animal studies won't sort it out for us," says Horowitz. Many differences exist between human and mouse immune systems and their MSCs. Instead, he says, more clinical trials looking at biomarkers of response are needed.

Osiris's Mills says Prochymal shows "plenty of activity" and that Osiris will sit down with the FDA soon to discuss the GvHD data. It's possible the company has just had a string of bad luck, but Adam Feuerstein, columnist of the financial news website *The Street*, says the real problem is "bad product." In a March column, Feuerstein charged the company with practicing "spin-doctoring." The Crohn's disease study was deemed "futile," he points out, because the product wasn't providing any benefit, not because of a study design flaw. "Now they've taken this phase 3 GvHD study data and mined the hell out of it," he says. "Good luck taking that to the FDA."

Prochymal's lackluster performance should have little impact on the broader field of stem cell therapy. "I don't even see this as a real stem cell therapy," says Feuerstein. Graig Suvannavejh, a former Wall Street analyst and now a managing director of the consulting firm Axon Healthcare Partners, points out that "Prochymal data may influence the public, but sophisticated investors know the differences between stem cell products," he says.

Genzyme and Osiris' partnership hinges heavily on Prochymal (*Nat. Biotechnol.* **27**, 106–107, 2009). "The big question is whether Genzyme will stick with the deal, buy up the assets for a song or just walk away," says Suvannavejh. "In an [economic] environment like this one, you can't tell what they will do."

Osiris continues undaunted. On September 30, researchers at the University of California, San Francisco announced they were enrolling patients in a phase 2 study of Prochymal in first-time heart attacks. The university plans to enroll just 10 patients, but a total of about 220 are scheduled to participate nationally.

The study aims to see whether a one-time infusion of Prochymal reduces tissue damage after a heart attack. Phase 1 data released in 2008 "exceeded" expectations in terms of safety and efficacy, according to a press release from Osiris. Left ventricular ejection fraction (LVEF), which indicates how well the heart is working, was significantly improved in treated patients compared with patients given placebo, suggesting this treatment could "alter the course of disease," Osiris CEO Randy Mills said in the press release.

As for the prospects of the heart attack trial, Feuerstein, for one, remains skeptical. He points out that Boston Scientific, in Natick, Massachusetts, had a deal with Osiris for Prochymal in heart applications but returned the rights to the product in early 2008.

Genzyme, meanwhile, is referring to this as a bump in the road. "We were disappointed with the [GvHD] results but are looking forward to moving ahead," says Joe Lobacki, senior vice president of transplant and oncology business at Genzyme. There is positive data, he says, and "to move ahead, we need to know what we have."

Malorye Allison *Acton, Massachusetts*

IN their words

"That model worked well until a couple of years ago, when the guy who was supposed to take the baton wasn't there." Peter Wirth, executive vice president at Genzyme in Cambridge, Massachusetts, laments the recent difficulty of finding partners willing and able to take on the risks and expense of developing novel products. (*The Boston Globe*, October 2, 2009)

"If this virus was killing more of its victims, there'd be lots of questions about whether this vaccine was [produced] soon enough." Michael Osterholm, director of the Center for Infectious Disease Research and Policy, comments on the reliance of US manufacturers of the pandemic H1N1 vaccine on 50-year-old flu-vaccine production methods and 30-year-old testing technologies. (*USA Today*, October 8, 2009)

New product approvals

Stelara (ustekinumab)	Centocor Ortho Biotech, of Horsham, Pennsylvania (a unit of Johnson & Johnson)	The US Food and Drug Administration approved Stelara September 25, 2009, for adult patients 18 years or older with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy. The drug is a first-in-class human monoclonal antibody that selectively targets the cytokines interleukin-12 (IL-12) and interleukin-23 (IL-23).
Berinert (C1-esterase inhibitor, human)	CSL Behring, of King of Prussia, Pennsylvania.	The US Food and Drug Administration granted approval for Berinert for acute abdominal or facial attacks of hereditary angioedema in adult and adolescent patients. Berinert, a plasma-derived therapy that provides C1-INH–deficient patients with the missing human protein, is the first product approved for this indication in the US, though it is already marketed in Europe.

IN brief

One shot at H1N1

A single injection of unadjuvanted vaccine could provide adequate immunity to protect most people during the expected influenza A (H1N1) pandemic, an early study suggests. The findings published in September (*N. Engl. J. Med.* **361**, 2009, doi:10.1056/NEJMoa0907413) suggest vaccine stockpiles could go twice as far as originally predicted, potentially allowing health authorities around the world to reduce their vaccine orders. So far, the US Health and Human Services Department, which has ordered over $1.4 billion in nonadjuvanted H1N1 vaccines, has left manufacturing contracts and vaccination plans unchanged. "We have the ability to deliver 251 million doses of vaccine," said Tom Skinner, a spokesperson for the Centers for Disease Control and Prevention in Atlanta, Georgia. "We just don't know what the demand will be." In September, the US Food and Drug Administration cleared four H1N1 vaccines produced following the same egg-based process as seasonal flu strains (*Nat. Biotechnol.* **27**, 489–491, 2009). Vaccine manufacturers expect to meet the demand for the US vaccination campaign, which began mid-October, following a two-dose schedule. European authorities have licensed two adjuvanted and one nonadjuvanted vaccine. They anticipate reviewing the current primer and booster schedule in coming months pending results from single-shot vaccination trials. *Wendy Wolfson*

'GMO-free' logos

Food manufacturers in Germany and the US will soon have voluntary 'GM Free' labels to identify products that are free of genetically modified (GM) ingredients in a bid to provide consumers with accurate information about their food. Germany's agricultural minister Ilse Aigner on August 10 approved the "Ohne Gentechnik" logo, and in September, the Upland, California–based Non-GMO Project launched its own "Non-GMO Project Verified" label scheduled to appear in stores in the coming months. But with so many of the world's farmers growing genetically engineered crops, manufacturers will find it difficult to avoid ingredients completely free of the technology to meet the criteria. Both labeling systems allow some room for unintentional contamination. To receive the German logo, the product must be completely free of gene technology, with a contamination allowance of up to 0.1%. Food verified by the not-for-profit Non-GMO Project allows up to 0.9%. The US-based project chose the figure, in part, because it is used as a threshold in the EU's labeling regulations. Those rules say that food unintentionally containing biotech ingredients does not have to labeled as a GMO product—as long as the contamination is below 0.9%. But the EU's threshold is arbitrary, say agricultural policy researchers. "The decision [to choose 0.9%] was a purely political one," says Jens Katzek, managing director at BIO Mitteldeutschland, a biotech consulting group in Halle, Germany. "There was no scientific or economic basis," he says. *Emily Waltz*