

Biotechs adjust to new landscape as US healthcare reform takes off

Even before the political uproar surrounding the passage of the Patient Protection and Affordable Care Act (PPACA) in March had subsided, biotech-industry watchers were applauding the passage of the historic health care bill. Among the favorite measures in the legislation are generous exclusivity terms for innovative therapeutics within a newly drafted pathway for biologics, a lucrative tax credit for eligible smaller companies developing therapeutics, and a substantial boost—30 million or more—in the number of potential clients for biotech therapeutics due to the expansion of health insurance to so many more Americans.

“The health care reform bill...includes key provisions that will lead to new and improved treatments, cures and cost-savings for patients, while driving job growth in our industry and maintaining our nation’s global leadership in biotech innovation,” says Jim Greenwood, president of the Biotechnology Industry Organization (BIO) in Washington, DC. Peter Pitts, president of the Center for Medicine in the Public Interest (CMPI) in New York, agrees: “This legislation will have a huge impact on biotech companies—the most affected of any industry.”

However, some observers balk at sizing up the impact of the new legislation too quickly. “There are too many unresolved variables to know whether the position of the biotech industry will be improved under the new health care law,” says Gregory Conko of the Competitive Enterprise Institute (CEI) in Washington, pointing to several “ambiguities over how various provisions will be implemented.”

What’s more, Conko continues, despite the expanded market, “the industry will be overtly penalized by the addition of a tax on pharmaceutical manufacturers, starting at \$2.8 billion in 2012, peaking at \$4.1 billion in 2018 and then falling again to \$2.8 billion annually. And several new cost-cutting programs in the Department of Health and Human Services could result in much lower sales prices.”

That tax on pharmaceuticals reflects an early deal that the Pharmaceutical Research and Manufacturers of America (PhRMA) in Washington forged with Congress and the Administration over healthcare reform. The deal includes, among other matters, a provision to reimburse the government for costs falling within the widely scorned ‘donut hole.’ The donut hole is the term used to describe a coverage gap in the 2003 Medicare Part D health plan for prescription drugs. Many seniors find that



President Obama signs the most sweeping social legislation in decades. The Patient Protection and Affordable Care Act, enacted on March 23, will ensure coverage for almost all Americans.

they are initially reimbursed for drug expenses up to a certain limit, but on reaching the ‘donut hole’ are left responsible for drug costs until expenses reach the higher catastrophic coverage threshold. For example, in 2009 (reimbursement limits change yearly), Medicare paid for drugs for seniors through the first nearly \$2,700 outlay, but then individuals paid out of pocket until a second tier of drug benefits kicked in for costs exceeding about \$6,100. In that year, the three top-selling biologic drugs under part D were Enbrel and Remicade for autoimmune diseases, and the anti-cancer agent Avastin, according to a report by La Merie Business Intelligence. “The donut hole has been a thorn in the side of seniors,” says Boston-based Glen Giovannetti, global biotech leader for Ernst & Young. As part of a deal to remove that thorn, PhRMA agreed to phase in price reductions and close the donut hole for seniors by paying a special tax for several years, he adds. The impact on companies’ balance sheets is proving hard to fathom. “The excise tax kicks in, and it’s a weird formula that has companies trying to figure out when it hits their PNLs [profits and losses]. The tax, which is based on total share of drugs sold to the government in the prior year, means companies have to pay to play.” He estimates that, overall, the effects of this tax will probably swing positive by 2014 because by then so many more people will be covered by insurance, making up in volume what will be lost in the short term to the new tax and reduced prices.

But Giovannetti and others say that these estimates are crude at best. On the bright side, the biologics provisions in PPACA guarantee 12 years of exclusivity to innovator companies for their products and also prohibit manufacturers of follow-on products from using brand names of original products, Pitts of CMPI says. This latter provision is “good for the industry” because it means that the innovator companies “can still make money,” even past those 12 years of exclusivity. Thus, he predicts that many physicians will continue prescribing original brand-name products, particularly if price differentials with biologics remain low.

“A lot of companies are salivating at the possibility of biosimilars,” says Washington-based Thomas Sullivan, the founder of the website Policy and Medicine (P&M) and president of Rockpointe in Columbia, Maryland. “But [companies] will have to prove they work the same, and they will be like a sub-branded category.”

Certainly, the current biosimilar pathway has received a less-than-lukewarm reception from traditional generics manufacturers. The Generic Pharmaceutical Association (GPhA) in Arlington, Virginia, near Washington, calls these provisions “a biogeneric pathway in name only,” and says it gives “false hope to patients who desperately need access to life-saving biogeneric medicines.” GPhA also calls the legislation a “missed opportunity to inject real pharmaceutical cost containment into the US healthcare system” and claims that the new law “locks down indefinite brand product monopolies at a deep cost to patients and taxpayers.”

Another provision in PPACA is the therapeutic discovery tax credit, which according to BIO’s Greenwood could prove “critical” to biotech companies. This new \$1 billion program is aimed at research-intensive, small biotech companies, providing them with tax credits equal to 50% of investments in qualified therapeutic discovery projects for 2009 and 2010.

Giovannetti of Ernst & Young calls this tax credit provision a “big win” for firms with fewer than 250 employees. In terms of qualifying for the credit, he says, “There’s not a lot of detail because the criteria are being developed. But companies are very interested, contacting us to learn how to queue up with applications.” Importantly, he adds, unlike an earlier federal measure set up to stimulate the energy sector, this measure steers credit away from large, established corporations and toward “emerging companies. It’s a big win when capital is so tight.”

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 Biotherapeutics 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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