BUSINESS AND REGULATORY NEWS

Clinical trials halted

Citing failures in patient monitoring, the FDA has suspended 11 clinical trials a New Jersey cancer center has been running for a nearby biotechnology firm, Immunomedics (Morris Plains, NJ). The company and the nonprofit Garden State Cancer Center at the Center for Molecular Medicine and Immunology were founded and are run by the same man, David Goldenberg. "We believe that virtually all of the issues raised by the FDA involve paperwork and record-keeping deficiencies, not treatment," said Goldenberg on September 26. "We are confident that our patients have been treated with the highest level of professionalism, safety, and concern for their welfare." In a related action, the US attorney's office in New Jersey subpoenaed a former clinical trial investigator at Garden State demanding all documents and communications related to Immunomedics and the center; the investigator resigned in August. Shares of Immunomedics, which is working on binding radioisotopes to monoclonal antibodies as cancer treatments, fell 17% to $18 in early October. *EN*

Power shortages affect firms

Unexpectedly rapid regional growth in some areas of Southern California has resulted in electricity demand outstripping supply which, combined with government deregulation of power companies, has resulted in skyrocketing electric rates. Terese Ghio, Ligand Pharmaceuticals' director of environmental health and safety (EH&S), says Ligand's electric bill doubled compared to last year. "This does not help in our efforts to become profitable," she says. Although San Diego Gas & Electric, the company that distributes power for the region, threatened two-hour roving blackouts, this did not occur. For the biotechnology industry, "a blackout of two hours could result in a loss of two years of work," says Ghio. And Idec Pharmaceuticals senior manager of EH&S Mark Thompson points out, "It's not really practical, nor is it feasible to build out an endless supply of emergency generators." Meanwhile Ghio worries about the continued growth of the region. "Additional power plants have been sited for the region, but cannot be built fast enough to meet the demand." *MW*

Business and regulatory news briefs written by Karen Birmingham, Aaron Bouchie, Emma Dorey, Jeffrey Fox, John Hodgson, Eric Niiler, and Myrna Watanabe.

Structural genomics boost

The US National Institutes of General Medical Science has announced it will provide $150 million over five years to seven collaborative projects at US laboratories and academic centers as part of the Protein Structure Initiative (PSI). The consortium aims to develop new automated X-ray crystallography and nuclear magnetic resonance imaging techniques to speed up the process of determining three-dimensional protein structures. PSI director John Norvell says the seven centers will catalog all existing protein structures into a large public database, and then begin producing 100 to 200 protein structures a year. NIGMS hopes to secure funds for a second five years, ultimately determining 10,000 protein structures. While the UK's Wellcome Trust and several companies have discussed creating an international consortium to speed output of protein structures (*Nature* **406**, 923, 2000), NIGMS officials say the PSI will remain separate from any corporate effort (*Nat. Biotechnol.* **18**, 1036, 2000). *EN*

UK allows genetic testing

The UK government's Genetics and Insurance Committee will, for the first time, permit the use of genetic testing for insurance purposes. Following the Committee's conclusion that tests for Huntington's disease are "reliable" and that "an abnormal result is associated with the significant clinical effects with an increased probability of a claim on life insurance," the UK Department of Health announced the go-ahead for the test in mid October. People will not have to take the tests but they will be compelled to tell insurers of the results if they have been tested. Government decisions on tests for other conditions including breast and ovarian cancer, and Alzheimer's disease are expected in the next few months. A spokesperson for the Association of British Insurers, however, has already said that the industry saw no reason to wait for those decisions and that it would continue to use the tests until told to stop. The approval for the Huntington's tests paints the test as simply a way of distinguishing those in affected families who have inherited the dominant disease allele from those who have not. However, the severity and onset of Huntington's disease is influenced by length of repeated non-coding regions within the gene. It is unclear whether the insurance industry is able to react flexibly to such genetic veracities. *JH*

GMO roundup

Lord Peter Melchet is throwing open his farmland near Hunstanton in the UK in order that disgruntled scientists with views opposed to his own can destroy some of the organic crops planted there. Melchet said that, as "a fair minded person, it was only right that the scientific community [also known as "The Silent 800,000"] should have the opportunity to give vent to their own rational beliefs." Melchet's move follows the decision of a jury to acquit all the "Greenpeace 28" defendants, including Melchet, of charges of criminal damage (*Nat. Biotechnol* **18**, 1015) after they flattened and removed parts of an experimental crop of Aventis GM maize from another Norfolk farmer's fields in July 1999. The British press considered the verdict "legalised sabotage". Melchet agreed with farmers' representatives who said that the "extraordinary" decision gave the green light to "wanton vandalism and trespass." Melchet said that, as the property of a rich enterprise that could well afford the ensuing losses, his own crops would make an ideal target for those whose minds were encumbered by rational thought processes. "It's important in a free country that those with destructive tendencies have every opportunity to express themselves." *JH*

AAAS cautions against germ line gene therapy

Human Inheritable Genetic Modifications: Assessing Scientific, Ethical, Religious and Policy Issues, a report released this autumn by a 20-person committee of the American Association for the Advancement of Science (Washington, DC), recommends against germ line gene therapy for now or the immediate future. However, critics note, the panel does not recommend an outright, permanent ban against such procedures. Instead, it calls for establishing a "public body…to monitor and oversee research and developments" that might lead to such procedures, and it also recommends "extensive public education and discussion" to determine "societal attitudes about proceeding" with such efforts. It further calls for careful standard setting to meet safety and efficacy requirements, and also warns that "market forces…should be carefully assessed to ensure that adequate attention is paid to public priorities and sensibilities." *JF*