Biosimilars

Concerns about growing expenditures in health care have focused national attention on areas that represent significant cost to the system. Cancer treatment, particularly the increasing expense associated with biologic agents, is one of these. As a result, policymakers have begun to raise the issue of biosimilars as one means of controlling cost. While generic versions of drugs have brought significant savings to the health care system, there is debate over the extent to which such savings can be achieved through development of generic biologic agents.

As physicians engaged in cancer care and research, the American Society of Clinical Oncology has as its key concern the safety and well-being of cancer patients. As such, our position on this important policy question rests on the overriding objective of assuring our patients receive evidence-based, high quality care most effective in the treatment of their disease.

These principles are based on current state of the science. Any legislative proposal should enable approval requirements to change as our understanding matures and ability to work with these products develops.

1. Clinical trials to demonstrate sufficiently similar safety, efficacy and immunogenicity in biosimilars would be necessary in most, if not all, cases.

2. While FDA should be given substantial discretion in forging the regulatory pathway for approval of individual classes of biosimilars products, transparency in the process is essential so that clinicians and the public can be satisfied that the process contains adequate safeguards. Notice-and-comment procedures would be appropriate in fashioning the contours of the biosimilars pathway on a class-specific basis. Guidance documents—either on a class-specific basis or in some cases on a product-specific basis—should be published to ensure consistency of standards and predictability of regulatory action.

3. In any instance in which FDA decides that clinical trials are not necessary for follow-on products, the agency should publicly disclose that decision and provide a detailed rationale.

4. No system should be adopted that would limit physician choice among “biosimilar” products or require substitution of products that have been designated “interchangeable.” In every instance, the physician should decide which among similar products should be prescribed.
5. Biosimilar products should be subject to initial review and oversight post-approval by the Office to which the original innovator product is assigned, rather than a separate “generics” Office.

6. Every biosimilar product should be subject to meaningful post-marketing safety surveillance.

7. Interchangeability should be determined only through clinical trials adequate to support substitution of the biosimilar product for the innovator product without sacrificing safety or efficacy.

8. Non-patent data exclusivity should be adequate to ensure continued innovation, both in new products and in new indications for existing products. Additional years of exclusivity should be provided as an incentive to development of new indications.

9. Legislators should extend “pediatric exclusivity” incentives to biologics in a manner consistent with those for drug products in order to enhance incentives for research in specific pediatric indications.

10. Congress should ensure that FDA is provided adequate resources to meet the new demands of assessing bioequivalence in the number of biosimilar products that will be presented to the agency once standards are in place.