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SEC advisory panel favors Sarbanes-Oxley reforms

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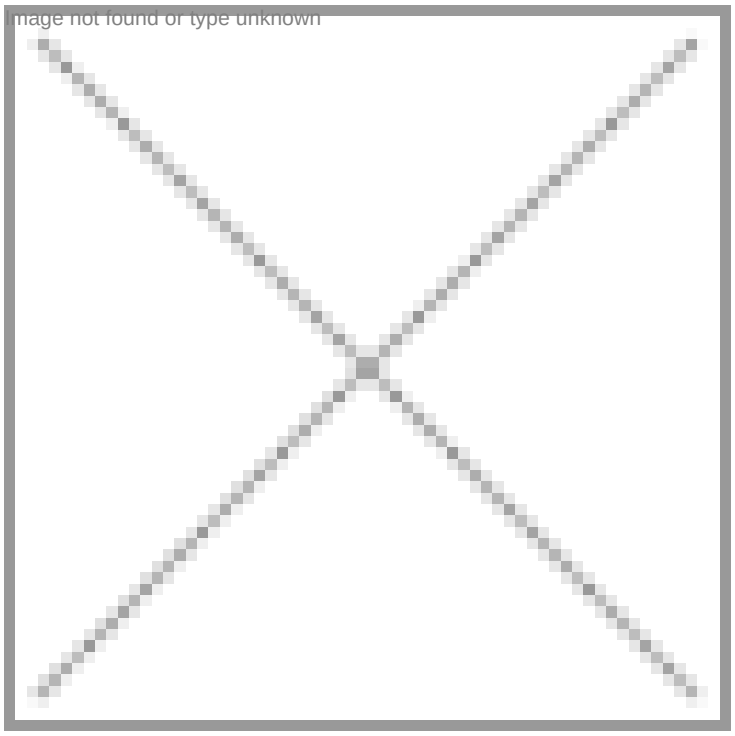

SEC advisory panel favors Sarbanes-Oxley reforms

The Securities and Exchange Commission's (SEC) Advisory Committee on Smaller Public Companies has voted overwhelmingly in favor of reforming Section 404 (internal controls) of the Sarbanes-Oxley Act of 2002.

"This is an indication that the committee understands the financial burden that Section 404 of Sarbanes-Oxley places on small public companies. We are not recommending a legislative change to Sarbanes-Oxley, instead we are asking the SEC to ease sections that are creating harmful, unintended consequences for small public companies," said Jim Greenwood, president and CEO of the Biotechnology Industry Organization (BIO).

The SEC formed the 21-member advisory committee to consider ways of improving the impact of Sarbanes-Oxley on small public companies. Sarbanes-Oxley, the corporate governance law, requires publicly traded companies to adhere to standards that broaden board members' roles in overseeing financial transactions and auditing procedures. The committee's recommendation will be released for public comment prior to its meeting on January 23, 2006. The final recommendations are due in April.

BIO has formed a coalition of biotechnology, healthcare technology, high technology and venture capital industries to seek reform to Section 404. Coalition members argued that complying with the Sarbanes-Oxley external auditor requirement can cost upwards of $1 million, often doubling a small firm's operating costs. The coalition recently sent a letter to the SEC advisory committee recommending that smaller public companies be: defined as the bottom 6 percent (based on a quarterly

average) of the total US public market capitalization or by a revenue threshold set by the average revenues of companies at the bottom 6 percent of total market capitalization; exempt from having external auditors attest to internal controls. This would not exempt small public companies from complying with Sarbanes-Oxley as a whole; allowed to take a risk-based approach to prioritizing their key financial controls and to alternate the frequency of control testing to every second or third year.

Source: www.bio.org

Benefits drive demand for biotech crops in the US

As a result of increasing benefits from biotechnology-derived (biotech) crop varieties, farmers are adopting the technology with greater ease than ever before, according to a new study update released by the National Center of Food and Agricultural Policy (NCFAP).

In 2004, farmers in the US planted biotech crops on 118 million acres, an increase of 11 percent over the previous year. Compared to conventional crops, biotech varieties increased food production by 6.6 billion pounds, a 24 percent improvement from 2003, and provided $2.3 billion in additional net returns for the US growers, a 21 percent increase from the previous year. Biotech crops also reduced pesticide use by an additional 34 percent, or 15.6 million pounds. Pesticide use dropped by 15.6 million from 2003 to 2004.

The study examined 11 case studies of six biotech crops planted in the United States in 2004 - corn, soybean, cotton, papaya, canola and squash - and is based on data from the US Department of Agriculture's National Agricultural Statistics Service and surveys of Crop Specialists from various universities.

According to the study, insect-resistant crops again produced the greatest yield increase among the crops studied, improving food and fiber production by 6.5 billion pounds. While insect-resistant traits increased production, herbicide-resistant varieties generated the greatest reduction in production costs. Herbicide-resistant varieties cut costs by $1.8 billion and reduced pesticide use by 55.5 million pounds.

Source: www.ncfap.org

Singapore accepts guidelines on genetic research

The government of Singapore has accepted ethical guidelines that spell out the limits of genetic testing and research. The Bioethics Advisory Committee (BAC) had recently announced the publication of its recommendations for genetic testing and research.

In its report entitled "Genetic Testing and Genetic Research", the BAC sets out considerations for the ethical use of genetic testing in the detection of specific heritable genetic conditions and susceptibilities, as well as the genetic information thereby derived. In addition, the BAC also provides ethical guidance on the conduct of human genetic research in general. Researchers who run foul of the guidelines can be stripped of their funding, be suspended from practice and even fined, depending on the severity of the breach. This report is the culmination of an extensive research, which began in October 2003, and a public consultation process.

Source: www.biomed-singapore.com

USA, Singapore to work together on emerging diseases

The governments of the US and Singapore signed an historic agreement renewing their joint commitment to work together to prevent and respond to pandemic influenza and other emerging diseases in Southeast Asia. The document provides for the operation of the Regional Emerging Diseases Intervention (REDI) Centre, and follows an earlier Memorandum of Understanding between the Singapore Ministry of Health and the US Department of Health and Human Services (HHS) pledging to cooperate on a range of health issues, in particular emerging infectious diseases such as Severe Acute Respiratory Syndrome (SARS) and avian influenza. The Redi Centre will be located at the Biopolis.

Source: www.biomed-singapore.com

EuropaBio hails initiatives of EMEA on biosimilars

EuropaBio, the European Association for Bioindustries, has welcomed the initiative of the European Medicines Agency (EMEA), a decentralized body of the European Union with headquarters in London, to publicly debate and engage in a direct dialogue on the development and approval of similar biological medicinal products (biosimilars).

The EMEA/DIA workshop has offered all stakeholders, including the industry, the opportunity to present comments on the recently released draft EMEA/CHMP guidelines on biosimilars. The EMEA is willing to finalise these guidelines in a transparent manner, which is most appreciated.

In a release, EuropaBio said, "It appreciates EMEA's comments recognising that other stakeholders, such as physicians and patients should become more involved and informed about the issues around biosimilars."

However, EuropaBio believes that there are still important issues to be discussed in a transparent manner in order to ensure that biosimilars will be used safely and effectively, including the need for a unique name and label for a biosimilar. Clear and distinct labelling is essential to avoid confusion between the innovator product and a biosimilar and to facilitate pharmacovigilance obligations.

Dr Andrea Rappagliosi, chairman of the EuropaBio Healthcare Council and member of the Programme Committee of the EMEA/DIA joint workshop said, "EuropaBio is confident that this conference will allow the EMEA to finalise the sound and science based guidelines and we look forward to further discussions on the outstanding issues".

EuropaBio therefore calls on the EU to further consider these important issues in the run-up to the issuance of the finalised guidelines, expected in the first semester of 2006, and before the approval of the first biosimilar medicines.

Source: www.europabio.org

World's first Biotech Code of Best Practice for Reporting launched in Australia

To promote better communication between the life science industry and investors, Australia's biotechnology industry body, AusBiotech, and the Australian Stock Exchange (ASX) released the world's first Code of Best Practice for Reporting by Life Science Companies. The Code was officially launched by the Victorian Minister for Innovation, John Brumby in Melbourne.

Life Science companies are not always fully understood by the market, making accurate assessment more difficult, because brokers and investors are simply not in a position to comprehend the science involved and lack awareness of the fundamental issues and events that drive value in these companies. The Code is designed to bridge this "information gap" by providing a disclosure framework that identifies the key drivers of value for life science companies and gives guidance to companies on the information investors need to make informed investment decisions.

The release of the Code follows an extensive consultation phase involving key representatives of the life science sector and the investment community. A committee jointly formed by ASX and AusBiotech in December 2004 has reviewed the existing draft, in circulation since April 2004, in the light of submissions received from the industry and the investment community. The 17-member committee was chaired by Michael Hirshorn of Nanyang Ventures and consisted of senior representatives of listed companies, analysts, and other stakeholders. While the Code encourages best practice in reporting and is expected to be adopted widely, it is not mandatory. Existing disclosure obligations under ASX Listing Rules will be complemented by the Code to assist companies in meeting those obligations.

Source: www.ausbiotech.org

Continue reforms in favor of biotech companies, govt urged

France Biotech, the French biotechnology industry association has urged the government to finalize the tax reform for innovative companies in order to confirm the national priority it has granted to biotechnology, research and innovation.

On the right path with the Young Innovative Enterprise Status (JEI â€“ Jeune Entreprise Innovante), which has experienced resounding success with biotechnology firms, the reform of the Research Tax Credit along with various other measures in the sector, this reform will be truly achieved only by setting up a favorable environment for significant fund raising on stock markets and if the fiscal incentive cap is not detrimental to productive investments in the economy.

Thus, FCPI (Fonds Communs de Placement dans l'Innovation â€“ Common Funds for Investment in Innovation) that invest 60 percent of its funds in innovative companies may drastically decrease since the new, low and uniform cap of â¬ 8000 on all fiscal incentives was introduced in the 2006 Finance Bill. This cap is totally inconsistent with an ambitious policy that would

effectively be favorable to innovative businesses. This cap will lead taxpayers who often invest â‚¬ 10,000 to 25,000 in FCPI to now give priority to tax cuts linked to home improvement or to child minding!

The stock exchange relay is also vital to the creation of French and European champions in the biotechnology and high technology sectors. The fourth edition of the annual biotechnology industry report points out at the national level the problems already observed in Europe: the lack of stock market relay paralyzes the chain of financing for innovative companies, and the gap between Europe and the United States has been growing. Significant efforts should rapidly be made so that the biotechnology industry can quickly reach its phase of maturity and hold its driving role in Europe and internationally.

Source: www.france-biotech.org

BIA hails govt stand on funding of stem cell research

The BioIndustry Association (BIA) welcomed the announcement made by the Chancellor, Gordon Brown, and health secretary, Patricia Hewitt, that the government is to put in place measures to help make the UK a world-class environment for health research, development and innovation. These include more integration and coordination within the national health service, increased IT capability facilitating the recruitment of patients into clinical trials and collection of data, and reforms to improve performance and streamline regulatory procedures.

Aisling Burnand, chief executive of the BIA, said, "The BIA warmly welcomes these steps which are designed to increase innovation and will ultimately result in new and improved medicines for patients."

The government also announced its response to the UK Stem Cell Initiative (UKSCI) report and recommendations, a panel chaired by Sir John Pattison. The government accepted the recommendations and committed to £100 million of funding over 2006 to 2008, an additional investment of £50 million.
Commenting on the UKSCI recommendations, Dr Simon Best, BIA Board member said, "The BIA strongly welcomes the government's recognition of the national strategic importance of this new area of medicines, and the commitment of additional funds for stem cell research. The BIA believes that the existing stem cell networks in the UK should be used as a base from which to coordinate further national research in order to convert stem cell technology into new medical treatments for patients as quickly as possible. The BIA has been actively involved in dialogue on stem cell research since the introduction of the Human Fertilization and Embryology Act and welcomes further public dialogue on this subject."

Source: www.bioindustry.org

Israel passes Bill allowing generic R&D in patent period

The Knesset (the house of representatives of the State of Israel) Constitution, Law and Justice Committee unanimously approved for its second and third readings an amendment to the Patents Law (1967) (amended 1998) to allow generic drug companies to prepare for the manufacture of generic alternatives to ethical drugs before the patents to the latter expire. As a counterweight, the Israel Patent Office will be authorized to grant five-year extensions of ethical drug patents.

International pharmaceutical companies and Israeli generic drug makers reached agreement on limiting the list of countries that extend the patents for a given drug, which will be the basis for Israel extending the patent.

Under the original wording, a patent holder may apply to extend a patent in Israel only after applying to do so in all 120 member states of the World Trade Organization (WTO), including countries with no interest in the drug. At the recommendation of Constitution, Law and Justice Committee chairman MK Michael Eitan (Likud), the number of countries was limited to 21, including the US, UK, some other European and Scandinavian states, and Australia.

A key clause in the amendment is intended to prevent harm to Israel's interest not to lag in the distribution of generic alternatives, while also not affecting the import of the relevant ethical drug. Therefore, the patent extension granted in Israel will match the shortest among the extensions the patent holder obtained in other countries.

Source: www.globes.co.il

bioProcessUK estimates 30 new biopharmaceuticals by 2012

bioProcessUK, the UK's national bioprocessing network, estimates that up to 30 new biopharmaceuticals, products currently being developed by UK companies, using cell-based manufacturing techniques, could be approved over the next seven years.

The estimated figure is based on the probability of approval for biopharmaceutical candidates currently in clinical trial phases

I, II and III and pre-registration phase.

Biopharmaceuticals, drugs based on large complex molecules produced in a living system in contrast to chemically synthesized pharmaceutical drugs, are a major advance in modern medicine. Biopharmaceuticals have the potential to transform the treatment of many serious diseases for which there is currently no safe or effective therapy.

bioProcessUK's research has unveiled that there are over 50 UK companies involved in biopharmaceutical development, the transformation of a candidate drug into a biopharmaceutical product utilizing living cells as their manufacturing unit. The current pipeline of these companies is composed of 127 products in pre-clinical trials, 70 products in clinical trials and 4 products in pre-registration. The results also confirm that the UK is second in the world, behind the US,
in the initial development of biopharmaceuticals.

The research also involved an analysis of types of biopharmaceuticals in development, showing that proteins and protein antibodies make up two-thirds of the UK's pipeline. Other active substances in development include cells and nucleic acids.

This promising pipeline is a driving force in the number of bioprocessing contract manufacture and supply companies based in the UK. These companies are involved in the scale-up and manufacture of biopharmaceuticals, which have been engineered by a bioprocessing development company.

Source: www.bioindustry.org

Tailor-made stem cells research under cloud

A major controversy has erupted over the work of the Korean scientist Prof. Hwang Woo-Suk in the stem cell arena. In May 2005, Hwang's team announced in a paper published in Science that it had successfully cloned 11 different stem cells tailored to individual patients, paving the way for future development of therapies for hard-to-cure diseases. This was hailed as a revolutionary step in stem cell research and had brought Hwang instant adulation and fame, not only in South Korea but also in the entire world.

However, since the past one-month serious doubts regarding the authenticity of his work have surfaced. An investigative panel of experts from the Seoul National University, where Hwang worked and also South Korea's top university said in an interim report that the laboratory data for 11 stem cell lines, which were reported in the 2005 paper, were all data made using two stem cell lines in total. To create fake DNA results purporting to show a match, Prof. Hwang's team split cells from one patient into two test tubes for the analysis, rather than actually match cloned cells to a patient's original cells, the university said.

Meanwhile, a report supporting Hwang's claim appeared in South Korea's Yonhap news agency. It mentioned that the DNA fingerprints of some of five cloned embryonic cells from his laboratory matched those of original patient somatic cells, quoting an unidentified source. However, it is too soon for them to be considered legitimate stem cells as they are in an early stage of growth, the report said.

At present, the Seoul National University has commissioned tests on more cell samples taken from Hwang's lab and the investigation panel at university has asked three outside labs to conduct the DNA tests to determine whether Hwang was ever able to develop a colony of stem cells from a cloned embryo. The panel plans to give a final report on the investigation in January.

Amidst these allegations, Prof. Hwang maintains that he had produced the technology to create patient-matched stem cells as he claimed to do in a May article in the journal Science. In the aftermath of this controversy, he has resigned from Seoul National University. "There is no doubt that we produced 11 patient-specific stem cells, and possess the core technology to create them (again)," Hwang said during the televised press conference at Seoul National University (SNU) recently.

However, the professor admitted six of the 11 cloned embryonic stem cells cultivated in his research were severely "contaminated" earlier this year and it was impossible to keep them alive. Hwang said his team is working on thawing the five remaining stem cells, which will take about 15 days to complete. "If the five stem cells match those of the donor, the entire controversy will be resolved," said Hwang.