BIOSIMILAR DRUG THERAPIES

Background:
The field of biotechnology holds great promise for the development of many new biologic products to treat such serious diseases as cancer, multiple sclerosis, anemia and rheumatoid arthritis, and millions of Americans depend on these therapies. The U.S. Food and Drug Administration (FDA) has recently been authorized to establish a process through which “biosimilar” versions of existing biologic drug therapies may be approved.

AMCP Position:
In recognition of the fact that biologic products are often prohibitively expensive, and many therapies have expired patents, the Academy supports an expedited approval process for biosimilar biologics. This process should provide a needed incentive for the development of new, lower cost, therapeutic products that hold the promise of preventing, treating or curing otherwise inevitable, untreatable and incurable diseases. AMCP believes that the current exclusivity period of 12 years is more than adequate time for innovator manufacturers to recoup their research and development costs. AMCP would support legislative efforts to shorten the exclusivity period to seven years or fewer.

Talking Points:

- Safe alternatives to biologic products have existed for years.
- Legislation has granted the FDA discretionary authority to make case-by-case determinations based upon science in regards to clinical study and trial requirements.
- The FDA is empowered to determine whether a biosimilar product is considered interchangeable with the innovator product.
- The current period of market and data exclusivity is sufficient to allow a manufacturer to recoup its investment in the research and development of a new product plus realize a profit.

1 See AMCP’s Where We Stand Position Statement on Biosimilar Drug Therapies.
http://www.amcp.org/amcp.ark?p=B8260E53