of $128,666 (Loo, 2015). Some of these expensive biologics are so-called orphan drugs; namely, they are used for a relatively small patient population. Soliris is such a drug. To encourage their development, orphan drugs receive a tax credit for 50% of R&D costs, grants to help defray clinical trials, and 7 years of marketing exclusivity. Orphan drugs are typically priced 19 times that of nonorphan drugs. In 2014, of the 41 new molecular entities approved by the FDA, 17 were orphan drugs (Loo, 2015).

16.10 HATCH–WAXMAN AND GENERICS

Thirty years ago, the US developed a regulatory framework for the entry of generic chemical drugs. The resulting Hatch–Waxman Act (H–W) was intended (as is the BPCIA) to balance competition and innovation. The major public policy goal was to enhance competition from generics, which would lead to lower prices but still provide the originator with the incentive to innovate.

The H–W was enacted in 1984 and enabled the entry of generics. Prior to its passage, few generics were available. In fact, only 35% of the drugs that lost patent protection had generic competition (Blackstone and Fuhr, 2012). Further, between 1962 and 1984, 150 drugs lost patent protection but did not encounter generic competition (Behrendt, 2006). There was no abbreviated pathway for generic competition. H–W, also known as the Drug Price Competition Act and Patent Term Restoration, developed such a pathway. The Act created an abbreviated new drug application (ANDA) under which a generic applicant only has to show bioequivalence to the branded product. The generic applicant can claim that no patent is involved, that it will not enter until the relevant patent or patents expire, or make a so-called paragraph 4 certification that the patent is invalid or not infringed. If it succeeds in such a challenge, the first such claimant receives a 6 months exclusivity, which means that no other generic can be marketed during that period. This provision gives a generic entrant the incentive to be the first to file such a paragraph 4 application.

At the same time, to encourage innovation, H–W provided a 5-year market exclusivity for the originator, during which no generic can be marketed. H–W also provided the possibility to extend patent protection for up to 5 years if the FDA approval process took an inordinate time.

H–W seems to have worked quite well in balancing innovation and competition. However, it took some time for consumers and providers to be comfortable with the use of generics. Especially important was the development of automatic substitution, under which the pharmacist can substitute a generic in most states unless the physician specifically prevents that substitution.

H–W has succeeded in its efforts to encourage both competition and innovation. Drug development has continued. Thirty-five new drugs were approved by the FDA through December 3, 2014, compared to a yearly average of 24 for the 2003–2014 period (Loo, 2014). Further, Evaluate Pharma indicates that between 2014 and 2020, "The R&D pipeline is strong" (Loo, 2014). At the same time, generics have increased their share of all prescriptions. Specifically, in 1984 when H–W was enacted, only 19% of all prescriptions were for generics. The percentage increased to 33 in 1990, to 72 in 2008, and to 86 in 2013. Given that generics are sometimes 80% or 90% less expensive than the brand-name drug (Zirkelback, 2014), such a growth in generics