16.1 INTRODUCTION

The current US health care system is unsustainable as health care expenditures approach 20% of GDP. One way to cut costs is through competition from biosimilars, which has decreased costs for biological drugs in the EU. Biologics are becoming an even more important part of the pharmaceutical industry. They treat some of the most serious and life-threatening diseases. Their development and production are more costly than the previously dominant small-molecule or chemical drugs. Until passage of the Biological Price Competition and Innovation Act (BPCIA) as part of the Patient Protection and Affordable Care Act of 2010, there was no pathway for biosimilar competition to enter in an expedited and relatively less costly application process. This was similar to the situation for chemical generics before passage of the Hatch–Waxman Act in 1984. Accordingly, even after patents expired on these biologics, lower price biosimilars were not available.

This chapter examines the situation for biologics and biosimilars in light of the new possibilities afforded by the BPCIA. It includes the experience of other countries where biosimilars have been available since at least 2006. Accordingly, we consider the role of patents, provision for data and market exclusivity, entry barriers, competitive considerations, and regulatory matters, among other issues. We also note distinctions between biologics and chemical drugs and their impacts on the market.

16.2 SOME TERMINOLOGY

A biologic is a large-molecule drug produced in living organisms. Unlike a generic in the case of chemical drugs which is equivalent to the originator, biosimilars are highly similar to the originator referred to as a reference product. A reference product is the originally licensed biologic to which the biosimilar is compared to determine if it is highly similar. In both the US and EU, biosimilars must go through the respective regulatory bodies and are rigorously and scientifically assessed. The BPCIA's definition of a biosimilar is "highly similar to the reference product notwithstanding minor differences in clinically inactive components; and … no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency of the product." (42 U.S.C. 2006: § 262(i)(2)(A), (B)). Since they are produced in living organisms and in batches, even for the originator each batch varies and is not identical (McKinnon and Lu, 2009).

Drift occurs frequently among biologics (Schiestl et al., 2011). Given the nature of the production process and the fact that biologics are produced in batches as liquids,