Budget politics jeopardizes US drugs credit

Washington. A popular tax credit that encourages US pharmaceutical companies to produce drugs for rare diseases may soon fall victim to the budget politics that are now embroiling Washington.

The 'orphan drug tax credit' — so called because patients with rare diseases say that in the past they were 'orphaned' by researchers and drug manufacturers — expired at the end of 1994. Its beneficiaries in industry would therefore first feel the bite of its disappearance this April, when their 1995 taxes are due.

Republicans in Congress have included a retroactive extension of the credit, covering the two years 1995 and 1996, in their proposal to balance the budget over seven years. But they are at loggerheads with President Bill Clinton over how the budget should be balanced. Many predict that no agreement will be reached, and if the Republican proposal dies then the tax credit will die with it.

The credit allows companies that develop drugs for rare disorders to deduct half of the costs of clinical testing of the drugs from their tax bill. The US Treasury says the credit cost $17.8 million in 1992, the most recent year for which figures are available, and Congress's Joint Committee on Taxation estimates that the proposed two-year extension would cost $40 million.

The extension would also extend the scope of the current law to allow companies to claim unused credits backward for three years, and forward for 15 years; at present, credits must be applied to the tax year in which costs were incurred. Those likely to gain significantly from such a change are the small biotechnology companies that now carry out about half of orphan drug research; they often do not pay enough tax early in drug development to benefit from the current credit arrangements.

The law defines "rare disorders" as those affecting fewer than 200,000 Americans. Most are relatively rare forms of cancer or genetic diseases, such as Huntington's disease and amyotrophic lateral sclerosis (known as Lou Gehrig's disease or motor neuron disease).

The tax credit was first enacted as part of the 1983 Orphan Drug Act, a package of financial incentives aimed at enticing drug manufacturers into the rare disease market. Drugs that are designated as eligible under the act by the Food and Drug Administration include Amgen's antianaemic drug Epogen and Genzyme Corporation's Ceredase, for Gaucher's disease.

The tax credit has drawn a rare combination of support from both patient advocates and the drug industry. Ironically, both the White House and congressional Republicans also support it. "It's one of the few things that Democrats and Republicans have been able to agree on," observes Lisa Raines, vice president for government relations at Genzyme.

But advocates of the credit are quick to point out that while Clinton endorsed an extension of the credit in his 1996 budget request, and sent a Treasury Department official to the Congress to testify in favour of making it permanent, he did not designate funding for it, leaving that job to Republicans in the Congress.

The Republicans funded the extension in the massive Balanced Budget Act of 1995, which they passed in November and which also contains the new language allowing the credit to be applied forward and backward in time. But Clinton vetoed the entire budget package in early December, objecting, among other things, to its massive projected spending on Medicare and Medicaid, the health programmes for the elderly, disabled and poor. That led to the current impasse, of which the tax credit is a hostage.

Despite the strong political backing for the credit, debt-minded Washington also has its objectors among fiscal conservatives. "This is a tax credit and tax credits are bad economic policy," says Dean Stansel, a fiscal policy analyst at the free-market Cato Institute.

Nonetheless, the provision has found abundant friends among Republicans in the Congress, who see it as a cheap yet effective means of stimulating private investment in medical research while winning friends among both patients and the pharmaceutical industry.

Its broad support may not save the credit from going the way of the balanced budget negotiations. But some observers remain optimistic that the tax credit will still survive. "It will be passed because the [drug] industry wants it, and the industry is very powerful," says Abbey Meyers, the president of the National Organization for Rare Disorders, predicting the passage of separate legislation to extend the credit if the budget negotiations fail.

In Europe, there have been few financial incentives agreed by governments to encourage the development of drugs for rare diseases, but the European Commission has indicated its intention to put forward a directive on orphan drugs. The commission established a task force last year to consult researchers and pharmaceutical companies on the need for new vaccines for a range of diseases. **Meredith Wadman**

International papers register decline

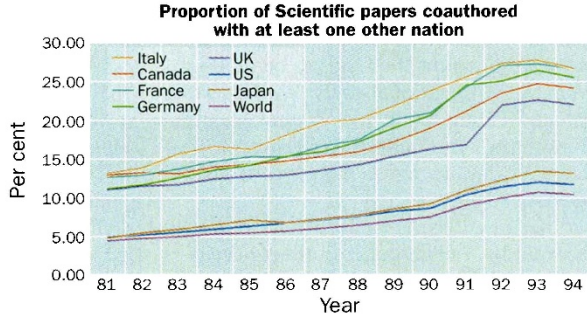
Washington. **After a decade of continuous growth, international collaboration on published scientific research papers appears to have peaked in 1992–93 and has since started to decline, according to figures released last week by the Institute for Scientific Information (ISI) in Philadelphia.**

ISI researchers have measured the percentage of papers published in all scientific journals that had at least one co-author working in a different country from the lead author. Their analysis tracks about 10 million papers published between 1981 and 1994. It shows a consistent pattern in all leading industrial nations, with the percentage of papers with international authors peaking in either 1992 or 1993, and falling in 1994.

In countries where international collaboration is more prevalent — European countries and Canada — the level of international collaboration peaked at around a quarter of all papers published. Japan and the United States peaked at half of that level. In the United States, for example, just over 12 per cent of the several hundred thousand papers tracked by ISI had at least one foreign author;in the following year, that figure fell to 11.7 per cent.

The world average dipped from 10.7 per cent to 10.4 per cent between 1993 and 1994, ending 12 years of uninterrupted growth. Papers with lead authors from smaller countries with high levels of international involvement, including Switzerland and Mexico, echoed the general trend.

Chris King, editor of the ISI newsletter *ScienceWatch*, which published the data, declines to speculate on the cause of the reversal. But the change may reinforce a suggestion by officials of the inter-national division of the National Science Foundation (see *Nature* 379, 3; 1996) that pressure on scientists who wish to retain their grants is discouraging some from engaging in international collaboration. Colin Macilwain



Source: ISI's Science Indicators Database.