SARS vaccines on the fast track

Just a few months after the virus causing severe acute respiratory syndrome (SARS) was identified, scientists have developed vaccines that they hope to test in humans in the near future.

Researchers at Sinovac Biotech in Beijing have created a vaccine using the inactivated SARS virus, and have already received approval for clinical tests from the Chinese National Institute for the Control of Pharmaceutical and Biological Products. Human trials are expected to begin by the end of December 2003.

Meanwhile, Canada's multicenter SARS Accelerated Vaccine Initiative is testing three types of inoculations to develop a vaccine that could be ready as early as next fall, and US scientists have engineered a SARS vaccine that triggers the production of protective antibodies in rhesus macaque monkeys. Both groups are planning further animal tests and human clinical trials. It is unlikely that either vaccine will be available if the virus, which infected 8,000 people worldwide last year, returns this winter.

Getting the vaccines ready for public consumption may be hindered by the manufacturing process, which requires level 3 biohazard facilities available in only a few cities worldwide. Some scientists warn that the research is moving ahead before long-term effects of the vaccines can be evaluated. *PL*

US to test pediatric drugs

President Bush on 3 December signed the Pediatric Research Equity Act of 2003, which grants the US Food and Drug Administration (FDA) the authority to require drug companies to test adult medicines in children.

Only a quarter of the drugs on the market are specifically tested and labeled for use in children. Doctors often have to estimate the appropriate doses based on adult indications, which can lead to under- or overmedication in children. The new act aims to eliminate that guesswork by making it mandatory for drug companies to conduct pediatric trials of drugs that are to be used in children, even if the companies lack the financial resources to do so voluntarily.

The new law became necessary after the federal court last year struck down the FDA's 'pediatric rule', under which the agency granted itself the authority to require child drug testing (*Nat. Med.* **9**, 631; 2003). *PL*

News briefs written by Aparna Surendran and Pierrette Lo

Europe to back some stem cell research

The European Commission will consider funding proposals on human embryonic stem cell research on a case-by-case basis, even though the European Union (EU) could not agree on comprehensive ethical guidelines at a meeting held 3 December.

Funding for stem cell research in Europe was frozen until the end of 2003 while the Commission proposed ethical guidelines in July. Those guidelines passed in Parliament, but the Competitiveness Council, which decides on such proposed EU legislation, was split on the guidelines. Germany, Austria and Italy opposed spending money on embryonic research, whereas Britain, Sweden and the Netherlands supported the work.

Ireland will take on the EU presidency for six months, beginning January 2004. It is possible that Ireland could ask the Council ministers to revisit a vote on the guidelines, but Irish Deputy Prime Minister Mary Harney has said she could not see the issue being resolved under Irish leadership.

Meanwhile, the United Nations General Assembly in December upheld its earlier decision (*Nat. Med.* 9, 1440; 2003) to postpone a vote on human cloning. The organization's legal committee had initially voted to postpone the vote for two years but after a bloc of 40 countries led by the US and Costa Rica reintroduced the issue, it has agreed to review the decision after one year. *AS*

China approves world's first gene therapy drug

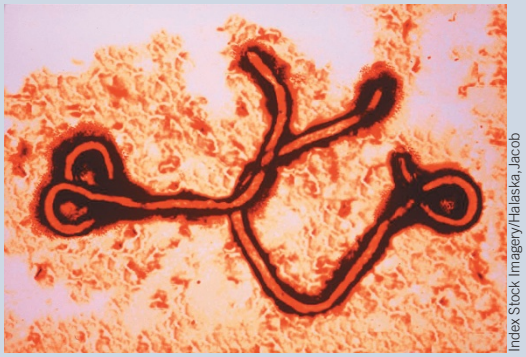
China's State Food and Drug Administration has approved the world's first commercial gene therapy drug for cancer. The drug, Gendicine, is manufactured by Shenzen SiBiono GeneTech and will hit the market in January.

Some researchers say it may be too early to commercialize gene therapy. But the regulatory system in China—where the technology has not been dogged by controversy as it has in the West—may be more open to its benefits. There are at least six other biotechnology firms worldwide with phase 2 or later trials of gene therapy products for cancer.

Gendicine contains an adenovirus expressing the p53 oncoprotein, known to trigger apoptosis. Many cancers result from mutant or inactive p53. SiBiono tested the therapy in patients with late-stage head and neck squamous-cell carcinoma, which comprises 10% of all new cancer cases in China. Mutant p53 is found in more than 60% of those tumors.

In the largest trial, 64% of patients showed complete regression of tumors after eight weeks of radiotherapy and weekly Gendicine injections. The patients were monitored for up to five years after the trial. The rate of complete regression in the radiotherapy-only patients was three times lower; 32% of patients who received radiotherapy and Gendicine injections showed partial regression of tumors. *AS*

Ebola rears ugly head as vaccine enters trials



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The Ebola virus resurfaced in November in the Republic of Congo, claiming 29 lives, according to the World Health Organization. In May 2003, the hemorrhagic fever caused 148 infections, including 128 deaths.

Officials say the outbreak might have begun after a group of hunters ate an infected dead boar in the Mbomo region of the country. There is no cure as yet, but scientists at the US National Institutes of Health are conducting the first human clinical trial to test an Ebola vaccine. In November, researchers gave their first volunteer a DNA vaccine—manufactured by California-based Vical—with modified, inactivated genes from the Ebola virus.

The vaccine trial will enroll 27 people, including 6 controls. Volunteers will each get three injections over two months, and scientists will observe their immune reactions to the vaccine for a year. *AS*