Proteomics: Basic research climbs aboard

In an effort to make proteomics analysis a routine part of clinical trials research, the United States National Cancer Institute (NCI)—which owns half of the hospital beds available in the US for clinical trials—and the Food and Drug Administration (FDA) have announced funding of \$1.1 million annually for the next three years to apply laser-capture microdissection to studies of new anti-cancer drugs. By analyzing the protein composition of tumors, the Clinical Proteomics Program aims to help companies determine the beneficial and toxic effects of treatments in the lab before they are used in patients, thus optimizing chemotherapy.

Laser-capture microdissection was developed jointly by FDA/NCI scientists and unlike traditional cell-isolation methods, enables the isolation of normal, precancerous and tumor cells from a patient biopsy while maintaining the protein expression patterns of the cells. Program coordinator Emanuel Petricoin of the FDA's Center for Biologics Evaluation and Research, says that this approach is critical for clinical studies in which "we don't have the luxury of growing a million cells in a cell culture flask—what we get are biopsies from patients during clinical trials where we only have a few hundred cells to work with." In contrast to other areas of biotechnology, academic and government scientists have lagged behind in proteomics research compared with the

A breast cancer biopsy before **a**, and after **b**, laser capture microdissection, with the isolated cancer cells ready for proteomic analysis **c**.

dozens of pharmaceutical and biotechnology companies that have been investing heavily in the field.

Joshua LaBaer, director of the Institute of Proteomics at Harvard Medical School, is also trying to make up academic ground: "It's probably fair to say that there has been more of an effort to do proteomics on a large scale in the commercial sector, largely because it is expensive to set this work up. Academia is not as used to building the ... large biology [equipment]." In addition, proteomics is closer to profitable applications than genomics, which might also explain keen industrial interest. LaBaer's institute is establishing a comprehensive collection of general-purpose gene-expression vectors representing the entire human genome. LaBaer estimates that the project, called Flexgene, will cost \$100 million.

The realization that proteomics projects

will require a more centralized organization than is typical of academic science was the driving force behind the creation of the Human Proteome Organization (HUPO) this Spring (*Nature Biotechnol.* **19**, 297; 2001). "Data pertaining to proteomics is scattered in different ways and there's no central repository," says president of HUPO Samir Hanash, a professor at the University of Michigan Medical Center. In addition to establishing such a repository, Hanash hopes that HUPO will be able to serve as a coordinating body analogous to the Human Genome Organization. Presently, HUPO is still in its infancy and comprises only a council and a scientific advisory board representing academic, government and private-sector researchers. The organization is holding a series of meetings around the world to determine its exact structure and mission.

Alan Dove, Philadelphia

Journals develop policy to liberate authors

A group of major medical journals, including *The New England Journal of Medicine* (NEJM), the *Journal of the American Medical Association* (JAMA) and *The Lancet*, announced last month that they will implement a joint policy to safeguard the intellectual independence of authors who want to publish commercially sponsored studies. The policy includes a requirement that authors who submit manuscripts vouch for the independence of their research and the integrity of their conclusions.

According to Drummond Rennie, adjunct professor of medicine at the University of California, San Francisco and deputy editor of *JAMA*, the move was prompted by "enormous problems", the most serious of which is authors being pressured not to publish negative results. Rennie, who has also served as editor for the *NEJM*, believes that these problems exist across all scientific journals.

Many believe that responsibility to protect the academic freedom of researchers also lies with their parent institutions, yet policies to regulate the degree of control that a company has over a research study vary widely across those organizations. The task is rendered even more difficult when drug companies not only fund a study but also give money to the host institution. Earlier this year, the Association of American Medical Colleges (AAMC) launched a taskforce to formulate guidelines to address financial conflicts of interest both at the individual investigator and the institutional level. The latter is completely "uncharted territory" according to David Korn, senior vice president for the AAMC. "There is even no consensus on what it means," he says.

According to many researchers most large, experienced companies have successful and productive relationships with re-

searchers and research institutions—although when problems do occur, they are extremely damaging. But Rennie points out that the problems are much more widespread than people realize. "Those who say that there are no problems just don't see them because they are not publishing the papers," says Rennie.

The case of Nancy Olivieri from Toronto's Hospital for Sick Children (HSC) exemplifies the problem that researchers can face (*Nature Med.* **7**, 644; 2001).

Despite the attention Olivieri's case has attracted, she says very little has changed at her own institution and she is about to embark on a sabbatical to pursue a Master's degree in medical ethics and law in England, which she says will focus on "the inappropriate influence of drug companies on research." She also plans to write a book about her personal experience.

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