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January 11, 2010

The Honorable Margaret A. Hamburg, MD
Commissioner
Food and Drug Administration
5630 Fishers Lane, room 1061
Rockville, MD 20852

RE: Draft Guidance for Industry and FDA Staff on Dear Health Care Provider Letters: Improving Communication of Important Safety Information

Dear Commissioner Hamburg:

The American College of Cardiology (ACC) is pleased to submit comments on Food and Drug Administration's (FDA's) draft *Guidance for Industry and FDA Staff – Dear Health Care Provider Letters: Improving Communication of Important Safety Information*. The College is a 39,000-member nonprofit medical society composed of physicians, nurses, nurse practitioners, physician assistants, pharmacists and practice managers, and bestows credentials upon cardiovascular specialists who meet its stringent qualifications. The ACC is a leader in the formulation of health policy, standards and guidelines, and is a staunch supporter of cardiovascular research. The College provides professional education and operates national registries for the measurement and improvement of quality care. As the representative of cardiovascular professionals, the College appreciates the opportunity to provide recommendations regarding communications with health care professionals.

Based on the College's experience, the ACC largely agrees with the recommendations for communicating safety information to health care professionals. Below are a few items of concern that we recommend be addressed in the final guidance.

Specific comments

Page 4, Section V.A.

The draft guidance contains the recommendation that the letter not exceed two pages. Cardiovascular professionals are generally busy treating patients and running their practices. Two pages seems long for a busy professional who is simply interested in obtaining the information needed to treat his or her patients appropriately. The ACC would recommend that these letters be kept as brief as possible and provide the professional with a location for additional information if needed.

The mission of the American College of Cardiology is to advocate for quality cardiovascular care — through education, research promotion, development and application of standards and guidelines — and to influence health care policy.

Page 8, Section V.A.6.

Generally, manufacturers and the FDA make additional information regarding safety and adverse events available online. As such, the College suggests the letter's final paragraph also contain the web address for the additional information that is available online.

Page 9, Section V.B.

The draft guidance recommends using various text emphasis techniques to draw attention to major points in the letter. The ACC recommends not using italics as one of those techniques. Physicians often find italics difficult to read. Rather than emphasizing the text, they create clutter. Using one of the other techniques would better achieve the intended purpose. The College does agree that use of all capitals should be avoided; instead, the appropriate mixture of upper and lowercase letters is preferable.

Page 9, Section VI

The College supports the use of evaluations by industry to determine the efficacy of the particular Dear Health Care Provider letter. To encourage industry to conduct such evaluations, it would be helpful to include some examples of how the evaluations might best be conducted. These might included surveys, electronic mechanisms, telephone calls or other means that the FDA believes will be the best indicator of collecting feedback from health care providers.

Conclusion

We appreciate the opportunity to provide feedback on this draft guidance based on our unique position representing and working with cardiovascular professionals. We look forward to continuing to work with the FDA on this and other related issues. Please direct any questions or concerns to Lisa P. Goldstein at (202) 375-6527 or lgoldstein@acc.org.

Sincerely,



Steve Erickson
Chief Communications Officer
Senior Vice President, Marketing and Communications

cc: Jack Lewin, MD – CEO, ACC