to innovate; thus, some beneficial biologics may not be developed. If the period of exclusivity was too long, a type 2 error, then there would be less competition and less access due to higher prices during the exclusivity time period. Thus, given that an error must occur and given the great uncertainty and risk involved in drug innovation, it would make sense to err on the side of too long, since without the drugs there would be no benefit to society; optimal public policy should err on the side of innovation.

16.8 DRUG DEVELOPMENT: A CASE STUDY

A recent blockbuster drug, Sovaldi, illustrates the process of drug discovery and development. Sovaldi is a small-molecule drug, but its discovery and development are common for biologics. The drug was developed by a relatively small firm, Pharamasset, whose senior vice president for chemistry, Michael Sofia, headed a team that discovered the breakthrough therapy for hepatitis C. They surmounted the problem of developing a drug that would pass through the bloodstream and reach the liver where it could act to destroy the virus. The breakthrough occurred by creating a shield that would break down once in the liver to allow the drug to work (Sell, 2015).

Pharmasset was sold in November 2011 for $11.1 billion to Gillead Sciences. Sovaldi was approved in 2013 and achieved revenues of $10.3 billion in 2014, the largest amount ever in so short a time period. This blockbuster drug illustrates many of the elements associated with pharmaceuticals and, to an even greater extent, biological research. In particular, the original developer was not the firm that finally brought the drug to market. A leading figure in the development of Sovaldi, chemical name Sofosbruvir, in referring to biotech R&D, stated "More often than not in the biotech world, the gamble leads to nothing and you are forced to look for a new opportunity" (Sell, 2015).

Sovaldi also illustrates the issues of access. Its price in the US was set at $1000 per day of treatment or $84,000 for the 12-week course of treatment. The World Health Organization would like a lower price, so more of the world's 150 million sufferers of hepatitis C would obtain treatment (Sell, 2015). This concern with pricing is common for insurers, some of which have restricted coverage of Sovaldi to those with advanced liver disease. On the other hand, it is important to provide incentives for R&D so that drugs like Sovaldi are developed. It is also important to note that most drugs are not blockbusters and often do not even cover the cost of their R&D. In effect, the few blockbusters like Sovaldi help cover the costs of developing the low-profit drugs and motivate others to try to duplicate their success. Also, even though its patent has not expired, Sovaldi presently faces competition from another hepatitis C drug, Viekira Pak; this competition and its implications to biosimilar markets will be discussed later in this chapter.

16.9 BIOLOGICS AMONG THE HIGHEST PRICED DRUGS

Biologics are among the highest priced drugs. In particular, the annual price for Soliris in 2015 was $536,529, and for Naglazyme it was $485,747. These are the two most expensive biologics. The 10th most expensive, Revlimid, had an annual price