Clinton courts research hospitals

Washington. President Bill Clinton is seeking support for his health-care reform legislation from the leaders of US academic medicine — a group not previously courted in what is going to be a bruising congressional fight.

During a private meeting with the leaders of Boston's many top research and teaching hospitals, the president promised that his bill will provide billions of dollars to subsidize the higher-than-average cost of care at institutions such as the Harvard-affiliated Massachusetts General Hospital (MGH), where the cost of taking care of patients is intermingled with the costs of doing research and training the next generation of scientists and physicians.

Although the president made no binding promise in dollars, Philip R. Lee, the assistant secretary for health in the Department of Health and Human Services, has estimated that $10 billion is the least needed annually, while agreeing with medical school administrators that something like $18 billion is a more realistic figure.

Health-care reform is built on the premise that the costs of seeing a physician or staying in a hospital can be driven down through efficiency, cost controls and a form of competition that will induce people to flock to low-cost consortia of doctors and hospitals functioning on the theory that high volume can lower per unit (or per patient) costs. If such a system were to become universal in the United States, the country's research hospitals could be driven out of business.

Clinton promises money to research hospitals — among many others.

During a trip to Boston, Clinton had a 45-minute meeting with a dozen medical policy luminaries, including Mitchell Rabkin, head of Harvard's Beth Israel Hospital, Samuel O. Thier, president-designate of the MGH, Daniel C. Tosteson, dean of Harvard, and Kenneth I. Shine, president of the Institute of Medicine in Washington, DC.

According to those present, the president was at his political best in this small group. Well-briefed, he knew who had recently written about health reform, who had cancelled a meeting to come to see him, who was on his side and who was wavering.

Clinton made a clear commitment to federal support of the education and innovation that are the hallmark of academic teaching hospitals, quite apart from the funds they receive from the National Institutes of Health and other federal granting agencies.

For years, US teaching hospitals have lived off a complicated structure of cross-subsidies. For instance, Medicaid (the federal health insurance programme for the poor) has given hospitals a fixed per-patient premium or bonus to cover the cost of educating physicians-in-training. In addition, it has been common practice for hospitals to charge insured patients a kind of premium to make up for the cost of services to patients who cannot afford to pay.

These sources of revenue have been the life-blood of teaching hospitals, which treat more uninsured patients than do smaller, community hospitals, and which also treat the most seriously ill among the population. That is what their high-technology resources are for, but it also increases the bill.

Under Clinton's plan for universal coverage and a broad network of regional alliances — which are likely to die before legislation passes Congress (see *Nature* **368**, 178; 1994) — the old pattern of cross-subsidization would disappear. One viable alternative is outright federal support. And this is what Clinton promised, urged on by Senator Edward M. Kennedy (Democrat, Massachusetts), chairman of the Labor and Human Resources Committee that will play an important role in fashioning health-care legislation.

The president's trump card in Boston was that none of the many competing health-care reform bills before Congress even mention academic health centres. Therefore, he said, academic medicine should support his bill. Speaking on behalf of the group, Rabkin says: "The consensus is that the president's bill is a winner."

But the president has made more promises lately about health reform to more groups than he can possibly keep, and bills competing with Clinton's are likely to include the care and nurture of academic medicine before the day is done. Thus, Clinton's promise is just a blip in the present fast-paced political debate. Nonetheless, it was a positive blip. **Barbara J. Culliton**

Drugs bill to rein in profits

Washington. A bill introduced in Congress would amend existing laws to curb excessive drug company profits from monopoly supply of so-called 'orphan drugs' developed to treat rare diseases.

Sponsors of the bill say that it would still allow sufficient incentive to stimulate research on true 'orphans' — drugs of limited commercial potential aimed at treating rare diseases and disorders with a target population of fewer than 200,000.

The proposed legislation has bipartisan backing and was introduced in both houses last week by Congressman Henry Waxman (Democrat, California) and Senator Nancy Kassebaum (Republican, Kansas). Co-sponsors include the Democrats Ted Kennedy (Massachusetts) and Howard Metzenbaum (Ohio) in the Senate and Gerry Studds (Massachusetts) in the House.

Support for the proposed changes to the 1983 Orphan Drug Act has come from both industry and patient advocacy groups.

Under current law, an unlimited number of companies can apply for an orphan drug designation from the US Food and Drug Administration (FDA). But, in a first-past-the-post system, the first orphan drug to receive FDA approval is granted seven years of market exclusivity, during which time no other company can be licensed to market drugs to treat the same rare disease. A new provision in the act would shave three years off the period of exclusivity, although this could be extended to seven years for drugs of very limited commercial potential.

Past attempts to amend the act have met with opposition from some segments of the drug industry. Efforts to introduce sales limits and to apply any amendments retroactively to drugs already enjoying market exclusivity were strongly resisted. The new provisions would apply only to drugs not yet in human clinical trials or on the market. Orphan drug status would be rescinded, however, if at any time the target population rose above 200,000. Market exclusivity would also be shared if two or more companies could demonstrate that they had developed their drugs simultaneously.

The original act was designed to provide special market and tax incentives to companies developing drugs for rare diseases. Few would dispute that the act has been a success: Waxman says that more than ten times as many orphan drugs have been developed in the 10 years since its enactment than in the previous decade.

Some of the earliest drugs to be designated as "orphans" — recombinant human growth hormone used to treat pituitary dwarfism, the anti-anaemia drug, Epogen, and Ceredase, developed to treat Gaucher's disease — turned out to be extremely lucrative for the manufacturers, leading to calls for new legislation. **Diane Gershon**