

Proposed FDA Policy Statement with Respect to Manufacturer Dissemination of Information Regarding Off-Label Uses of FDA-Approved Products

The Washington Legal Foundation requests that FDA issue a Policy Guidance along the following lines:

- (1) FDA will not in any way prohibit, restrict, sanction, or otherwise seek to limit any pharmaceutical or medical device manufacturer or any other person:
 - (a) from disseminating or redistributing to physicians or other medical professionals any article concerning prescription drugs or medical devices previously published in a bona fide peer-reviewed professional journal, regardless of whether such article includes a significant or exclusive focus on unapproved uses for drugs or medical devices that are approved by FDA for other uses and regardless of whether such article reports the original study on which FDA approval of the drug or device in question was based;
 - (b) from disseminating or redistributing to physicians or other medical professionals any reference textbooks (including any medical textbook or compendium) or any portion thereof published by a bona fide independent publisher and otherwise generally available for sale in bookstores or other distribution channels where similar books are normally available, regardless of whether such reference textbook or portion thereof includes a significant or exclusive focus on unapproved uses for drugs or medical devices that are approved by FDA for other uses;
 - (c) from suggesting content or speakers, or providing product samples, to an independent program provider in connection with a continuing medical education seminar program or other symposium regardless of whether unapproved uses for drugs or medical devices that are approved by FDA for other uses are to be discussed.
- (2) For purposes of this Policy Guidance, a "bona fide peer-reviewed journal" is a journal that uses experts to objectively review and select, reject, or provide comments about proposed articles. Such experts should have demonstrated expertise in the subject of the article under review, and be independent from the journal.
- (3) For purposes of this Policy Guidance, a "bona fide independent publisher" is a publisher that has no common ownership or other corporate affiliation with a pharmaceutical or medical device manufacturer and whose principal business is the publication and distribution of books through normal distribution channels.
- (4) For purposes of this Policy Guidance, an "independent program provider" is an entity that has no common ownership or other corporate affiliation with a pharmaceutical or

May 23, 2001 Citizen Petition
Exhibit A

medical device manufacturer, that engages in the business of creating and producing continuing medical education seminars, programs, or other symposia and that is accredited by a national accrediting organization pertinent to the topic of the seminars, programs, or symposia.

(5) Nothing herein should be construed to limit FDA's application or enforcement of any rules, regulations, guidances, statutes or other provisions of law that sanction the dissemination or redistribution of any material that is false or misleading. However, FDA will not deem the fact that disseminated material discusses product uses not approved by FDA as evidence that the material is false or misleading, or that the manufacturer intends to market the product for the use discussed, provided that the manufacturer discloses its interest in any product mentioned in the material, and affixes to the material a statement substantially as follows: "This material includes discussions of uses for [name of FDA-approved product] that have not been approved by FDA."