BUSINESS AND REGULATORY NEWS

GMO roundup

- UK civil servants prove themselves as adept as ever at handling potentially sensitive genetic modification issues. In the run up to the trial of four people accused of vandalizing crops in Scotland, Mae-Wan Ho of the Institute of Science in Society (London) announced at a press conference organized by the Scottish Green Party that an enzyme toxic to human health was present in crops currently in UK field trials. The enzyme she had in mind was barnase, *Bacillus amyloliquifaciens* RNAse, used in some oil-seed rape crops as part of a "terminator" approach. There is some evidence that the enzyme can be toxic to isolated human cells. In an attempt to smooth over the rumpus that was threatening, a spokesperson from the UK's Department of Environment, Transport, and the Regions said that it was the barnase gene and not the enzyme that was present in the crops, adding reassuringly that whereas the gene was not harmful, the enzyme would be poisonous.
- Responding to the US EPA's deliberations over Aventis' StarLink corn (see p.11), a spokesperson for the US Organic Consumers Association said, "The health of Americans should not be put at risk simply for the convenience of the biotech industry." Quite so, and neither should it for the sake of organic farming, a user of *Bacillus thuringiensis* insecticidal toxins for many decades.
- "In the light of the increasing consumer awareness in Germany, we already decided this year to approve only animal fodder that does not contain genetically engineered ingredients." This come from Matthias C. Baumgarten, director of communications at McDonald's Deutschland (although not himself a Hamburger). Now weren't McDonalds the folks whose customers were so aware that the company had to put a notice on its coffee cups warning that their contents might be hot? *JH*

Business and Regulatory News Briefs written by Aaron J. Bouchie, Liz Fletcher, Jeffrey L. Fox, John Hodgson, Sabine Louët, Chris Morrison, Eric Niiler, and Ellen Peerenboom.

FDA gene rules impractical

Current US Food and Drug Administration guidelines for long term followup are unfeasible for trial sponsors and patients, especially individual investigators on five-year NIH grants and less well-financed biotechnology companies. So concluded the Biological Response Modifiers Advisory Committee (BRMAC) of the FDA's Center for Biologics Evaluation and Research during its November 16–17 meeting. Citing high costs and multiple logistical issues—such as patient compliance, investigator relocation, companies abandoning trials or dissolving—the BRMAC recommended that at five years, data collection from gene therapy trial participants fall under the umbrella of a government or non-profit organization. The committee noted that this long-term followup should be observational and conducted through a series of postcards and telephone calls. BRMAC also concurred with current FDA guidelines that require clinical trials halted when gene therapy vector is detected in a patient's semen, and that all vectors less than 40 kb—including retrovirus, adenovirus and adeno-associated virus—be sequenced prior to phase I trials. The NIH plans to hold a policy conference on follow-up requirements for gene therapy research later this year. *CM*

Blech settles with SEC

US Federal officials have settled a civil lawsuit with David Blech, barring the former biotechnology financier from being associated with a broker or dealer. In the early 1990s, Blech bankrolled such startup firms as GeneMedicine (Woodlands, TX), Incyte Genomics (Palo Alto, CA), and Guilford Pharmaceuticals (Baltimore, MD), until news of his own financial woes in 1994 caused several, including Parnassus (San Francisco, CA), to collapse (*Nat. Biotechnol.* **15**, 23-26, 1997). The US Securities and Exchange Commission (SEC), in a civil suit filed in 1999, accused Blech of unlawful and unauthorized trading, and sought the return of illegal profits from Blech's "massive manipulative scheme designed to increase and/or stabilize the prices" of companies he was involved in. In the December 2000 settlement of the case, the government has waived civil penalties because Blech is unable to pay. In a separate criminal trial in 1998, Blech pleaded guilty to criminal fraud charges and was sentenced to a five-year term of probation. *EN*

OGS/Glaxo biomarker deal

Proteomics company Oxford GlycoSciences (Oxford, UK) has signed a deal with Glaxo Wellcome (Greenford, UK) to identify biomarkers—proteins whose expression change during illness. Biomarkers can be used not only to detect and monitor a disease, but also to improve the design and assessment of clinical trials, thus speeding the clinical development process. But OGS has struggled to sell the concept to industry, signing up only Pfizer (New York) and Bayer (Leverkusen, Germany) in similar disease-based studies over the past two years. The deal with Glaxo, says OGS's business development manager Robert Burns, is a sign that the drug industry has woken up to the potential impact of proteomics on clinical development. The collaboration should fuel both Glaxo and OGS's clinical development efforts, helping to fill OGS's currently sparse product pipeline and consolidate its intentions to become a drug developer. In the longer term, OGS foresees using biomarkers as the building blocks for new types of diagnostics, a market which, says Burns, is currently undeveloped and undervalued.

On December 7, OGS sold 13.4 million shares at $18.36 in an IPO on Nasdaq, trading up at $20.00 the following day. *LF*

Aventis to shed ag

The supervisory board of Aventis SA (Strasbourg, France) revealed plans in November to divest the agricultural business Aventis CropScience (Lyon, France) by the end of 2001 in order to focus on pharmaceuticals, which accounts for 75% of the parent business. The divestment may take the form of an initial public offering under the name "Agreva," but big players in the agrochemical market have shown interest in purchasing the division, most notably Bayer AG (Monheim, Germany). However, 24% shareholder Schering AG (Berlin) is contractually able to veto major strategic decisions involving the division. Citing the less-than-stellar debut of Syngenta (Basel, Switzerland)—the merged agriculture divisions of AstraZeneca and Novartis—which hovered between $8.31 and $9.12 in the first three weeks after its November 14 opening of $8.625 on the New York Stock Exchange, spokesperson Friedrich von Heyl says "We are not in a hurry."

Aventis says the plan for transition from life sciences to strictly pharmaceutical was made before the StarLink controversy (see p. 11). *AJB*