

It was postponed “due to information request pending with the sponsor of the application.” The FDA has asked for more details of its statistical analysis (Stanton, 2015).

There are other biosimilar applications under consideration by the FDA. So far, all of the applications have been for biosimilars that have already been approved in the EU, and one would expect this trend to continue. As of the end of February 2015, 50 biosimilar development programs referencing 15 biologics had been submitted to the FDA (Serebrov, 2015). Again, the BPCIA was designed to encourage both competition and innovation, and the former looks promising.

16.24 REIMBURSEMENT ISSUES

The US reimbursement system is much more complex than that of the EU, with both large private and public payers. Biologics are among the most expensive drugs, and they are accounting for an increasing share of drug expenditures. They also treat some of the most serious diseases. The issue of their coverage or reimbursement by insurance companies is likely to become a contentious issue. In some cases, insurance companies already require copayments of \$500 per prescription or coinsurance rates of 33% (Blackstone and Fuhr, 2012).

Further, some of these drugs extend life for a short time at a high price. For example, the drug Nexavar extends the life of liver cancer patients on average <3 months (Blackstone and Fuhr, 2012). The National Institute for Clinical Excellence in the UK decided not to pay for this expensive drug, determining that the cost was greater than the benefit. New cancer drugs often cost \$10,000 or more per month. Sometimes, the benefit is less than the cost, and physician groups are beginning to question the value of some of these drugs (*Cancer Drug vs. Value*, 2015). The risk for biological producers is likely to increase.

In the US, under the Patient Protection and Affordable Care Act (PPACA) of 2010, a major emphasis was to fund studies on the comparative effectiveness of medical treatments, including drugs. Along with the other factors, this should make drug development riskier as insurance coverage may become more of an issue. Some payers have entered into risk contracts with pharmaceutical firms in which the payer will only reimburse for the drug if it results in positive outcomes. In Germany, in instances when its cancer drug Avastin is not successful, Roche has offered refunds to hospitals and insurers (Blackstone and Fuhr, 2012).

16.25 INCENTIVIZING MARKET ACCEPTANCE

The financial incentives created, particularly through pricing, will determine the development of the biosimilar market. Cost containment is a major issue in the US. Biologics are coming under greater scrutiny because of their high prices. Stakeholders (physicians, patients, and payers) will greatly influence the biosimilar market. In the case of generics, some time was required before they gained acceptance. Biosimilar uptake in the EU has been successful when stakeholders have the right incentives. High biologic prices could lead payers to switch to lower priced biosimilars. For example, Germany has encouraged the use of biosimilars and has experienced some of the highest market shares for biosimilars. Bundling will give physicians