IN brief

FDA to steer nanotech

With more and more companies touting nanotechnology as a means to improve drug delivery, US Food and Drug Administration (FDA) officials are developing guidelines for companies to ease such products through the regulatory process. The goal is "not to create additional hindrances to developers but to identify and provide infrastructure for the development of products," said Nakissa Sadrieh from the FDA's Center for Drug Development during an agency-sponsored public meeting on nanotech, held last month in Rockville, Maryland. Representatives of several biotech companies see the agency's approach as promising but urge that the guidelines be neither reflexive nor rigid. "We're not seeking to change the regulations or short-circuit anything at FDA, and we're perfectly fine with the collegiality," says Lawrence Tamarkin of Rockville, Maryland–based Cytimmune Sciences, a company that attaches tumor necrosis factor to nano-gold particles for use in cancer treatment. "But we want no additional barriers put up." Whereas David Hobson of Houston-based nanoTox suggests the FDA follows a strict case-by-case approach in regulating nanotech-based therapeutic products, Kathleen Pirollo, who works with Washington, DC–based SynerGene Therapeutics, urges the agency to recognize that "soft" nanotech-based drug-delivery systems, such as those that depend on lipid bilayers, should not be regulated along with inorganic materials. *–Jeffrey L Fox*

Plant biotech bonanza

The US Senate has recommended up to $30 million to develop biotech crops for Africa and Asia in its 2009 budget. If approved, this will be the tenth consecutive year—except 2008—in which Congress has appropriated funds for such projects. The US Agency for International Development (USAID) controls the money and focuses on developing genetically engineered varieties of crops that affect incomes of small-scale farmers. In the past, the agency has funded research on insect-resistant cowpeas for West Africa and virus-resistant papaya for the Philippines and Bangladesh. Next year's focus: drought- and salt-tolerant rice and wheat. USAID biotech funding is prioritized well but may be spread too thin, say experts. "It takes roughly $10–20 million to get to a genetically modified crop," says Florence Wambugu, CEO of Africa Harvest Biotech Foundation International in Nairobi. "It would appear that [USAID] money has been spread across many areas, and it may be of greater benefit to focus on specific areas, especially where there is synergy with other funds." The $30 million isn't guaranteed yet: the Senate's recommendation must be passed by the full Senate, agreed upon by the House of Representatives and signed by the incoming president. *–Emily Waltz*

Plasma product companies outmuscle small recombinant players

Several small biotech companies with recombinant therapeutic proteins are finding it hard to make ground against large players that have traditionally marketed products derived from human- or animal-derived sources, with the large players now also moving into recombinant technology. As biotechs go head to head with the marketing muscle of these large companies, which have extensive experience dealing with complex hospital procurement systems, they are finding it difficult to gain product share. Indeed, the recent $3.1 billion bid by Melbourne, Australia-based CSL to buy plasma product company Talecris Biotherapeutics, based in Research Triangle Park, North Carolina, testifies to the robustness of the plasma product business and suggests that the safety and traceability advantages of recombinant alternatives are no guarantee of market success.

Recombinant alternatives to proteins purified from plasma or human and animal materials were the backbone of the early biotech industry—at least 16 have become blockbusters. For example, recombinant insulin for diabetes now accounts for more than 70% of the worldwide human insulin market. Other successful recombinant products include erythropoietin, interferon alpha and human growth hormone.

One of the main innovators in the recombinant protein sphere has been Genzyme of Cambridge, Massachusetts. Tim Edmunds, Genzyme's vice president of therapeutic protein research, believes there are no longer any convincing reasons to use 'natural' products now that technology can produce large quantities of recombinant proteins by cell culture or transgenic means. He cites several examples of a switch from natural to recombinant product where improved safety has been at least a factor. Genzyme's own Cerezyme (imiglucerase), for example, is a recombinant form of the enzyme glucocerebrosidase to treat Gaucher's disease and was launched as a follow-on to placental-derived enzyme Ceredase (alglucerase). It succeeded partly because there were not enough placentas to meet demand for Ceredase, but also, says Edmunds, "because regulatory agencies were becoming increasingly concerned about human-derived products, even though that has never been an issue with Ceredase itself."

But large, established makers of human plasma proteins like Melbourne's CSL, the world's second-largest producer, have a good record at defending their market shares. Sales for all its products in 2008 topped AU$3.8 billion ($3.1 billion), results in part because of strong brand promotion and constant innovation. CSL's tradition is in human plasma-derived therapeutic proteins, but it is expanding into recombinant technology, too.

Cross-species transmission remains a cause for concern with products purified from animals. These scrapie agents in goats and sheep could cause human spongiform encephalopathies, including Creutzfeldt-Jakob disease.

CSL's success has attracted a huge amount of investment. In August, CSL managed to raise a loan from merchant bank Merrill Lynch, of New York, to acquire Talecris. The US company is the former plasma product business of Bayer (Lerekusen, Germany), spun off in 2005 to private equity firms Cerberus of New York and Ampersand Ventures of Wellesley, Massachusetts—who have made a small fortune out of the deal. Talecris will add a further AU$1.4 billion ($1.2 billion) to CSL's sales.

Why is the natural-protein business still so attractive? Because, despite their advantages, many recombinant rivals are slow to take off. In some cases, price is certainly an issue—for example, complaints about the cost of Cerezyme are widespread (even though if adjusted for inflation it is cheaper today than when first launched). But cost is not the only, or even the usual, reason.

One example is the recombinant thrombin Recothrom, launched earlier this year by ZymoGenetics of Seattle. Since receiving approval from the US Food and Drug Administration (FDA) in January, Recothrom has been slow to displace natural bovine thrombin, of which the market leader is Thrombin-JMI made by King Pharmaceuticals, located in Bristol, Tennessee. Recothrom is priced at a 15 percent premium over bovine thrombin, but