

FDA advisor conflicts and voting weakly linked

A study in April of US Food and Drug Administration (FDA) advisory committees found that many voting members had financial ties to drug companies, but their influence did not change the outcomes of decisions. The FDA convenes panels of outside experts to make recommendations on whether a drug or device should be approved. Since 2002, the agency has required from its advisory committees more detailed disclosure of financial conflicts. At 73% of the meetings between 2001 and 2004, at least one voting member disclosed a conflict of interest, according to the study (*JAMA* **295**, 1921, 2006). The researchers, who are part of the consumer group Public Citizen's Health Research Group in Washington, DC, found a 'weak' relationship between financial conflicts and voting behavior. Only 1% of committee members who disclosed conflicts were dismissed from the meetings. Finding experts without some kind of financial tie is difficult, say analysts. The most knowledgeable scientists are frequently paid to be consultants for companies or speakers at conferences. "What's the point of being an expert without getting any of those perks?" says Chris Milne at the Tufts Center for the Study of Drug Development in Boston. "This study says the system is working as well as it can."

EW

Internet icons bet on white biotech

Some highly successful early internet investors are setting their sights on white (industrial) biotech, a recent stream of venture capital suggests. This could give fresh momentum to attempts by white biotech companies to attract much-needed investors. On April 17, Pacific Ethanol, a Fresno, California-based company planning to build four ethanol production facilities in west coast states, announced it had completed the sale of shares worth \$84 million to Cascade Investment, a firm investing the personal fortunes of Bill Gates, the cofounder and chairman of Microsoft of Seattle. In February, investment firm Kleiner Perkins Caufield & Byers of Menlo Park, California, which is closely associated with John Doerr, a venture capitalist best known for jump-starting internet household names

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Europe approves two follow-on human growth hormones

On April 12, the European Commission granted the first marketing authorization for a biogeneric, Omnitrope (somatropin), Sandoz's recombinant human growth hormone (rhGH). Several months earlier, the European Medicine's Agency (EMA) had concluded that Omnitrope has comparable quality, safety and efficacy to Genotropin, a somatropin rhGH product marketed by Pfizer of New York. In 2003 Sandoz, which is based in Holzkirchen, Germany, had submitted an abbreviated application to the US Food and Drug Administration (FDA), presenting Omnitrope as indistinguishable from FDA-approved Genotropin. After waiting years for the FDA's decision, Sandoz officials sued the agency in the District of Columbia's US District Court (*Nat. Biotechnol.* **23**, 1327-1328, 2005). The company alleged that the FDA had violated its statutory obligation to act on the Omnitrope application within 180 days, a time frame that the FDA characterized as merely a congressional aspiration. On April 10, Judge Ricardo M. Urbina ruled in Sandoz's favor; the FDA must move forward with its assessment. Although the ruling may expedite Omnitrope's arrival in the marketplace, it does not signal the beginning of US biogeneric regulation. "The Omnitrope decision doesn't really deal with the process," says David L. Rosen, an attorney with Foley & Lardner's Washington, DC, office, "it deals with the time frame that the FDA has to make a decision." Rosen, an expert on FDA legal matters, says that progress on a biogeneric regulatory scheme is "still slow sledding here," but that European leadership and experience with biosimilar therapeutics should eventually galvanize US efforts. On April 24, the EMA granted Swiss biopharmaceutical company BioPartners marketing approval for Valtropin (somatropin), the second biosimilar version of human growth hormone to be cleared for marketing in Europe. Valtropin has been approved for the treatment of human growth deficiency in children and Turner's syndrome, and BioPartners has said it aims to launch it before the end of the year.

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Human growth hormone is used to treat children with growth deficiency.

like Netscape, Amazon and Google, put aside \$100 million for investments in technologies producing cleaner energy, transportation, air and water. This adds to the \$50 million Doerr has already devoted to green ventures. "Greentech could be the largest economic opportunity of the 21st century," Doerr said in a statement. Perhaps answering his call, on May 1, New York-based bank Goldman Sachs poured CA\$30 (\$27) million into Iogen Corporation, a biotech company based in Ottawa, Canada that plans to build its first cellulose ethanol production facility near Idaho Falls, Idaho, next year. According to Iogen CEO Brian Foody, the deal makes Goldman "the first major Wall Street firm to make a commitment to cellulose ethanol."

PV

VC fund for plant biotech

On April 11, 2006, agricultural company Syngenta International of Basel launched a \$100-million venture capital fund that will

invest in growth companies and biotech startups working on plant biotech, the company's core business, as well as other fields like human health, animal nutrition, biomaterials and biofuels. The new fund is called Bioventures and will be managed from the recently opened Boston office of Life Sciences Partners (LSP), a venture capital firm based in Amsterdam. LSP has funneled \$350 million into 40 European biotech startups over the past ten years. Fresh funding for agricultural biotech was also announced by Hans Kast, president of the newly formed plant science unit of chemical giant BASF of Ludwigshafen, Germany. On April 11, in Chicago, Kast told reporters at the BIO 2006 conference that his company plans to invest \$320 million over the next three years in the development of second and third generation genetically modified (GM) crops. Basf's first GM crop plant, a potato with modified starch composition destined for nonfood markets, is awaiting approval by authorities in the EU.

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Selected research collaborations

Partner 1	Partner 2	\$ (millions)	Details
FivePrime (San Francisco)	Boehringer Ingelheim (Ingelheim, Germany)	75	A two-year collaboration to discover treatments for rheumatoid arthritis. FivePrime will make available its extensive library of human proteins and receptors and its rapid protein discovery system. Boehringer Ingelheim will contribute its expertise with proteins and disease biology. FivePrime will receive an upfront fee and research support. Boehringer Ingelheim will hold exclusive rights to develop and commercialize resulting products and targets, in exchange for future milestones and royalties.
Myriad Genetics (Salt Lake City, Utah)	Abbott Laboratories (Abbott Park, Illinois)	*	A five-year agreement to discover a broad range of novel therapeutics. Myriad will use its genetics and RNA expression profiling to identify disease-related genes. Abbott will identify targets and leads for drug discovery by advancing these genes through its chemical genomics platform. Each company will receive exclusive rights to resulting targets and compounds for their pipeline, with Myriad to hold ~40% and Abbott, ~60%.
AdipoGenix (Boston)	Unigen Pharmaceuticals (Lacey, Washington)	*	A deal to codiscover natural products targeting human fat. AdipoGenix will apply its proprietary human fat cell-based technologies to Unigen's collection of medicinal plant extracts to discover natural substances that reduce the fat content of human fat cells. Unigen will produce active molecules from extracts, and AdipoGenix will characterize their mechanism of action. The companies will share equally the costs and profits for discovery, development and commercialization. AdipoGenix will hold worldwide rights for commercialization of any resulting pharmaceutical products, and Unigen will maintain rights for cosmeceutical and nutraceutical products.
Alcon (Fort Worth, Texas)	Amgen (Thousand Oaks, California)	*	A partnership to discover treatments for eye diseases. Amgen will provide existing or future molecules shown to be relevant for eye diseases. Alcon will lead clinical development and commercialization, based on its expertise in ophthalmology. Alcon will hold an exclusive license for resulting products in the field of ophthalmology; Amgen will retain rights for non-ophthalmological uses.

*Financial details not disclosed.

AK

UK charity to test shelved drugs

The London-based charity Cancer Research UK (CRUK) has launched a unique scheme under which it is offering to 'borrow' dormant drug candidates from pharmaceutical companies and take them into clinical trials at its own expense. The charity expects to see four to five such partnerships each year, including both phase 1 and 2 trials. If a trial proves positive, CRUK will get a share of any resulting revenues. But the partner drug company will retain marketing and intellectual property rights to its original molecule, and will get first sight of the trial data. CRUK says many promising anticancer molecules are trapped in drug companies' pipelines because there are too few commercial resources to take them into the clinic. This is especially true of treatments for rarer cancers because they are less profitable, says the charity's chief executive Alex Markham. Richard Tiner of the Association of the British Pharmaceutical

Industry comments the £2 (\$3.8)-million scheme is a "simple, rapid and cost-effective way for pharmaceutical companies to boost their pipeline." Alan Fairlamb, Wellcome Trust principal research fellow at Dundee University, and an expert on drug development in the non-profit sector, is also upbeat: "Clearly, there are issues surrounding intellectual property and the exploitation of future knowledge, but it's an excellent strategy if the drug companies are prepared to collaborate with not-for profit organisations." *PM*

E&Y study cites industry 'stability'

On its 30th birthday, the biotech industry this year is showing signs of stability, according to the 2006 Ernst & Young *Global Biotechnology Report* published in April 2006. Revenues of the world's publicly traded biotech companies grew by 18% in 2005,

reaching an all-time high of \$63.1 billion. Companies raised \$19.7 billion in financing, slightly less than 2004 figures. "This report shows two straight years of stability," says Jim Greenwood, president of Biotechnology Industry Organization in Washington DC. "The investment numbers indicate that the industry is maturing and the spikes and valleys are leveling out." But the industry faces significant challenges ahead. Venture capitalists are reluctant to invest in biotechs in their formative years, instead gravitating toward companies in later stages of development and creating a gap in funding. Cost of development continues to plague the industry as well. As one solution, companies are looking to partner with enterprises in developing economies. Asian and Pacific regions are increasingly providing researchers, labor, agricultural land and a market. *EW*

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New product approvals

Product	Details
Dacogen (decitabine) MGI Pharma (Bloomington, Minnesota) and SuperGen (Dublin, California)	On May 3, the FDA granted approval to Dacogen, an injectable hypomethylating agent for myelodysplastic syndromes (MDS), a group of disorders characterized by a malfunction of red blood cell production in the bone marrow. MDS affects about 10,000 people in the US each year, and some forms can progress to acute leukemia. Dacogen reduces DNA methylation and is thought to exert its therapeutic effect by normalizing the function of genes involved in cell proliferation.

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