

FDA STATEMENT

Some drugs or medical devices demonstrated at the Open Meeting/Specialty Day have not been cleared by the FDA or have been cleared by the FDA for specific purposes only. The FDA has stated that it is the responsibility of the physician to determine the FDA clearance status of each drug or medical device he or she wishes to use in clinical practice.

The American Shoulder and Elbow Surgeons' policy provides that "off label" uses of a device or pharmaceutical may be described in the ASES' CME activities so long as the "off label" status of the device or pharmaceutical is also specifically disclosed (i.e., that the FDA has not approved labeling the pharmaceutical and/or device for the described purpose). Any device or pharmaceutical is being used "off label" if the described use is not set forth on the product's approved label.

- ◆ Indicates those presentations in which the FDA has not approved labeling the pharmaceutical and/or device for the described purpose (i.e., the pharmaceutical or medical device is being discussed for an "off label" use).

POLICY ON COMMERCIAL SUPPORT FOR THE AMERICAN SHOULDER AND ELBOW SURGEONS

REVIEWED AND READOPTED 2/10/12

ADOPTED 7/18/01

In order to provide a financial support for membership activities, the ASES solicits support for its mission and to fulfill its educational objective.

DEFINITIONS

Sponsorship: The commercial entity provides support for the ASES activity. ASES recognizes the commercial firm for its contribution. Language acknowledging the sponsors' contribution will take the form:

"This activity was funded in part by an unrestricted educational grant from XYZ Corporation."

Advertising: A commercial entity purchases advertisements and/or name placement and/or logo placement in selected publications.

POLICIES REGARDING COMMERCIAL SUPPORT

1. Any commercial support will be clearly identified including the identities of the sponsors or advertisers that have contributed funding, services, or materials.
2. ASES retains the sole discretion in determining the types of sponsorship or advertisement that would be accepted or displayed.
3. ASES reserves the right to reject or discontinue sponsorship or advertisement.
4. ASES will not accept advertisements that in the sole opinion of the ASES make unsubstantiated claims of therapeutic benefit for a particular product. The ASES may request valid reliable scientific data to support any claim made in the advertisement.
5. The ASES will not accept advertisements regarding pharmaceuticals or medical devices not cleared for marketing by the FDA in the United States without a statement regarding the products' current FDA clearance status for the particular use described.
6. The ASES will not accept an advertisement that includes a photograph, picture, or likeness of a specific physician or that including endorsement by a specific physician. The policy of the ASES is designed to satisfy the guidelines for commercial support according to the FDA, Accreditation Council for Continuing Medical Education (ACCME) and the AMA.
7. The sponsorship of an ASES activity shall not be considered endorsement of the sponsor or product advertised.
8. ASES maintains a clear separation between sponsorship and advertisements and its educational, editorial and decision making. Current or potential providers of commercial support may not dictate the form or substance of ASES activities, content or publications.
9. The ASES will provide its membership with information as to this "Policy on Commercial Support."