

BUSINESS AND REGULATORY NEWS

Xenotransplantation regs

Officials in the US Department of Health and Human Services (HHS; Washington, DC) released revised guidelines on xenotransplantation late in May, reaffirming the need for the FDA to continue its regulatory oversight of this field. The guidelines specifically call upon blood centers and other clinics to reject blood or organ donations from xenotransplant recipients and their close contacts, such as family members, to reduce the risk of transmitting novel pathogens from animal sources. They also call for more stringent procedures in handling animals whose organs are used for transplants, such as use of surgery to deliver animals at birth, breeding of closed herds in specialized facilities, and active monitoring of those herds for evidence of infectious agents. In addition, there will be extensive counseling of patients who receive xenotransplants, who will essentially be required to cooperate with long-term surveillance programs. Following another recommendation within the revised guidelines, HHS is establishing a new public advisory committee, the Secretary's Advisory Committee on Xenotransplantation, to discuss both scientific and ethical concerns that arise from this area of medical research; the new committee will meet initially sometime this summer. *JF*

Pioneer settles for \$100 M

Cargill (Minneapolis, MN) and Pioneer Hi-Bred (Des Moines, IA) announced on May 16 that they had settled the lawsuit Pioneer filed in October 1998 alleging that Cargill's seed business had stolen genetic material from Pioneer. Under terms of the settlement, Cargill must pay Pioneer \$100 million for past damages and to resolve ownership rights for use of some of the disputed material. In addition, Cargill will destroy the misappropriated genetic material. According to a statement released by both companies, an intensive internal investigation launched by Cargill after the suit was filed uncovered "ethical problems" in its corn-breeding program. Allegedly, a former Pioneer employee who worked at Cargill (and has since left) had provided some of the disputed genetic material to Cargill. The companies have been working on a settlement since February 1999, when Cargill admitted its mistakes. *JG*

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First Finnish biotech IPO

BioTie Therapies (Turku, Finland), a developer of drugs for inflammation, blood coagulation, thrombosis, and cancer, plans to raise about \$20 million on the Helsinki Stock Exchange's New Market, an index created in October 1998 for development-stage companies. Despite the fact that there are more than 100 biotechnology companies established in Finland, BioTie is the first to go public. "The problem in Europe," says BioTie CEO Markku Jalkanen, "is that the business model of a biotechnology company is still poorly understood among investors." Jalkanen has been somewhat of a pioneer of biotechnology enterprises in Finland, founding BioTie (one of Finland's oldest and largest biotech companies) and participating in numerous biotech centers around the country. He believes successful flotation of BioTie's shares will encourage other Finnish biotech companies to go public this year. Likely candidates include Hormos Medical (Turku), a developer of hormonal therapies, and FibroGen Europe (Oulu), which develops recombinant collagens. *RL*

DeveloGen/HepaVec deal

May 16 saw the first biotech-biotech merger in Germany—between functional genomics company DeveloGen (Goettingen) and gene therapy firm HepaVec (Berlin). DeveloGen, which has been focused on discovering genes associated with obesity, diabetes, and liver damage, hopes to use HepaVec's gene-delivery systems for "regenerative gene therapy." This involves delivering a developmental control gene (e.g., *Pax*, which triggers the development of insulin-producing cells) to a defective cellular structure (e.g., the pancreas), at which point transient expression of the gene would start a biochemical cascade to regenerate cells and restore the organ's function.

Although as a larger entity the new company is more likely to attract investments, it wasn't financial necessity that prompted this merger—HepaVec had just seen its second round of financing of DM8 million (\$3.9 million). "Both companies have their own merits in their own right," says Tom Giemer, biotech analyst at Apax Partners (Munich), the merger is "a very well-thought-out development." Herbert Stadler, DeveloGen CEO and founder of both companies, says combining the companies will increase the critical mass DeveloGen needs for an initial public offering on the Neuer Markt next year. *ED*

GMO roundup

- Misdirected anti-biotech activity has finally teed off in Oregon. In June, a group calling itself the Anarchist Golfing Association (AGA) destroyed experimental grass plots belonging to Pure Seed Testing (PST)—the research arm of Turf-Seed (Hubbard, OR), a company that sells grass seed for sports fields, parks, lawns, and cultivated pastures. "Grass, like industrial culture, is invasive and permeates every aspect of our lives," writes the AGA. "The biotech industry usually hides behind the racist aura of 'feeding the Third World,' but as you can see, it is quite obvious that these crops are grown for profit and the pleasure of the rich and have no social value."

During the AGA's "nocturnal golfing tournament," PST's sign was modified to read "GE Seed Testing," the AGA boasts that it overturned, stomped, and ripped up hundreds of experimental grass pots, and that "insightful messages" were left behind. Crystal Fricker, PST's director of research, tells *Nature Biotechnology* these messages came in the form of golfer figurines and golf balls labeled with—wait for it—the insignia "AGA." This "insight" is clearly in line with AGA's sagacious rampage, which actually resulted in the damage of natural breeding projects, according to Fricker. Damaged varieties included a salt-tolerant rag grass and a naturally herbicide-resistant creeping bent grass. "We don't have any genetically modified projects that we're trying to bring to market," says Fricker. She adds that PST was also doing a gene-flow study for environmental risk assessment involving creeping bent grass and that AGA destroyed the plants from one year of that project. *ED*

British Biotech downsizes

Floundering British Biotech (Oxford, UK) announced in June it will axe another 90 employees, reducing its total staff to 140. The "reorganization" is expected to save £8 million (\$12.8 million) per year, which the company says will be used to fund its expanding portfolio. Compounds in development include matrix metalloproteinase inhibitor Marimastat, currently in phase III trials, and huN901-DM1, a tumor-activated pro-drug recently in-licensed from ImmunoGen. British Biotech shares have fallen 19% this year to 24p but the company, which estimates the £75 million (\$120 million) it currently has in the bank will keep it going for another 4 years, denies it is planning to merge with another biotech company. *ED*