

enhanced both the length and quality of life. The National Academy of Sciences states, “Few families know the suffering caused by small-pox, tuberculosis, polio, diphtheria, cholera, typhoid or whooping cough. All those diseases have been greatly suppressed or eliminated by vaccines” (National Academy of Sciences, 2007). Consumer welfare is increased considerably by the replacement of older drugs by newer, more effective drugs (Lichtenberg, 2001). Drug discovery also often reduces medical expenditures. Lichtenberg estimated that the reduction in inpatient spending was four times the prescription costs (Lichtenberg, 2001). Drugs can decrease the need for expensive medical procedures. For example, beta blockers can reduce the need for expensive and risky heart surgery. Antibiotics now treat some ulcers that previously required more extensive and expensive therapies. Drugs, including biologics, can also decrease absenteeism and presenteeism, increasing workers’ productivity. Griliches (1992) found that pharmaceutical innovation increases consumer welfare. Thus, public policy should and does encourage innovation.

The primary policy to encourage innovation is that of patents which provide a theoretical 20-year legal monopoly. Also, the government funds some R&D through grants from the National Institutes of Health. However, none of these gains will accrue to people who do not have access to these drugs. The high price of biologics has made access an issue. People without insurance cannot afford the drugs, and even those with insurance often have such high copays that they, too, cannot afford the drugs. However, consideration might be given to some government support for low-income people. This issue is beyond the scope of our chapter. Accordingly, the exception is for communicable diseases whose vaccine usage arguably should be required. In general, once patents expire, more people should have access to these drugs as competition increases and prices decrease. Biosimilars will increase access. We focus on both innovation and competition.

16.4 BIOLOGICS VERSUS CHEMICAL DRUGS

Biologics are large-molecule drugs produced in living systems such as a plant cell or microorganism. Their manufacturing is more complex and costly than chemical drugs (Blackstone and Fuhr, 2012). They are much larger and more complex than chemical drugs (Blackstone and Fuhr, 2015). For example, the biologic Epogen has a molecular weight 168 times that of the small-molecule drug aspirin (Kanter and Feldman, 2012). Their complexity is illustrated by the large molecular drug Remicade, which requires 310 separate production stages (Blackstone and Fuhr, 2007). Biologics’ R&D costs are much higher, and their manufacturing is more costly and complex than chemical drugs. Also, small changes in manufacturing can lead to health risks such as immunogenicity. “[U]nique to biologics, is ‘immunogenicity’: Immunogenicity is a patient’s adverse antibody reaction to a drug in which the body perceives a drug to be a foreign microorganism or virus” (Kaldre, 2008). Biologics treat many life-threatening diseases and are generally priced high with few alternative therapies available. Some biologics are priced at more than \$500,000 per year per patient. Many biologics are orphan drugs that treat diseases that are relatively rare (Loo, 2015). Finally, biologics are often infused which affects the nature of marketing and advertising and quite possibly even their expected market share.