Easier access to clinical trials

In an attempt to widen access to clinical trials, two United States Senators have introduced a bill that would require the government health program Medicare to pay the routine medical costs of patients in trials of new therapies for cancer. At present, thousands of elderly people are excluded from such trials because Medicare, which pays treatment costs for people over the age of 65, labels clinical trials as "experimental" and therefore exempt from its coverage. This policy not only distresses desperate patients, but may also makes trial populations unrepresentative. Patients and researchers both lose.

If Congress approves the bill, Medicare will be expected to reimburse patients for the routine care that accompanies their experimental therapy. Private insurers, many of which also refuse to pay for patients' routine costs in trials, will then be under pressure to follow suit. The bill is not intended to make Medicare pay for clinical trials themselves. The costs of the research that leads up to a trial, the design of the protocol, monitoring and statistical analysis will continue to be met by the National Institutes of Health, or by pharmaceutical or biotechnology companies.

Senator Jay Rockefeller

Senators Jay Rockefeller (D-WV) and Connie Mack (R-FL) introduced the bill in the Senate on 27 February. The Medicare Cancer Clinical Trial Coverage Act of 1997 — which Rockefeller wryly admits "has one of those catchy names that people will never forget" — is a modest attempt to knock down existing barriers to clinical trials. The Senators see the bill as "a demonstration project focused on cancer," but, if it succeeds, they hope it will set an obvious precedent for Medicare to pay the support costs for clinical trials of therapies for many other diseases.

Clinical trials are the mainstay of medical advances — the route by which basic science reaches the bedside. Yet partly because of the refusal of private and federal insurance programs to cover routine costs, currently no more than 5 percent of all cancer patients in the United States participate in trials, often leaving researchers frustrated in their attempts to compare the benefits of different therapies. Individual patients also suffer. Rockefeller cites the case of a constituent from West Virginia who was being treated for lung cancer with a new drug under a clinical protocol approved by the National Cancer Institute. The NCI paid for the drug and the research physician's time, but not the cost of being hospitalized while the drug was administered. Medicare, which would have paid the hospital costs if the patient had been given a standard drug, refused to pay for experimental therapy.

The unwillingness of Medicare and the private insurers to pay for trial costs has increased as the flexibility of funding in American medicine has decreased. In the past, for example, Medicare paid a sum for each medical resident in hospitals, and the excess over the resident's salary was partly used to subsidize trials. Private insurers were also more flexible. But with private insurers and Medicare now unwilling to pay anything more than exact costs, clinical trials are in crisis.

Yet the benefits of trials are clear, not just in improving treatment but in saving money. For example, researchers recently answered a long-standing question that affects the thousands of women who develop breast cancer each year: how long to continue prophylactic tamoxifen therapy after initial surgery for the tumor. While most cancer specialists are convinced that the drug adds years to women's lives, an important unknown was just how long therapy should continue. Patients are typically treated for 10 years, yet recent trials show that 5 years of prophylactic therapy appear to be sufficient for long-term survival. And, according to Allen Lichter, an oncologist at the University of Michigan, a year's worth of tamoxifen costs about US$1500. So the trial has potentially saved $7500 for each woman treated.

The proposed legislation has widespread support from cancer treatment advocacy groups in the country, including the Leukemia Society of America, the National Breast Cancer Coalition, the American Society of Clinical Oncology and the Susan G. Komen Breast Cancer Foundation.

BARBARA J. CULLITON

Hughes expands in the Americas

The Howard Hughes Medical Institute, which has been gradually expanding its purview in support of science outside the United States, has just expanded its roster of grantees in Latin America and Canada. Hughes has selected 27 scientists from Argentina, Brazil, Chile, Mexico, and Venezuela, and 20 researchers from Canada as the recipients of US$15 million in new research funds. If the stories the Latin American scientists told at a recent gathering at the Hughes headquarters in Chevy Chase, Maryland, are indicative, the institute's decision to fund researchers in countries whose governments do not provide much funding for biomedical science could have an impact well beyond the immediate $15 million.

Lourival Domingos Possani, of the National Autonomous University of Mexico (Mexico City), said the institute's support has had a domino effect on his research. Possani's research passion is scorpions, including the handful of species that are toxic to humans and those that are toxic to other insects and are therefore useful as pest controls in agriculture. Possani said he believed that his support from Hughes had been the key to getting supplemental funds from his own government. He hoped a similar pattern might be replicated in other Latin American countries.

Among the 47 recipients of new Hughes grants, selected from a pool of