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What health reform means for innovation

Healthcare reform will not only boost biotech investment by massively expanding the US drug market, but also change the dynamics of biotech innovation in the longer term.

Last month, President Obama kept his election promise and signed into law the most comprehensive piece of legislation concerning healthcare provision in the United States since the introduction of Medicare by Lyndon Johnson in 1965. Positioned as pro-industry and pro-recovery, the reform had become politically viable, despite equivocal support from large parts of the US Congress and the American people. In return for supporting the bill and stumping up $90 billion in fees and discounts on Medicaid and Medicare pricing, the drug industry receives tax breaks, a biosimilars pathway and a massively expanded drug market. In the longer term, the legislation promises to radically transform the economic drivers for biotech innovation.

The legislation—officially, the Patient Protection & Affordable Care Act (H.R. 3590) and the Health Care & Education Affordability Reconciliation Act of 2010 (H.R. 4872)—is less about healthcare reform than health insurance reform. It contains a scattering of measures that immediately benefit life science companies. The Biotechnology Industry Organization (BIO) has made much of the adoption of a 12-year exclusivity term for biosimilars, which for reasons of political expediency, was left intact despite the preference of the Obama Administration and generics manufacturers for a shorter brand monopoly. Referring to the Therapeutic Discovery Project Credit—a measure that gives tax credits (or grants for non-tax-paying companies) equivalent to half the cost of investments in "qualified therapeutic discovery projects" undertaken in fiscal 2009 or 2010—BIO also trumpeted the fact that the legislation will "provide some financial relief to research-intensive, small biotechnology companies." What qualifies is vague, but potentially the credit can apply to any preclinical, clinical, diagnostic or technology development undertaken by companies with <250 employees. The program is worth $1 billion ($500 million a year)—a large sum, although still only 11% of the annual R&D spending of public biotech companies with <250 employees.

Perhaps the biggest immediate boon to biotech, though, lies in the expansion of the market for prescription drugs. Having an additional 32 million people enter the world's largest healthcare market will provide an immediate stimulus to health-related businesses. Industry newsletter *The RPM Report* estimates that the new legislation could result in $115 billion in new business over 10 years. Given that drug companies dodged the bullets of drug price controls and drug importation, this means that extraordinarily high profits will likely continue for the sector, at least for a while, and investment will continue to be attracted to drug-related innovative biotech.

In the longer term, however, the most important aspect of the reform package lies in the enfranchisement of the previously uninsured and progress towards universality of healthcare access.

A new insurance pool will mean that people with pre-existing conditions will be able to obtain affordable health insurance. Furthermore, insurers will not be allowed to deny coverage to children because of pre-existing illness, and they won't be able to drop insurance coverage when a person becomes ill. Provisions in insurance plans that limit 'lifetime' coverage to some arbitrary age or impose annual limits on benefits will become illegal. In short, US insurers now have to insure and support the sick and vulnerable. Consequently, they need to assimilate the potential financial burden within their business models.

Until now, US health insurance profitability has been about circumventing the difficult and expensive burden of dealing with sick people. Insurers have treated illness as a type of 'insurance excess': they either capped their outlays or shifted sick people outside the insurance system. Now that this has been disallowed, insurers will have to find other ways of dealing with people with disease. At face value, at least, the legislation requires them to embrace the sick wholeheartedly and for as long as they are sick. And the pressure on insurers to reduce the costs of these patients has huge implications for life science innovation.

The recently passed legislation does relatively little to reduce the cost of biotech treatments. Although it does create a pathway for approval of biosimilar products, the prolonged market exclusivity period and burden of clinical proof make it unlikely that the biosimilars market will be sufficiently attractive to encourage enough generic players to create price competition to rival the traditional generics market.

Thus, the insurance sector is likely to look to other solutions. One way of making treatments cheaper will be to improve medical triage, especially during the highly expensive last 6 months of life. The cold truth is that not everybody's disease is treatable. If tests can show definitively, or even on the balance of probability, that a patient won't benefit, then doctors may stop treatment and divert spending elsewhere—on palliative care, for instance. Thus, insurers will demand development of more diagnostic tests like the HER2-detecting HercepTest from Dako or the MammaPrint genetic profile from Agendia that spare breast cancer patients treatments that would be unnecessary or ineffective.

Another way to reduce disease cost will be to cut down the number of sick people. There is now a huge incentive to get behind R&D in immunization and prevention. Indeed, the legislation explicitly says that all new healthcare insurance plans will have to offer preventative care and immunizations at no cost. An integral part of any prevention program ought to be reliable and facile lifestyle diagnostics that confirm (or otherwise) patients' reporting of health-related habits such as smoking, drinking, diet and exercise—and importantly for the biotech sector, diagnostic tools that monitor and detect the early physiological signs of disease.

The need for insurers to reduce the healthcare burden also increases the incentives for developing drugs and other treatments that actually reverse disease, therapies that ameliorate the condition rather than simply treat symptoms. Disease cures—yes, we should use the phrase—are now what the US healthcare payments system will demand. And that is a real turnaround, possibly even a revolution.