Troubled times force old pharma to learn new tricks

A combination of the floundering economy, a stringent regulatory environment and the dwindling number of drugs in the pharmaceutical pipeline are forcing translational researchers to re-think the way they structure pharma-academic partnerships, heard attendees at the Days of Molecular Medicine conference in March.

"Pharma is in the middle of a major paradigm shift," said Jeff Leiden, chief scientific officer at Abbott Laboratories. After the golden age of drug development in the 1980s and 1990s, pharmaceutical companies expected their good fortune to continue. Rapid developments in biomedical research only strengthened that expectation, Leiden said. But, "things have certainly changed in the last three years."

The number of new drug approvals has steadily decreased in the last few years. Researchers also filed fewer applications for patents and inventions in 2002 than in 2001. At the same time, pharmaceutical companies face the daunting costs of bringing a drug to market, pricing pressures and stringent requirements from regulatory agencies; the average size of a clinical trial has nearly tripled in the last 20 years.

Leiden says the existing model, which is a series of hand-offs from academia to biotech companies to large pharma, will soon be obsolete. Instead, he says, his company is actively recruiting both 'scientist-physicians'—traditional M.D/Ph.Ds who can perform research—and 'physician-scientists,' who understand clinical trials and the regulatory hurdles in translational research. Companies like Abbott are also negotiating with universities to train students in both scientific and management principles. "I think you're going to see a lot of those kinds of programs," Leiden said.

Some universities are already one step ahead. The University of California in San Diego—which organized the conference along with the Salk Institute and *Nature Medicine*—is developing a new inter-institutional program called the College of Life Sciences (COILS). COILS is designed to bridge the chasms in translational research and will include the university's Institute for Molecular Medicine as the preclinical arm, the Clinical Investigation Institute for early-phase clinical trials and the Academy of Clinician Scholars to deliver therapies. The university will also offer joint training in science, public health and business.

Award winners all: Lloyd "Holly" Smith, Myra Biblowit (on behalf of Evelyn Lauder) and Charles Sawyers took top honors

In the UK, the Medical Research Council (MRC) has in the past two years reorganized its approach to translational research and has begun novel partnerships. For instance, it transferred several MRC employees to a new company, established with Amersham, that provides imaging facilities to the pharmaceutical industry.

The MRC's new policies reward all staff involved in generating a new patent, a "real important part to encourage young people," according to MRC chief executive George Radda. The MRC also owns all intellectual property that emerges from research done by its employees at academic institutions, allowing industry to negotiate licenses with a single organization, Radda said.

Researchers who form links with private companies need to be vigilant about potential conflicts-of-interest. Speakers bemoaned the lack of infrastructure to support the training of savvy translational researchers who can navigate such murky waters. M.D./Ph.Ds who exit the university system are better trained in basic research and are pressured to stay in those areas rather than venture into translational research, suggested students who attended the meeting.

Critical to training new physician-scientists is the role of mentors who can help young researchers find their footing. Lloyd "Holly" Smith, associate dean of the University of California in San Francisco, is one such "mentor of mentors," and was awarded the Mentorship Award at the meeting. Attendees also honored Brian Druker and Charles Sawyers, for their work with the tyrosine kinase inhibitor Gleevec, with the Translational Medicine Award and philanthropist Evelyn Lauder, for her role in raising breast cancer awareness, with the Service Award.

Apoorva Mandavilli, La Jolla

UK's National Health Service joins publishing free-for-all

Researchers at the UK's National Health Service (NHS) can, beginning this month, publish their findings for free in any of BioMed Central's 90 peer-reviewed journals. News of the partnership comes on the heels of the Public Library of Science's announcement that it will publish its own open-access journals, funded by a $9 million grant from the Moore Foundation (*Nat. Med.* **9**, 154; February 2003).

BioMed Central, an online publisher, charges an article-processing fee to the author but the journals are freely available to its subscribers. Under the agreement, the author fee will be waived for the more than 1 million people on the NHS staff and will be replaced by a membership fee for the organization as a whole.

The NHS provides free medical care in Britain—a costly endeavor. The agreement with BioMed Central is an opportunity to save money from journal subscriptions and the cost of publications, the organization says, allowing NHS funds to be more focused on patient care and health services. NHS researchers are not obligated to publish in open-access journals, however.

Fees for BioMed Central's institutional membership range from $1,550 per year for very small institutions—defined by the number of faculty, students and postdoctoral fellows in medicine and biology—to $7,750 for very large institutions (more than 5,000 researchers). The NHS joins 113 other members, including the World Health Organization, the US National Institutes of Health and other top research institutes.

Stacie Grossman, New York