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January 24, 2006

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Dear Sir or Madam,

I am writing regarding the problem relating to direct patient advertising on TV and in print ads. I have read recent articles about this and would like to make some comments regarding this.

- 1) **I believe that all direct marketing of specific products to consumers should be banned.** There are many complex interactions and considerations that require a physician's input to make decisions regarding the best drug treatment. Further, many of these drugs being advertised directly to the public, in particular, antihypertensives are certainly high priced new drugs, that have often been proven to be no better than older generic drugs that are far less expensive. Nonetheless, the drug industry is spending billions of dollars advertising to the public. This money could be better spent on research and development or decreasing the cost of drugs to patients, particularly helping to fund free drugs to our disadvantaged seniors. I did see in a recent article, "Today in Cardiology" where the pharmaceutical industry spent 4 billion dollars in 2004 on direct patient advertising. I think that this is ridiculous.
- 2) There is one good aspect that I would like to emphasize regarding what I have seen related to the patient advertisements regarding drugs. I have seen several commercials that educate about disease processes or disease symptoms that patients may or may not be unaware of the importance of their diagnosis. As a cardiologist with an interest in peripheral arterial disease, I have noticed the commercials related to the risk of a heart attack with the lack of blood thinners and also the identification of patients who have high cholesterol and/or symptoms of peripheral arterial disease that patients often don't recognize as serious conditions. As I am sure that the FDA is well aware, these conditions have a very strong link to cardiovascular disease and stroke, and certainly relate to the #1 cause of death and disability in Americans.

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I believe that the type of ads that give patients general information and education regarding health conditions are good for the public. However, they should be limited to this and should direct patients to discuss these issues or symptoms with their physicians. This would be a better use of resources and would also serve the purpose that the pharmaceutical industry would like which is being able to bring their product to patients who would benefit from it. It would decrease some of the multitude of questions that I routinely answer regarding specific products; why are patients on this drug over that drug which they have seen on TV because they didn't see their drug (usually inexpensive generic drug) on TV. I have to go through a long litany of explanations of these issues and this usually of course satisfies the patient. However, this time has been taken away from patients who actually need me to spend more time with them regarding their diagnosis and treatment as opposed to explaining why a certain drug advertised on a commercial is not best for them. I certainly believe that it is important for physicians to keep up to date on drugs and new therapies, but I believe the vast majority of these direct to consumer advertisements are inappropriate and not in the public's best interest.

I appreciate you reviewing this letter and taking my opinion into consideration.

Sincerely,



Hollace D. Chastain, II, M.D., F.A.C.C., FSCAI

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