IN brief

Irish biotech buoyant

Dublin-based Elan recently announced it would eliminate 230 positions, with roughly half the losses at its biological manufacturing and related fill-finish facilities in Athlone, Ireland. But these job cuts, about 14% of its global workforce, are not symptomatic of a wider crisis within Ireland's biotech industry. Elan has always been a particularly tall poppy on the home front; the rest of the local sector comprises a clutch of small-scale specialty pharmas, whose relative immaturity seems to have protected it from the problems currently besetting the industry. Opsona Therapeutics of Dublin, the most prominent biotech firm to emerge in recent years, raised €18 ($24) million in a Series B round in February to progress a preclinical pipeline that includes an antibody targeting Toll-like receptor 2. Venture capital, historically in short supply for Irish life sciences firms, is becoming more readily available. In February, Seroba BioVentures, of Dublin, closed a new €75 million life sciences fund, less than one year after Fountain Healthcare Partners, also of Dublin, raised a similar sum. Meanwhile, New York–based Pfizer and Eli Lilly, of Indianapolis, are both building new biologics facilities in County Cork, and Merck, of Whitehouse Station, New Jersey, is building a new vaccines plant in Carlow. "I would say if you were to do a tot-up at the end of the year there would be an increase in biotechnology employment in Ireland," says Michael Gillen, director of the Irish BioIndustry Association. *Cormac Sheridan*

Hospital to genotype all tumors

New patients admitted to the Massachusetts General Hospital Cancer Center will now have their tumors molecularly profiled to personalize their cancer treatment. The Boston hospital is the first to incorporate tumor genotyping as part of standard patient care. The aim is to conduct targeted DNA sequencing of all positive biopsies and tumors within one year. "In the short term, what we are trying to do is to identify specific molecular alterations in [a patient's] particular tumor that can then be matched with their specific therapy," says Darrell Borger, the lab's codirector. Tumor profiles will be obtained from a genotyping platform including more than 110 single nucleotide polymorphisms known to be present in human cancer genes, ten of which have targeted therapies either commercially available or in clinical trials. Most of these mutations are in the usual cancer suspects—*KRAS*, *TP53* and *EGFR*. The plan is to complete the tumor's molecular profiling within two to three weeks of a patient's admission, enabling physicians to prescribe targeted therapies. Gary Schwartz, chief of Melanoma and Sarcoma Services at the Memorial Sloan-Kettering Cancer Center, New York, says, "As the technology becomes standardized, the costs will come down and this methodology will become part of the standard of cancer care." *James Netterwald*

Institute for Regenerative Medicine, in San Francisco, is considering shifting resources to support sorely needed clinical trials—a move that could prove helpful to companies trying to bring hES cell–based products to market.

Such measures are welcome but do not go far enough, according to Michael West, who is CEO of BioTime, in Alameda, California, and founder of Geron of Menlo Park, California. "It helps enormously for the government to remove hES [cell] restrictions," he says. "But the strategic thing to do would be to stimulate the economy and the biotech industry with a federal initiative on degenerative diseases. They will cost the country trillions of dollars in the next ten years as the 'age wave' of baby boomers hits shore." Such an initiative, particularly if based on a venture capital model could leverage investments, stimulate the industry and eventually save taxpayers in terms of reducing healthcare costs, he adds.

Current increases in federal research spending, such as the stimulus package, "make investors more comfortable, [and] make it more likely that VCs [venture capitalists] will receive funding instead of that money going for T [US Treasury] bills," says Arthur Klausner, who was until recently with Pappas Ventures, located in Durham, North Carolina. "If you go back six months, people had no idea when the economic situation would turn around; now in 2009, there is more of a sense that there is light at the end of the tunnel."

Both the federal stimulus package and the omnibus appropriation boosted funding for the US Food and Drug Administration (FDA), according to the Alliance for a Stronger FDA in Silver Spring, Maryland, near Washington. The appropriations bill, for instance, added $325 million to the FDA for 2009, an increase of almost 20% over the previous year that puts the agency appropriation in excess of $2 billion for the first time (not counting user fees). This additional funding will help the agency to move forward with plans to consolidate many of its offices and laboratories into a campus-like setting in White Oak, Maryland, in suburban Washington.

Also in mid-March, President Obama named Margaret Hamburg as the next FDA commissioner and Joshua Sharfstein to be principal deputy commissioner at FDA (*Nat. Biotechnol.* **27**, 297, 2009); the President also said he was forming a federal food safety working group. Hamburg, a former New York City health commissioner, recently focused on biodefense issues while working at the Washington-based Nuclear Threat Initiative. Sharfstein, who served as health commissioner of Baltimore, is now the acting FDA commissioner pending Senate review and confirmation of Hamburg.

Both Hamburg and Sharfstein are "impressive" because they are inclined to "seek the counsel" of the professional staff at the agency, according to Peter Pitts of the Center for Medicine in the Public Interest in New York. "If they set the agenda and seek buy-in, they will succeed," he says. Moreover, while serving as acting commissioner, Sharfstein is proving a "very thoughtful listener, and what's going on is going well."

Whether the FDA will be split into two agencies—one to deal with drugs, therapeutics and medical devices, the other to deal with food and possibly tobacco—remains an open possibility, according to Pitts. Although it would be a "good thing" to move forward with such a split to enable each new entity to "focus on its own mission," he says, the White House indicates that this contemplated change "will not happen soon, even if it's highly plausible that it will be done eventually." The bigger problem is that "FDA needs more resources," he adds. "You can mix and match, but if you don't have more resources, it's just talk."

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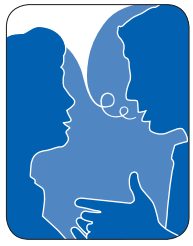
IN their words



"Virtually everybody outside the FDA has an opinion and is very vocal about it."

In a leaked departing memo, former US Food and Drug Administration acting commissioner Frank Torti seeks to boost staff morale and counter the barrage of external criticism. (*Wall Street Journal* Health blog, April 6, 2009)

"The only thing that is remarkable is that there is a very rich man who is going to fund it."

Kari Stefansson, chief executive officer of deCODE Genetics, provides his opinion of an online Parkinson's disease project backed by Google cofounder Sergey Brin. (*New York Times*, March 11, 2009)

"You can't just turn off the lights in a company in a day."

CFO Matthew Loar, after investors attempted to liquidate Neurobiological Technologies, a company that makes a stroke drug based on the Malayan pit viper. Among other things, the company must figure out what to do with 1,000 poisonous snakes. (*New York Times*, March 9, 2009)