US politicians want federal funding to discover cost effectiveness of new drugs

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A bill before the US Congress calls on health authorities to investigate whether expensive new drugs offer value for money, by comparing their risks and benefits with other treatments and older drugs.

Currently new drugs are approved on the basis of their superiority over a placebo, with no requirement to show an advantage over existing treatments or cheaper generic pills.

If passed, the new legislation would see US taxpayers spending \$75m (£47m; €67m) in 2004 to fund studies of the cost effectiveness of the nation's most expensive classes of drugs—something done routinely in other countries but a move that is bitterly opposed by the drug industry in the United States.

Annual spending on prescription drugs is rising by almost 20% a year in the United States, where it is now in excess of \$150bn. The cost of drugs is one of the fastest growing components of overall healthcare costs, which are also rapidly rising and becoming a key political issue in the race for the White House.

A group of Democrat and Republican politicians introduced the latest bill into the House of Representatives in June. Specifically the bill requires that the federally funded National Institutes of Health and the Agency for Healthcare Quality and Research gather scientific evidence “comparing effectiveness, cost-effectiveness, and, where appropriate, comparative safety” of the costliest and most commonly used prescription drugs “relative to other drugs or treatments for the same disease or condition.”

The bill, known as HR 2356, does not call for a change in the way new drugs are approved by the Food and Drug Administration, but it does demand more information on whether a new drug is worth its price once it is on the market, particularly when compared with other available treatments.

One of the bill's sponsors, Jo Ann Emerson, a Missouri

Republican, said that the studies would provide basic information to doctors and their patients about which drugs were best for them. The results could also be used to inform decisions on coverage by private and public insurers, including Medicare, which provides health care to people aged over 65. “I believe we have to do everything possible to use the principles of market competition to get prices of drugs down. This is one way to do that,” Ms Emerson said.

Jeff Trewhitt, a spokesman for the industry group

sored other bills to reduce drug costs, said that although the industry was quietly lobbying to kill her latest bill there was a good chance that some version of the plan for cost effectiveness studies would be passed by both the House of Representatives and the Senate and be sent to the president for approval later this year.

Australia has had laws for almost a decade requiring studies of the cost effectiveness of any new drug by comparing it with existing treatments before the drug can be listed on the publicly funded pharmaceutical benefits scheme.

Australia's system, which has been the target of sustained attack by elements within the drugs industry, has become something of a global model for how to obtain value for money in prescription drugs. Compared

tion of their effectiveness and cost effectiveness, comparing their costs, risks, and benefits with other treatments. An example is the recent guidance on glitazones for type 2 diabetes, which used cost effectiveness analysis to recommend against using the expensive new drugs as a second line treatment in combination with metformin or a sulphonylurea, except in certain restricted circumstances.

In British Columbia similar evidence based comparisons underpin the reference pricing programme used to price some classes of prescription drugs. In this programme several drugs in a class are compared; if they are essentially similar the subsidy offered to the public is based on the cheapest price in the class, and consumers pay for any difference if their doctor chooses a dearer drug.

Like the systems in Australia and the United Kingdom and the proposed plan in the United States, British Columbia's programme has been heavily attacked by the drug industry.

The studies used in the Canadian programme are provided by an organisation based at the University of British Columbia called the Therapeutics Initiative, and its managing director, Dr Jim Wright, says that what is really needed is “head to head” trials that compare different drugs, rather than studies that simply compare a drug with a placebo.

Like other experts around the world, Dr Wright argues that such head to head studies should be mandatory after a new drug has been approved. “It's essential to know the benefits and harms of newer therapies, compared to the best available existing treatment,” he said, giving as a good example a recent trial, the anti-hypertensive and lipid lowering to prevent heart attack trial (ALLHAT) of different anti-hypertensive drugs (*JAMA* 2002; 288:2981-97). Recent analysis of ALLHAT results indicate that the United States could save more than \$430m a year if doctors favoured the older and cheaper thiazide drugs.

Mr Trewhitt said that ALLHAT had already been contradicted by a subsequent trial and that head to head studies would slow down the delivery of drugs to new patients. □

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Two members of the US House of Representatives, Jo Ann Emerson (Republican, Missouri) and Tom Allen (Democrat, Maine), are sponsoring a bill that would require federal funding for the evaluation of the cost effectiveness of new drugs

Pharmaceutical Research and Manufacturers of America, said the studies being proposed in the new bill were highly subjective and that people “advocating cost effectiveness studies are often advocates of spending less.” When asked about the industry's lobbying efforts to undermine the bill, he said, “We are watching it.”

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sored other bills to reduce drug costs, said that although the industry was quietly lobbying to kill her latest bill there was a good chance that some version of the plan for cost effectiveness studies would be passed by both the House of Representatives and the Senate and be sent to the president for approval later this year.

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