reward for reference products and biosimilars. Medicare has ACOs and is considering reference pricing and bundling. Medicare is currently working on a reimbursement system for biosimilars.

16.27 OTHER ISSUES

16.27.1 State Substitution

There has been considerable debate about state laws concerning the automatic substitution of biosimilars. Many have claimed that such laws are premature and an effort to impede biosimilar competition. Unlike generics which under most state laws can be automatically substituted at the pharmacy level, biosimilars can only be substituted at the pharmacy level if they have been declared interchangeable by the FDA. There are various issues concerning how and under what conditions physicians should be notified about the substitution. Presently, physicians in the generic market can write "do not substitute" and the originator must be dispensed. The same requirement can be established in the biosimilar market. If the physician allows substitution, then for safety reasons and information purposes the pharmacist must notify the physician within a certain time frame specifically what biosimilar was substituted. Prior approval is not required since the physician has already permitted substitution to occur. The notification is required in case there is an adverse event so that the physician knows what drug has been dispensed. Thus, notification of physicians concerning substitution of biosimilars for originator reference products if done correctly should not impede competition and is essentially a nonissue.

Even though the substitution controversy remains, the contending parties currently agree on more aspects than they disagree. Both sides agree that only interchangeable biologics can be substituted; as in generics, the physician can designate do not substitute, the patient should be told by the pharmacist that a biosimilar is being substituted for the originator, the pharmacist should keep records of the substitution, and the physician should have access to dispensing information. The remaining debate is over the last two and how each one should be accomplished.

16.27.2 Naming Controversy

Much controversy has arisen over the naming of biosimilars. The basic issue is whether a biosimilar and reference product should have identical nonproprietary names or different but related nonproprietary names. One side claims that different names will result in a competitive disadvantage for biosimilars. The other side counters that since biosimilars are highly similar products and unlike generics not actually equivalent, different names are appropriate. Also, since most of the biosimilars are being produced by brand-name firms, biosimilars should be at less of a competitive disadvantage than generics since they were produced by relatively unknown firms. In any event, the FDA will have to decide this issue. It does not appear that different names will put biosimilars at a competitive disadvantage (Fuhr et al., 2015).