US HEALTHCARE REFORM REFLECTS CHANGING LIFE SCIENCES INDUSTRY
NORTH AMERICA

US healthcare reform reflects changing life sciences industry

by Hunter Rost | Waller Lansden Dortch & Davis, LLP

AFTER DECADES OF debate, US healthcare reform became a reality in 2010 when President Obama signed the Patient Protection and Affordable Care Act (ACA) in March. Yet public opinion remains sharply divided on the merits of this sweeping legislation, both in terms of its ability to address the problems of access to, and the rising cost of, healthcare services and in terms of the financial burden on the federal and state governments of implementing ACA. With the November mid-term elections shifting the balance of power in Congress toward Republicans, there are pledges to rescind portions of ACA, or even to repeal the law in its entirety. Nevertheless, as enacted, ACA contains a number of important regulatory measures impacting the life science industry, including increases in Medicaid drug rebates, discounts to close the Medicare Part D coverage gap, annual ‘industry fees’ for manufacturers and importers of drugs and medical devices, and transparency provisions requiring disclosure of financial relationships between manufacturers and providers.

Included in ACA is a long-anticipated approval pathway for ‘biosimilars’, or drugs that are shown to be clinically similar to, or potentially interchangeable with, brand name biologics. Congress created statutory authority for the FDA to accept and approve marketing applications for new biologics that would compete with established innovator biologics following expiration of the innovator’s patents. The legislation ensures 12 years of marketing exclusivity and other patent protections for the innovator, an important win for the biotech community. With the pathway in place, the FDA must now establish guidance and criteria to measure ‘similarity’ and ‘interchangeability’. The FDA is currently conducting hearings with biologics manufacturers, generics companies, physicians and others to solicit input on implementation methodology while ensuring patient safety and efficacy. A marketing approval pathway for biosimilars already exists in Europe, where the EMEA began approving biosimilar products in 2006, and the US biologics industry will look to European regulations for guidance.

Comparative effectiveness research has been one of the most-discussed topics among pharma and device manufacturers over the last few years, and ACA brought CER another step closer. The Act included provisions, and funding, for a private, non-profit Patient-Centered Outcomes Research Institute to set national priorities for researching and comparing post-approval efficacy of medical treatments. The goal of the research will be to analyse and interpret ‘real-world’ treatment outcomes utilising the vast amounts of data available today from multiple sources including payer databases,
online patient communities and electronic health records, as well as the FDA’s 2008 Sentinel Initiative to electronically track the safety of marketed drugs and devices. Manufacturers accept that they must prepare for and adapt to an environment in which comparative effectiveness data will be publicly available and relied upon by physicians, patients, regulators and payers to identify the most effective treatments for specific patient populations.

Access to capital during the recession for the development of promising new technologies remains a challenge for small biotech and device companies. To promote continued research and development, Congress included in ACA a provision for $1bn of new grants and federal tax credits for qualifying research and development projects that seek innovative therapies to prevent, diagnose and treat acute and chronic diseases. In November 2010, the Internal Revenue Service and the Department of Health and Human Services announced 4606 awards to 2923 small companies in 47 states, covering R&D investments made in 2009 and 2010. Under the final allocations, the maximum award for a single project was approximately $244,000 with some applicants receiving awards for multiple projects.

Outside ACA, litigation currently making its way through the federal courts could also have far-reaching consequences for the biotech industry in the genomics field. In March 2010, a US district court ruled in a case brought by the American Civil Liberties Union on behalf of various plaintiffs against Myriad Genetics, the US Patent and Trademark Office (USPTO) and others, that patents over isolated human genes were invalid. The court reasoned that genes are a ‘product of nature’ and therefore not eligible for patent protection, despite the USPTO’s long-standing practice of granting gene patents. The case is currently on appeal and in October 2010 the Department of Justice filed an amicus brief stating that isolated genes are not eligible for patents, although manipulated or modified genes could still be. The USPTO has indicated it will not immediately change its practice pending the outcome of the litigation.

Overall, growth in the US pharmaceutical market remains modest but steady – approximately 3-5 percent for 2010 according to market intelligence provider, IMS Health, with similar projections for 2011. Contracting revenue streams during the global recession have led to aggressive industry cost-cutting and workforce reductions to bolster earnings. Faced with looming patent expirations, mounting pricing pressures and increasing globalisation, pharma, device and biotech companies must re-examine their business models to maintain innovation and profitability in a shifting regulatory and payment environment. ■

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