

it can enter at a higher price before other biosimilars enter the market, but given the higher cost of R&D and manufacturing and other entry costs, one would not expect much of a return on investment before other biosimilars enter. As other biosimilars enter, price will decrease (Olson and Wendling, 2013). Moreover, in the case of biosimilars, the first mover faces various disadvantages. The first biosimilar in each class will have higher costs of entry than later entrants. FDA approval will be more uncertain, and thus there will be higher costs of preparing for the approval process. Also, the initial entrant may incur higher costs due to legal and patent issues. For example, it may need to resolve any patent issues that could lead to considerable litigation costs and entry delays. There are also the initial costs of educating physicians and patients concerning what a biosimilar is and the quality of biosimilars. The initial entrant will have to overcome the understandable consumer reluctance. Sandoz is facing all of these issues as it attempts to be the first biosimilar in the US market. Later entrants for the same reference product can free-ride on all or at least most of the above costs.

16.15 INTERCHANGEABILITY AND AUTOMATIC SUBSTITUTION

Biosimilars need to be highly similar. However, there is another issue—that of interchangeability. According to the FDA, “[a]n ‘interchangeable’ biological product is biosimilar to the reference product, and can be expected to produce the same clinical result as the reference product in any given patient” (FDA, 2014). Even though the FDA is still developing guidelines for interchangeability, it is unlikely that an applicant will attempt to get interchangeability in its initial FDA hearing for biosimilar status. In the first biosimilar application before the FDA, Sandoz did not apply for interchangeable status. It is possible that the FDA will not allow a biosimilar to be interchangeable until the biosimilar has a track record and has been demonstrated (through postmarketing studies) to produce results identical to that of the originator product. It is uncertain as to how long the interchangeable process might take, if it ever occurs (Fuhr et al., 2015).

Thus, before a biosimilar can apply for interchangeability, there may be two or three other noninterchangeable biosimilars on the market. The first interchangeable biosimilar receives a 1-year market exclusivity as an interchangeable biologic, but the first interchangeable could still be competing with originator and noninterchangeable biosimilars. An interchangeable biologic has the advantage of automatic substitution at the pharmacy level, depending on state law. However, there would be little competitive advantage for physician-administered biologics since physicians decide directly which product to use. There are also high costs involved in obtaining interchangeability since switching studies will probably be needed for the clinical trials (Shea and Muller, 2010). Payers probably do not care if a biosimilar is interchangeable and are probably not willing to pay a price premium. Noninterchangeable biosimilars may set lower prices, gain formulary status, and obtain most of the market. Finally there is the risk of failure. If a biosimilar tries for interchangeable status and fails, the product may be perceived as not that similar and not of high quality, thus damaging its reputation and market share. A biosimilar firm must weigh the advantages and disadvantages of attempting to achieve interchangeable status for its