A major issue initially concerning biosimilars is that of their safety. However, in the EU there have been very few if any safety issues. One safety issue concerning a biosimilar could yield devastating consequences on the biosimilar market. This is why it is especially important to distinguish between a true biosimilar and noncomparable originators. If there is a safety issue with a noncomparable biologic, one must be sure that it is not considered a biosimilar and thus have a negative effect on the biosimilar market. Further, strict regulation of biosimilars to ensure their safety and effectiveness is appropriate, especially in the early period before biosimilars have a track record.

16.5 BIOLOGICS AND INNOVATION: HIGH RISK, HIGH REWARD

Biologic firms spend substantial sums and a high share of their revenues on R&D in the hopes of developing a new drug. These firms are the originator biologic firms. There are also other firms that want to produce the biologic once the patents have expired or are not valid and they can legally do so. The industry thus contains two groups of firms: the originator or reference product producers and the biosimilar producers. Both groups of firms serve an important function. Sometimes the innovator company becomes a biosimilar producer for a particular reference biologic product other than its own biologic. Amgen and Sandoz (Novartis) are examples of originators developing biosimilars. This is somewhat different from the small-molecule or chemical generic drug market where the demarcation is generally stronger.

Innovator firms' spending on R&D as a percentage of biologic sales is among the highest of any industry. Public companies in 2013 spent 32.4% of their revenue on R&D (Loo, 2015). This compares to about 3%, which is typical for US manufacturing companies or industries. Among leading biologic companies, spending in 2014 ranged between 11.5% and 147.5% of revenues (Loo, 2015). Amgen, a leading biological firm, for example, spent 21.4% of its revenues on R&D. Vertex, which spent 147.5% of its revenues on R&D, had only $58 million in sales. Small or startup firms will obviously have such high figures. Spending is so high even though most R&D projects end in failure. Merck estimates that 75% of the R&D it spends is on failures (Blackstone and Fuhr, 2012). There is obviously great risk associated with R&D.

Biologics have greater risk in R&D than chemical drugs. The development of a new biologic is a long and difficult process. On average, a new biologic requires between $1.3 and $2.6 billion (Blackstone and Fuhr, 2012). A new chemical drug involves costs of $500–$800 million (Blackstone and Fuhr, 2012). Further biological development takes on average between 10 and 15 years, with many, if not most, of these efforts ending in failure. Taking failures into account, we find that the cost for an FDA-approved biologic (one able to be marketed) could be as high as $5 billion (Blackstone and Fuhr, 2015).

Moreover, many biologics are developed by small firms that often find it difficult to raise capital. These small firms, often startups, have been responsible for almost 50% of new biologics (Blackstone and Fuhr, 2012). They often partner with a larger firm to complete the development of a new biologic, or sometimes they are acquired by a larger firm. Further, given the increasing merger activities among pharmaceutical firms and even within the biopharma industry, there are fewer potential buyers