

## Doctors give guarded response to £100m for GP services

Mark Hunter *Leeds*

Doctors' leaders have given a guarded response to the launch of a £100m (\$150m) fund designed to improve GP services. The fund, announced this week in a speech to the Royal College of General Practitioners by the prime minister, Tony Blair, amounts to around £10 000 per practice.

Of this, £5000 will be offered immediately to help to provide extra clinics, extend opening hours, train GP specialists, and offer better heart and cancer services. The rest will be paid as a bonus to all practices that hit local incentive targets. GPs will be able to take the bonus as a cash sum for themselves, reward practice staff, or put the money back into services for patients.

Mr Blair's speech also included the announcement of a 36 point plan to help to reduce bureaucracy in general practice.

The chairman of the BMA's General Practitioners Commit-

tee, Dr John Chisholm, welcomed the measures as recognition of the enormous pressures being placed on GPs. However, he criticised the link between the cash and the provision of extra services, saying that this could place even more demands on overworked and demoralised GPs. "GPs are already working beyond the limits. Asking them to work even longer would be inviting yet more early retirements, burnt out doctors, and ultimately a poorer service for patients," said Dr Chisholm.

"An extra £5000 to £10 000 per practice for modernisation measures will be used up very quickly—for example, in paying practice staff. Practices deserve rewards for the changes they have already made, and they will not be able to cope if additional work is required before those incentives can be received."

Dr Chisholm did, however, welcome the moves to reduce



A lavishly illustrated 18th century book of medicinal herbs has been digitised and animated by the British Library. The book, *Curious Herbal*, by Elizabeth Blackwell, published in 1739, has been animated using a system known as Turning the Pages technology. The system, developed by the British Library, allows readers to simulate the action of leafing through a book and zoom in on any portion of a page.

GPs' red tape, which the government claims will offer annual savings of about 7.2 million appointments and 750 000 hours of GPs' time.

The measures include removing the requirement for

GPs to countersign applications for driving licences and passports, provide sick notes for jurors, and certify immunisation returns. Nurses will be allowed to provide sick notes for employees. □

## Company played down drug's risks, report says

Scott Gottlieb *New York*

Warner-Lambert played down the potentially fatal risks associated with troglitazone during the approval process and received help from federal drug regulators in pushing the drug towards marketing approval, an article published in the *Los Angeles Times* has claimed.

The newspaper based its report on company and government documents, some secretly obtained, as well as email communications, which showed that officials from Warner-Lambert had collaborated closely with certain senior officials in the US Food and Drug Administration (FDA) during the approval process and later, when the company was being pressured to take the drug off the market.

The FDA initially approved

troglitazone, marketed as Rezulin, in January 1997 for treatment of type 2 diabetes. The drug was pulled from the market in March 2000 because of the number of reports of liver failure associated with its use. At an FDA advisory committee meeting last year, regulators reported that there had been 90 cases of liver failure among patients taking the drug since its launch.

As portrayed in the records, FDA officials provided Warner-Lambert with inside information and favours at critical moments throughout the development and marketing of troglitazone, according to the *Los Angeles Times*. At least one senior manager believed that if an FDA medical officer who had questioned the drug's safety and effectiveness did not please the company, he would be "out." Soon enough, he was, prompting another executive to report internally that a "hurdle" had been cleared for troglitazone.

In addition, executives knew that patients who took the drug in clinical studies had developed life threatening liver damage, yet

the company assured an FDA panel that the risk was trivial. The company's assurances helped to win swift approval for troglitazone four years ago from the FDA. The newspaper, citing Warner-Lambert's emails and memorandums, said that the company knew as early as 1993 of at least one case of a patient who showed liver damage after taking troglitazone.

Dr John Gueriguian, an FDA medical officer assigned to examine troglitazone, told the company as early as 1994 that he was concerned about "potential toxicities." But Dr Gueriguian's boss, Dr G Alexander Fleming, told a Warner-Lambert executive in 1995 that he would "ease Dr Gueriguian out" if the executive was displeased with him, according to a memorandum from the executive.

Dr Gueriguian was removed from the case in 1996. Dr Fleming emailed a copy of Dr Gueriguian's unflattering medical review to the company, but it was withheld from the advisory committee that examined the drug, the newspaper said.

Two days before the advisory

committee meeting, Dr Fleming emailed Warner-Lambert's executive vice president for regulatory affairs, Irwin Martin, saying, "the drug looks like it ought to be on the market. Loosen up and put on a good presentation. Call if you need help."

Pfizer, which purchased Warner-Lambert last year, now faces almost 400 lawsuits related to troglitazone. In a statement issued on Monday afternoon, Pfizer said that it "strongly disagrees" with the characterisation by the *Los Angeles Times* of Warner-Lambert's behaviour.

"While it does not comment in detail on matters related to current litigation, Pfizer affirmed today that Warner-Lambert appropriately disclosed the risk of adverse liver events before Rezulin . . . was commercially marketed," the statement reads.

FDA spokesman Lawrence Backorik said that he was "not in a position to comment on allegations concerning the conduct of the company or former FDA employees who were involved in the review of troglitazone."

"The FDA bases its actions on science," Mr Backorik said. □