AIDS activists fail to block 'reasonable pricing' reform

Washington. A government task force agreed last week to back negotiations that are expected to lead to the National Institutes of Health (NIH) dropping the controversial 'reasonable pricing' clause in agreements between intramural researchers and industry.

Under pressure from critics on both these sides, who argue that the clause is an impediment to collaboration, the NIH is negotiating with the Department of Health and Human Services (DHHS) about alternatives; a decision to drop the clause is expected within the next few weeks.

In a majority vote, the National Task Force on AIDS Drug Development, agreed that the NIH should continue its current negotiations. But this led to a noisy protest by the AIDS activist group ACT-UP, which had urged the task force to press NIH to strengthen the clause. The group bases its case on the excessive costs of the anti-AIDS drug AZT, which was partly developed with federal funds.

The members of the task force, which is responsible for removing barriers to drug development for AIDS, include both Harold Varmus, director of the NIH, and David Kessler, head of the Food and Drug Administration. It is often a forum for policy debates — such as that on reasonable pricing — that go beyond AIDS alone.

Reasonable pricing clauses are included in the NIH's cooperative research agreements (CRADAs), introduced by Congress in 1986 to facilitate technology transfer from government agencies, and in exclusive licensing deals. CRADAs did not at first require such clauses. But NIH introduced them in 1989, following widespread outrage at the price of AZT.

NIH is the only major government agency to have such a clause, and many intramural researchers say that it prevents them from collaborating with industry. "The number of complaints from our scientists has increased during the past six months," says Sandy

Chamblee, acting director for science policy and technology transfer. Last December, members of advisory councils to three NIH institutes urged Varmus to drop the clause.

Many in industry also oppose the clause, saying that they do not trust the government's ability to decide on a 'reasonable price' for drugs, and that venture capitalists are reluctant to lend money if a company has a CRADA containing a clause allowing the government to do so.

Industry gave its opinions at a public hearing last July when the NIH hosted the first of two *ad hoc* meetings to hear views on the reasonable-pricing clause. It became clear during the meeting that NIH staff were listening favourably to industry's arguments (see *Nature* 370, 238; 1994). As a result, the NIH published a list of options at the end of last year, ranging from dropping the clause completely to making a variety of changes.

Chamblee, one of the NIH staff negotiating with the DHHS on the clause, says it is now expected to be dropped. But where the NIH has substantially reduced the risk to a pharmaceutical company involved in drug development, there is likely to be a rule that the company should offer some form of public benefit in addition to paying royalties.

For example, if a company takes on a compound that the NIH has already taken through Phase-I clinical trials, it might make price concessions or develop ways of making the compound available to those who could not otherwise afford it. Many companies already have such 'accessibility' programmes, but patient advocates claim that they do not always reach their target.

But whatever emerges from the negotiations, the NIH now appears to have accepted that reasonable-pricing clauses are a barrier to research. Varmus told last week's task-force meeting that the NIH is not a regulatory body, and needs to return to its central mission of supporting basic biomedical science.

Helen Gavaghan

Republican warns of \$35-billion cut in 1996 budget

Washington. Congress will try to cut \$35 billion from next year's discretionary, non-military budget of \$270 billion — the source of most federal funding for science — according to the chairman of the House of Representatives committee that divides up the budget pie.

"You are going to be shocked when you see how austere the 1996 budget will be," Robert Livingston (Republican, Louisiana), chair of the House Appropriations Committee, warned on Monday. Cuts on this scale would certainly come as a shock to federally funded research and development, which consumes \$36 billion, almost 15 per cent of the total.

Livingston says that many agencies and programmes will be eliminated in order to make the cut, and that the largest and most popular government science programme — the \$11 billion spent on biomedical research by the National Institutes of Health (NIH) — is "on the table" with everything else.

Proposals for such deep cuts from the House may be modified by both the Senate and the Clinton administration. But some constitutional experts argue that the House has almost unfettered — but previously untested — power to cut budgets by refusing to approve the spending of any money at all.

Livingston promises that if President Bill Clinton vetoes any of the 13 bills that make up the budget, the House will send him back an even tougher bill. If no bill is signed, Congress will appropriate nothing, obliging the President to shut down those parts of the government covered by the bill in question.

Asked whether he agrees with John Edward Porter (Republican, Illinois), chair of the House appropriations subcommittee with responsibility for the NIH, that biomedical research deserves more money, Livingston said: "There is never enough money for good, solid research that is going to help us fight disease and save lives. Everything has to be on the table, including programmes we never looked at before because we were in the minority". Livingston says that "re-examining the efficiency of NIH and the priorities of NIH is not something we'd take off the table entirely".

Livingston said the rescission package for the current 1995 fiscal year (see *Nature* 373, 179; 1994) being worked on by his committee would be modest, as President Clinton "would veto it if it were too austere". The President presents his 1996 budget proposal on February 6: the House and Senate will amend it during the spring and summer and ask the President to sign the new version in September, when the 1995 fiscal year ends and the brinkmanship begins.

Colin Macilwain

New hominid remains found in Ethiopia

London. A new adult skeleton of the recently discovered 4.4-million-year-old *Australopithecus ramidus*, the earliest known hominid, has been found at Aramis in Ethiopia.

The skeleton was unearthed by Yohannes Haile-Selassie, a member of the multinational Middle Awash Research Team led by Tim White of the University of California, Berkeley. Discoveries by the same team at Aramis during 1992 and 1993 led to the naming of the new species (see *Nature* 371, 306–312; 1994).

In contrast to the first report, which

was based on only 17 specimens, the newly found skeleton consists of more than 90 fragments which together make up about 45 per cent of a skeleton. It includes pieces of bone from the skull, arms, vertebral column, pelvis and legs.

Leg material is important; this was lacking from the original report, and will help clarify whether *Australopithecus ramidus* walked erect. But a definitive answer may take some time to arrive. The skeleton is extremely fragile, and remains encased in rock and plaster awaiting study.

Henry Gee