IN brief

Genentech, UCSF discovery pact

UCSF's Susan Desmond-Hellmann spent 14 years at Genentech

Genentech and the University of California, San Francisco (UCSF) announced in February a drug discovery partnership, a union they proclaim is a new model for industry-academic relationships. The deal, which focuses on neurodegenerative diseases, goes beyond providing

funds for several groups from the Small Molecule Discovery Center (SMDC) at UCSF. The company is offering the university up to \$13 million in development and commercial milestone payments and a share in any resulting royalties. Genentech, of South San Francisco, California, and SMDC scientists will pursue target pathways selected from lines of research on both sides, and the deal builds on their 2005 master agreement that put guidelines in place for future collaboration (it has so far facilitated 15 standard research agreements). The SMDC, which assists UCSF researchers in drug discovery, has a strong industrial bent: it is equipped to perform high-throughput assays and has a library of more than 180,000 compounds. The center also offers experience, as it houses a dedicated core of medicinal chemists and biomedical researchers, many of whom have industrial training in analyzing and advancing hits to lead compounds. The collaboration will perhaps serve as a boost for the San Francisco area after Pfizer pulled out of its Biopharmaceuticals and Bioinnovation Centre in Mission Bay recently. The group slated to work with Genentech is "staff, not students or postdocs," says SMDC director Jim Wells, and it is this expertise that sets the relationship apart from typical collaborations with academic labs. Wells also said that this partnership resembles a "biotech to pharma" arrangement, with the two teams working side by side and having a healthy amount of scientific exchange. "It's not, 'You do what they say and that's it,'" he explains. "And it's not like you have an asset that you sell off and never see again. There's real involvement, real give and take." Those are reasons enough for choosing SMDC for what might be a pilot program that Genentech could duplicate elsewhere, but there are others: Wells worked as a protein engineer at Genentech for 16 years, and the chancellor of UCSF is Susan Desmond-Hellmann, previously Genentech's president of product development.

Jennifer Rohn

Box 1 Threats to reform—could the Act be struck down?

Serious opposition to the Patient Protection and Affordable Care Act (PPACA) comes at two principal levels. First, in the Congress, the Republican leadership, including Senate minority leader Mitch McConnell of Kentucky and House minority leader John Boehner of Ohio, continue to inveigh against healthcare reform. "We've fought on behalf of the American people this week, and we'll continue to fight until this bill is repealed and replaced with common-sense ideas that solve our problems without dismantling the health care system we have and without burying the American Dream under a mountain of debt," McConnell said in March. Similarly, Boehner said, "Let's repeal this jobs-killing government takeover of health care and start over with common-sense reform to lower health care costs and help small businesses create jobs."

Elsewhere, individual members of the House and several coalitions of Senators or Representatives, all Republicans, have introduced bills seeking to repeal PPACA, though these are symbolic rather than realistic. In the near term, Republicans lack the votes necessary to enact a repeal, which also would need to withstand a presidential veto. The outcome of general elections next November is expected to shift the political balance in Congress but by how much no one can say.

The second level of serious opposition comes from 14 state Attorneys General—those of Alabama, Colorado, Florida, Idaho, Louisiana, Michigan, Nebraska, Pennsylvania, South Carolina, South Dakota, Texas, Utah, Virginia and Washington—who have filed lawsuits challenging PPACA on both practical and constitutional grounds. Predicting the outcome of these legal challenges remains impossible, although some experts in constitutional law argue that the American Civil War set the standard for states heeding federal statutes. In any case, no radical change is expected anytime soon, and the more time available for PPACA to become a practical reality, the less likely it is to remain a hot issue—unless, of course, some of the more dire predictions about its ill effects become a part of that reality.

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Additionally, PPACA authorizes the Cures Acceleration Network (CAN), which is intended to help National Institutes of Health (NIH)-funded researchers bridge the gap between basic research and commercial development of treatments, according to Ellen Dadisman of BIO. "This provision also will help expedite Food and Drug Administration (FDA) review of highly innovative safe and effective treatments for patients," she says. "If funded, CAN would significantly enhance the quality of health care for the American people by speeding up our ability to transition research originating from NIH."

Yet, along with these benefits for researchers and innovative companies, there could come some heavy lifting in store, says Giovannetti of Ernst & Young. Therapeutic agents "will need to be as good or better and also cheaper," he says. "We're seeing this in collaborations' milestones being set between pharma and biotech companies. Safe and effective might not be good enough; a product also has to be seen as gaining reimbursement [status]. Over the long term, this should play well for biotech companies that are truly innovative."

Of course, just how or whether reimbursement practices change—particularly with an aim of curbing costs—is one of the uncertainties embedded in healthcare reform. And comparative effectiveness research will surely be part of this new equation, according to Conko of CEI. "It's not obvious how

programs like the new Independent Payment Advisory Board for Medicare will work, how it and other programs will internalize comparative effectiveness research results from the new Patient-Centered Outcomes Research Institute, or what effect the 'value-based purchasing' program or the pilot programs for 'bundling' payments will have on drug and biologics prescribing," he says.

Yet another potential drag on innovation included in the healthcare reform is stringent reporting requirements for physicians and others who consult with industry, according to Sullivan of P&M. These are not "restrictions" as such, but the "paperwork will be burdensome," he says. "It doesn't stop people from consulting, but regulators will want to know exactly what it looks like, and it may have some effect on biotech when investment firms can see who all the consultants are."

Says Pitts of CMPI, "Industry lobbied hard for a good bill, but this bill is flawed in so many ways." (Box 1). However, he adds, "It's time to realize that it's no longer just about selling drugs, but for providing healthcare, and companies must walk the walk." Nonetheless, Sullivan says, the biotech industry can "look forward to having more patients who can afford treatments, especially for orphan diseases. And dropping insurance caps will totally help the industry as well as patients and their families."

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