16.28 POTENTIAL GAINS FROM BIOSIMILAR COMPETITION

Most commentators and experience from Europe suggest that prices of biosimilars will be about 25%–30% less than their reference products. That compares to price reductions on occasion of as much as 80% or 90% for small-molecule or chemical generics, and recall that prices may fall more in the US. In any event, the savings to consumers and society could be much greater in the case of biosimilars because of the higher prices of large-molecule biologics.

Consider the issue by comparing the savings for the tenth most expensive biologic, Revlimid, which treats multiple myeloma and whose annual cost in 2015 was $128,666 (Loo, 2015). A 30% saving on this drug would be about $38,600. Now consider, Lipitor, one of the world's blockbuster drugs which lost patent protection in 2011. The annual cost for a 20 mg regimen of treatment with Lipitor in 2011 was $1939 (Purvis and Schondelmeyer, 2013). Even if the generic price were 90% below that of Lipitor, annual per-patient savings would be $1745. Interestingly, the generic for Lipitor, atorvastatin, may be 90% less than the $1939 figure. In any event, the per-patient saving may be much greater for the expensive biologics than for most chemical drugs.

Biosimilar competition is also expected to result in substantial benefits. A RAND study estimated that savings from biosimilar competition could save $44.2 billion in the US (Mulcahy et al., 2014). However, unlike generics, many biosimilars are being produced by brand-name companies. Because of their reputation, branded biosimilar producers should be at less of a competitive disadvantage than generic entrants initially were.

16.29 CONSUMER WELFARE GAINS

The primary public policy objective is to increase consumer welfare. Thus, the market share of biosimilars is not a fully informative metric. The relevant welfare benchmark is not the price of the biosimilar relative to the reference product, but the comparison price before competition adjusted for inflation. The increase in quantity due to lower prices also increases access.

16.30 IMPLICATIONS AND CONCLUSIONS

The BPCIA was designed to encourage the innovation of biologics but at the same time to allow competition from biosimilars once an originator's legal monopoly, arising from patents or market exclusivity, expired. Similar to Hatch–Waxman for generics but in the case of biologics, biosimilars were effectively denied entry because there was no abbreviated pathway. Hatch–Waxman largely succeeded in that R&D continued, new small-molecule drugs have been developed, and generics comprise about 86% of all small-molecule or chemical drug prescriptions.

Turning to biologics, the question is whether the BPCIA is likely to be similarly successful. Biologics are high-risk and potentially high-reward products. Their R&D is more costly and typically more time consuming to develop than for chemical or small molecule drugs. Their manufacturing is also more complex and costly. A few