BUSINESS AND REGULATORY NEWS

GMO roundup

- · Scary messages from anonymous antibiotechnology protestors have been circulating around email networks. They are aimed at UK farmers growing or planning to grow GM crops. One particularly obnoxious message starts off with an admission that the sender was involved in sabotaging farm machinery belonging to Bob Fiddeman, spokesperson on biotechnology for the UK lobby group, the National Farmer's Union. Four of his tractors and his combine harvester had wires cut, locks glued, and corrosives poured over connections. The aim, says the e-mail, was not to cause damage but to send the message that if farmers continue in "complicity with the corporations, [their] business and private property WILL be attacked." The message continues, "Your security preparations will do you no good...Floodlights, alarms, dogs, security guards-it makes no difference to us-we are committed. . . . If you have crops in the ground- plough them up. If you have not yet planted-don't start. YOU DO NOT WANT TO ENTER THIS CONFRONTA-TION. . . . If you do not wake to the public's hatred of GMOs and to your responsibility to the living earth; you will instead wake to your machines and property in pieces."
- Taking a leaf out of Arpad Pusztai's studies, researchers at the University of East Anglia have published work on the impacts of GM crops "without doing any experiments." Computer modelers Andrew Watkinson and colleagues at East Anglia modeled the effects of GM herbicide tolerant beet on the population dynamics of a weed that is an important food source for farmland birds (Science, 289, 1554-1557 2000). The model predicts that bird populations will be low where weed densities are low, and that the use of GM herbicide tolerant crop will reduce weed populations. They extrapolate that GM crops will reduce bird populations. However, among the real-life facts the model ignores are field studies showing that herbicide-tolerant beets allow farmers to maintain weeds longer (because they can be treated after crop emergence not before), and the possibility that greater efficiency of GM crops may allow more land to be "set aside" for wildlife.

Business and regulatory news briefs written by Aaron Bouchie, Liz Fletcher, Jeff Fox, John Hodgson, and Eric Niiler.

Guilford halts Gliatech deal

On August 28, Guilford Pharmaceuticals (Baltimore, MA) shelved plans to acquire Gliatech (Cleveland, OH) after it emerged that the US Food and Drug Administration (Rockville, MD) had questioned irregularities in the clinical trial data of Gliatech's antiscarring gel, Adcon-L. The cancellation of the \$203 million deal sent Gliatech's share price plummeting over 60%, and shareholders threatened to sue the company.

In August, the FDA sent Form 483 to Gliatech questioning the recording and presentation of some of the data submitted for US regulatory approval in 1998. In particular, concerns were raised over the re-scoring of 115 out of 324 magnetic resonance imaging (MRI) scans, which were used to measure the thickness of the patients' scar tissue. The FDA also cited "erasures and writeovers" of the data, which made Adcon-L appear more effective at reducing scar tissue than the original data. Although Gliatech claims that the original MRIs had been rescored as part of an "intraobserver reliability study," it ousted its president and CEO Thomas Oesterling and started an internal investigation. Adcon-L is Gliatech's only financially significant product, generating sales of \$26 million last year. If the FDA finds Gliatech guilty of tampering with clinical data, it could withdraw the product from the market. Although Gliatech has variants of Adcon-L for use after other types of surgery, Jonas Alsenas of ING Barings (New York) says the confidence of both regulators and the investment community has been dented. Guilford, he adds, may have been "voting with its feet" and Gliatech could find it difficult to find a new partner.

Chiron buys PathoGenesis

biotechnology company Chiron (Emeryville, CA) has agreed to buy PathoGenesis (Seattle, WA) for around \$700 million in an all-cash deal that provides Chiron with revenue from a high-growth product and strengthens its infectious disease pipeline. Chiron already has around \$1.5 billion in assets, and the deal brings it PathoGenesis's inhaled antibiotic tobramycin, which will become a lead product in Chiron's anti-infectives portfolio. Furthermore, Chiron gains around 275 staff, world-class expertise in bacterial genomics (PathoGenesis has just sequenced Pseudomonas), and a rich R&D pipeline. Although PathoGenesis was in the rare position of having brought a product to market, a second product launch was a long way off and the company was not financially able to acquire a company with products closer to market. LS

State restricts biotech crops

California Governor Gray Davis was poised early in September to sign a bill aimed at protecting the export value of the state's \$320 million rice crop that would restrict sales of genetically engineered rice and could bode ill for other biotechnology crops grown in this agriculturally diverse state. Because some 40% of the rice crop is exported to Japan, where consumers are very particular about rice quality and many are also opposed to genetically modified (GM) foods, the bill specifies that different types of rice are to be kept separate after harvest and fees imposed on seeds of various rice varieties. Although the legislation does not directly single out GM techniques, biotechnology industry representatives in the state say it puts their products in a particularly bad light and they may be forced to take them elsewhere.

Meanwhile, late in August, city council members in Minneapolis, MN, passed a resolution calling for the labeling of GM foods and for including organic foods in city contracts. A statewide biotechnology industry group criticized the resolution and asked council members and the mayor to consider either rescinding the measure or drastically reworking it. And, in a similar frame of mind, officials in the small city of Boulder, CO, agreed to a measure that would ban planting of GM plants on some 15,000 acres of city-owned land.

Corning chips in

Affymetrix (Palo Alto, CA) has a new rival in the DNA chip business. Corning (Corning, NY), the manufacturer of high-technology glasses and the inventor of the optical fibre has announced that it has 10,000-sample microarrays in beta-testing in research laboratories in the USA and Europe, and that it aims to become number 1 or 2 in the market within the next five years. Corning's manufacturing process uses its optical fibre manufacturing experience to draw down a honeycomb-like glass substrate with thousands of cells to a microscopic dimension in which the diameter of each cell is reduced 500% or more. That microscopic honeycomb is then used as a massively parallel printer head to deposit DNA (provided by a number of potential partner companies) onto a glass slide. The chips are expected to be in commercial production by the first quarter of 2001. In a comment that is clearly directed at Affymetrix, Corning has said that its process will "allow researchers to avoid having to pay large up-front fees or to sign long-term contracts, as is common practice in the industry today." ΙH

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