



May 29, 2003

Commissioner Mark McClellan
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Re: Docket # 02P-0163

Dear Commissioner McClellan:

I am writing in follow-up to a March 27, 2003 letter from Mary Beth Brown, Director of the American Medical Commission, which is a project of Citizens United. In her letter, Mrs. Brown urges the FDA to reject WellPoint Health Networks petitions to switch the entire class of non-sedating antihistamines to over-the-counter status. I am writing to you today to re-enforce Mrs. Brown's comments and urge the FDA to deny the petitions in the interests of the future development of life-saving medicines.

The petitions in question were filed by WellPoint Health Networks, a for-profit managed care company; their petitions named certain newer, non-drowsy allergy medications for these OTC switches. These drugs provide vital relief to allergy and asthma sufferers and allow for an improved quality of life.

If the FDA endorses WellPoint's position, we are concerned about the impact this will have on the engines of innovation that drives the development of newer, more effective medications. The expensive risk borne solely by brand-name drug manufacturers to develop more effective and safer medications to treat chronic diseases is not to be taken for granted; do to these efforts, new treatments for cancer, AIDS and Alzheimer's are now available, with more treatments becoming available nearly every day.

But innovation will be stifled unless there are strong economic incentives for the development of newer drugs. Instead, innovator drug companies may focus exclusively on the most acute conditions, for which drugs with severe side effects will fill a void where at present no treatments exist at all. Or, companies may focus on developing new indications and iterations of existing drugs which require a less sizable investment. We will bear witness to a perilous drop in the number of drugs developed to treat complex and life-

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Letter to FDA Commissioner McClellan

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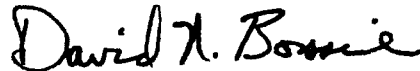
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threatening chronic diseases such as diabetes or hypertension, since it will become the norm that if a safe drug exists it will be approved only for over-the-counter use at the demands of for-profit insurers. Should the chances for a cure for cancer be held for ransom to the bottom-line interests of for-profit health insurers?

Denying WellPoint's petitions preserves the economic incentive for the development of new medicines that will play a vital role in protecting the health and welfare of future generations. Please consider this viewpoint when as your agency deliberates on this matter further.

Sincerely,



David N. Bossie
President

cc:

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