health stated that "it is essential that complaints about the exercise of clinical judgment must be based on an investigation by those with relevant professional knowledge." The committee challenged this view. A Labour member, Dr Tony Wright, described the NHS complaints system as a shambles with its total lack of an independent element. Far from complaints being "jewels to be treasured"—as Mrs Bottomley had said—the service regarded complaints as "pieces of infected material to be buried as soon as possible," Dr Wright remarked. Others questioned the impartiality of a procedure restricted only to professionals.

In reply, Mrs Bottomley made appropriate noises about her first concern being the wellbeing of the patient. But she more often reiterated her parallel concern for the integrity of clinical judgment and the importance of the professionals involved having confidence in the complaints process. In balancing priorities, she said, any secretary of state had to be satisfied that people who worked in the service were treated fairly, especially if their careers and livelihood were at stake. That was not to say that renewed discussion with the professions about a lay element in the clinical complaints procedure was inappropriate. She said that she would be extremely surprised if the Wilson review did not have some acute observations on that subject, but she would need to look at them on the basis of practical proposals.

Otherwise, Mrs Bottomley was all for encouraging patients to complain when they were dissatisfied, just as supermarkets did in order not to lose customers—an analogy she applied to the purchaser-provider split of the NHS reforms. Purchasers would want to satisfy themselves about complaints and how they were handled. If a high number of complaints from a hospital were fed back to purchasers they might place their contracts elsewhere. "Never before did we have that leverage," said the secretary of state, although the committee's chairman, James Pawsay, thought that it was rather a blunt instrument.

Mrs Bottomley spoke of the NHS going through a cultural transformation. In the old days it had lacked any regard for the users of the service in respect of the appointments system or opening hours. Now she believed that there was no better way of making sure an organisation checked its preconceptions about the delivery of its service than by listening to what the users said.

This was the first time a health secretary had appeared before the select committee on the ombudsman. The committee and the health secretary have different views of the complaints that go to the ombudsman: what the committee describes as appalling or horrifying cases that come before it Mrs Bottomley looks on as not the most serious. As for the ombudsman, William Reid, he welcomes the complaints review but notes that it is the shortcomings of NHS staff rather than the procedures themselves which are the nub of many complaints.—JOHN WARDEN, parliamentary correspondent, BMJ