explained below, provides a 180-day exclusivity, under certain conditions, for the generic manufacturer who is first to file.

The availability of technology and the cost of acquiring technology to manufacture the product will also impact the choice of generic drug product. For example, the proposed generic drug product might require special manufacturing equipment, a sterile environment, specialized packaging, or other expensive items. The firm must then consider whether this equipment, technology, and/or expertise are available in-house or must be acquired. Formulation considerations include the availability of raw materials, chemical purity, polymorphic form, and particle size of the API and any patents that the innovator company has filed, including patents for the synthesis of the API and composition of the dosage form. Experience with certain drug products will also affect the choice of generic drug product development. For example, some generic drug manufacturers may make a wide variety of dosage forms as well as solid and liquid oral dosage forms, including immediate-release and modified-release products as well as topical drug products (ointments and creams). Other generic firms may make specialty drug products such as transdermal, inhalation, or sterile drug products. Niche drug products, such as transdermal drug products, ophthalmic products, and others, may be difficult to make and also riskier but may have a greater financial reward due to less competition from other generic drug firms.

The decision to proceed with the development of a generic drug product should therefore be based on well-researched data that primarily indicate market value together with a sound knowledge of patent expiry dates, predicted market share, and growth rate for the product, among others. Government spending trends on medicines, which, in some countries, may be in the region of 40% or even more of the total market, should not be overlooked. The predicted profitability of the new generic product will require strategic planning for the subsequent launch timing, which must take into account the expected generic price and knowledge of anticipated competitors, such as who they are and when they are expected.

LEGISLATIVE AND REGULATORY ISSUES

The FDA was established in 1906 by the Federal Food, Drug, and Cosmetic Act (the Wiley Act) to prevent the manufacture, sale, or transportation of adulterated or misbranded or poisonous or deleterious foods, drugs, medicines, and liquors, and for regulating traffic therein, among others [7]. In 1938, the Act was amended to require drug manufacturers to file a New Drug Application (NDA) for each newly introduced drug product and to provide data to establish the safety of the drug product. In 1962, the Kefauver–Harris Amendments to the Act required all drug manufacturers to establish that their products were effective for their claimed indication(s), in addition to adhering to the safety requirements. Consequently, the FDA contracted with the National Academy of Sciences/National Research Council in 1968 to evaluate those drugs first introduced between 1938 and 1962 for effectiveness. This review program was called the Drug Efficacy Study Implementation (DESI) review, and drugs for which effectiveness was determined through the DESI review could be marketed with approval of an NDA. For drugs approved through the DESI review