Bush accused of blocking access to cheap AIDS drugs

Owen Dyer *London*

International health charities have accused George Bush's administration of trying to block developing countries' access to cheap AIDS drugs by questioning the quality of "three in one" generic combination drugs.

At a meeting this week in Gaborone, Botswana, the US global AIDS coordinator, Randall Tobias, said that the World Health Organization's drug pre-qualification programme is not a sufficiently stringent approval process to ensure consistency and quality of fixed dose combination drugs.

He told delegates from national drug regulatory agencies, the pharmaceutical industry, and non-governmental organisations that the United States was unwilling to spend the £8bn (\$15bn; €12bn) promised in the presidential emergency plan for AIDS

relief (PEPFAR) on drugs of unknown quality.

Médecins Sans Frontières and other non-governmental organisations working with AIDS patients in Africa accused the US government of trying to escape the 2001 Doha agreement on affordable drugs by the side door (*BMJ* 2001;323:1146). The objections raised by Tobias also threaten implementation of the World Trade Organisation's August 2003 agreement that specifies how countries with limited or no capacity to manufacture drugs can gain access to cheaper generic medicines (*BMJ* 2003;327:517).

Sharonann Lynch of the charity Health Gap said the US government is trying to ensure that the money from the US AIDS relief plan goes to brand-name manufacturers. "These

objections make no sense. The generic drugs are bioequivalent compounds, and the WHO pre-qualification process uses staff from Canadian and European regulatory bodies that the US recognises."

The cheapest generic combination pills cost about £77 per person per year under a price agreement negotiated with manufacturers by former US president Bill Clinton. The same combination from brandname companies costs about £310 per person per year.

Addressing Congress on 18 March, Mr Tobias, a former chief executive of Eli Lilly, said the US government's objections were motivated by concern for the safety of patients with AIDS. "We have been reading stories lately about some problems with some drugs around the world

where people with the best of intentions have made acquisitions of drugs that have turned out to not have the consistency, safety, and effectiveness that people had hoped." □

George Bush is accused of trying to evade the Doha agreement

New watchdog given power to overturn GMC acquittals

Clare Dyer *legal correspondent, BMJ*

Doctors who are cleared of serious professional misconduct by the General Medical Council risk having their acquittals overturned by a court following a ruling this week from a High Court judge.

The Council for the Regulation of Healthcare Professionals (CRHP), the new watchdog set up to oversee disciplinary bodies in the healthcare field, won a High Court test case this week against the General Medical Council over the extent of its powers.

The GMC had argued that the CRHP's power to refer cases to the High Court when it believes regulators have acted too leniently applies only to penalties imposed for serious

professional misconduct and not to cases where a doctor is cleared.

But this week Mr Justice Leveson gave the CRHP the go-ahead to refer to the High Court the case of Giuseppe Ruscillo, a Lancaster GP acquitted of serious professional misconduct arising out of a relationship with a woman patient.

The judge ruled that the CRHP had the power to refer such cases to court and did not have to wait until the GMC had dealt with a further, unrelated complaint against the doctor.

He gave the GMC and Dr Ruscillo permission to appeal, adding: "Clearly the issues raised are of great importance. Clearly they involve not merely the

medical profession but also other professions. It is obviously sensible that these issues are definitively resolved."

Unless the ruling is overturned on appeal, the High Court will go on to decide later this year whether Dr Ruscillo's acquittal was unduly lenient.

The judge said the CRHP had been set up in response to public concern that existing arrangements for self regulation "have not proved sufficiently adaptable" and that on occasion "professional self interest has been placed before the interests of patients."

The judge said it was important to underline the rationale of professional discipline and regulation: "In this field, it is intended to promote the interests of patients and other members of the public and to ensure that the public can have confidence that those who are entitled to practise their profession meet the high standards that are required."

Dr Ruscillo was accused of having an emotional and sexual relationship with a patient he had treated for psychiatric problems, but the GMC's professional conduct committee found him not guilty of misconduct after submissions that the evidence was insufficient.

A month later the chief executive of his primary care trust wrote to the GMC with information that could result in further proceedings against him.

But there was no logical justification for denying the watchdog body the right to refer a case to court because of some extraneous investigation unrelated to the original issues, and it was not constrained to await the outcome of the new investigation, the judge ruled.

A spokesman for the GMC said: "We welcome the court's clarification on these matters, and were happy to be part of the process." □