$100 million cancer research gift

Cancer research at the University of Pennsylvania, Philadelphia, received one of the largest gifts ever bestowed upon a National Institute of Cancer-designated center last month, when Leonard and Madyln Abrahamson donated $100 million to the program.

This is not the first time that Abrahamson—who made his fortune by selling the managed care group he founded (U.S. Healthcare, Inc.) to Aetna in 1996 for $8.9 billion—has acted as a benefactor to the department. Two professorships and an Institute within the University of Pennsylvania Cancer Center have already been set up in his name.

A recipient of one of those professorships, John Glick, said that the latest donation will go towards the construction of a new biomedical research building, due for completion in April 1999. The money will also be used to set up 25 new senior faculty positions in the department.

KAREN BIRMINGHAM, NEW YORK

Boston meeting blasts IRB's

"Although new technologies and practices, such as genetic testing and tissue banking, necessitate new mechanisms for subject consent, in the 20 years since [institutional review boards] (IRBs) were instituted in America to oversee human clinical trials, they have not changed at all." This statement by Boston University professor of health law, George Annas, set the tone at last month's "Ethical Research in an Ethical Society" meeting in Boston.

Annas was joined in his criticism of IRBs—the organizations responsible for reviewing and overseeing research protocols—by Leonard Glantz, professor of health law, Boston University School of Public Health. "Too often IRBs are seen as a fence to be jumped over by researchers," said Glantz. He added that "by law, better records are kept of animals used in research than humans involved in experiments."

A study of 942 IRBs throughout the US, spanning the years 1990–96, showed that 20 percent gave no evidence of continued safety monitoring and an equal number had no copies of signed consent forms. According to the study author, investigative journalist Keith Epstein, patients had not been told that their regimen was experimental in 16 percent of cases, and subjects were not appraised of alternative treatments to the experimental protocol in 13 percent of IRBs.

In addition to not keeping pace with newer technologies, one generally acknowledged reason for the sorry state of IRBs is that for many, their workload is far heavier than that which can support the meticulous protocol examination required—good study design, adequate informed consent and a favorable risk/benefit ratio. One IRB member noted that it was not unusual for her committee to review 200 protocols in the space of a few hours. Another reason for IRB failure is the financial pressure connected with approving clinical trials, "which have become big business," according to Gary Ellis, director of the National Institutes of Health (NIH) Office for the Protection of Research Risks. "Academic institutes now vie with each other for lucrative clinical trials and put pressure on IRBs to approve trials that may not be in a patient's best interest," he said. "Universities now speak of losing lucrative research trials as losing market share."

"While researchers have good intentions, there seems to be a consistent inability to juggle some of the conflicts of interest inherent in research, and a blindness when it comes to protecting subjects, even when the government itself is a sponsor," said Epstein.

Congressman Christopher Shays, adding to the troubling notion that federal involvement in trials gives no assurance that they are ethically conducted, revealed that more than half of the federally funded research projects inspected the by Food and Drug Administration between 1977–1995, failed in some way to inform subjects fully of the experimental nature of the medical procedure.

Neil Holtzman and Pat Barr of the NIH Task Force on Genetic Testing presented numerous recommendations for changes to genetic testing protocols, as well as a model for tissue collection and distribution that protects the identity of specimen donors. Barr also made proposals for standardizing IRB review of such trials. It was also hoped that awareness of past experimentation abuses discussed at the meeting will ensure future clinical trials will be conducted with higher ethical standards.

VICKI BROWER, NEW YORK

US boosts disease surveillance effort

The international community charged with detecting, fighting and preventing infectious diseases received a $50 million shot in the arm from the US Congress last month. The money, allocated to the US Agency for International Development (USAID) operations for FY98, is expected to assist organizations such as USAID, the World Health Organization (WHO), and the Centers for Disease Control and Prevention (CDC), in their effort to control the spread of antimicrobial resistant bacteria, tuberculosis, malaria and other infectious diseases with a large public impact.

The funds, which effectively double the amount—outside of child survival and HIV/AIDS—spent by the US to combat international infectious diseases, will also target global disease surveillance, according to USAID senior health advisor, Nils Daulaire.

Senator Patrick Leahy (Dem., Vermont), worried about the threat of infectious diseases such as malaria, tuberculosis and the Ebola virus, to people throughout the world and travelers to and from the US, guided the effort through congress. Leahy is said to be concerned that the CDC, normally bound only to investigate domestic disease threats, should take on more of an international role but lacks the funds to do so.

USAID, which is arguably the largest funder of global infectious disease issues, primarily in the areas of HIV/AIDS and children's susceptibility, will use new funds "to look at issues we have not had the resources to address," says Daulaire. For its part, the World Health Organization has been trying to establish an international framework to monitor the spread of infectious diseases for several years, but is hampered by the lack of finances. WHO's Nelle Temple Brown is hopeful that the US money will be spent in collaboration with her agency. The funds will put "flesh on the bones" of international networks formed to combat infectious diseases, says Brown. A meeting between representatives from Leahy's office, USAID, CDC, WHO, universities and industry has been planned to address specifically how the $50 million will be spent. "We don't just turn over a blank check," says Leahy aide, Tim Rieser. "We want to ensure that a thorough review is done to make sure that the money is used effectively, not frittered away in bits and pieces without a clear strategy."

CHRIS DICKEY, NEW YORK