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CITIZEN OUTREACH
Partnership for Prescription Drug Reform

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October 10, 2003

The Honorable Tommy Thompson
Department of Health & Human Services
200 Independence Avenue, SW
Washington, DC 20201

VIA FAX

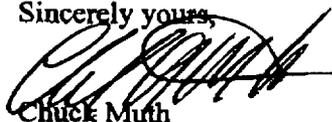
Dear Secretary Thompson,

I am attaching a letter we sent last March to FDA Commissioner Mark McClellan with regard to a petition (Docket #98P-0610) filed by WellPoint Health Network regarding the issue of forced switching of some prescription drugs to over-the-counter status.

It is my understanding that you and your office may weigh in on this matter and hope you will consider our letter and the points made therein. In short, we at Citizen Outreach are concerned over issues of safety and the precedent this could set should WellPoint's petition be granted. The out-of-pocket cost to consumers of pre-maturely moving prescription drugs to OTC status should also be considered.

Thank you for your consideration in this matter.

Sincerely yours,



Chuck Muth
President & CEO
Citizen Outreach



CITIZEN OUTREACH

Putting the Public Back in Public Policy

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Oct 14 2003 09:03:34 WS# 06
OFFICE OF THE SECRETARY
CORRESPONDENCE
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March 21, 2003

Mark McClellan, M.D.
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

RE: Docket # 02P - 0168

Dear Commissioner McClellan,

I am writing today regarding a matter currently under your consideration, a request by WellPoint Health Network to switch a number of prescription antihistamines to over-the-counter status. It is my understanding that such a request by a for-profit insurance provider is unprecedented and I'm writing to express serious concerns about granting such a request.

As an allergy sufferer myself, I'm all for making relief provided by certain drugs as widely and cost-effectively available as possible; however, the safety of the consumer using such products is a responsibility not to be taken lightly.

While Claritin has been on the market for quite some time and has the benefit of being tested and evaluated properly, some of the other antihistamines under consideration have been on the market for a considerably shorter period of time. Making these drugs available without a prescription before sufficient review and evaluation has been made is problematic. Just consider the current problems and concerns regarding the untested and unmonitored use of ephedra.

I'm also deeply suspect of the motivations of the petitioner.

Switching this class of drugs means WellPoint and other providers will no longer have to cover them in policies, nor will they have to cover the costs of the doctor visits necessary to obtain the prescriptions. While I can understand how moving these drugs to OTC status will benefit WellPoint from a financial point of view, I can't see how it benefits the consumer or patient. The effect of the petition would appear to be that consumers will have easier access to drugs not fully tested in the marketplace yet at a higher out-of-pocket expense.

I am also troubled by the precedent such a decision by the FDA could set.

If the for-profit health insurers are successful with this petition, it will open up a Pandora's box of new and additional petitions based solely on the health of the insurers' bottom line and not the health of the insured. What may seem like a minor request today involving a few allergy medicines has the potential for developing into a huge health-care rationing problem in what well could be life-and-death situations down the road.

For these reasons I therefore respectfully urge you to deny the petition by WellPoint Health Networks in this regard and maintain the current, established procedures of the FDA for considering the wise and safe switching of medications to over-the-counter status.

Sincerely yours,

Chuck Muth
President