



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville MD 20857

OCT 24 2001

The Honorable Paul S. Sarbanes  
United States Senate  
Washington, D.C. 20510-2002

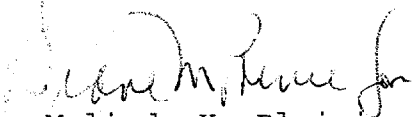
Dear Senator Sarbanes:

Thank you for your letter of September 18, 2001, on behalf of your constituent, Mr. George A. Miller of Adelphi, Maryland, regarding concerns about switching antihistamines from prescription to over-the-counter status.

Currently, the Food and Drug Administration (FDA or the Agency) has an open docket to receive comments on these prescription allergy drugs of concern to Mr. Miller. We are forwarding your letter to docket number 98P-0610 where it will be considered by the Agency.

Thanks again for contacting us concerning this matter. If you have any further questions, please let us know.

Sincerely,

  
Melinda K. Plaisier  
Associate Commissioner  
for Legislation

cc: Dockets Management Branch  
98P-0610

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**United States Senate**  
WASHINGTON, DC 20510-2002

September 18, 2001

Ms. Melinda K. Plaisier  
Associate Commissioner For Legislation  
Food and Drug Administration  
U.S. Department of Health and Human Services  
Parklawn Building 5600 Fishers Lane Room 15-55  
Rockville, Maryland 20857

Dear Ms. Plaisier:

Enclosed is a copy of correspondence I received from Mr. George A. Miller. The letter raises some serious concerns about the conversion of certain prescription drugs to "over-the-counter" medications. I would certainly appreciate it if you would carefully review this matter and provide me with an appropriate response.

With best regards,

Sincerely,



Paul Sarbanes  
United States Senator

PSS/jdp  
enclosure

01-4814

10513 Edgefield Drive  
Adelphi, MD 20783  
May 15, 2001

The Honorable Paul S. Sarbanes  
United States Senate  
309 Hart Senate Office Building  
Washington, DC 20510

Dear Senator Sarbanes:

Health Insurance companies are pressuring the Food and Drug Administration (FDA) to convert prescription drugs like antihistamines, blood pressure, and cholesterol drugs to "over-the-counter" medications. Their reason—pure greed.

Most Health Insurance companies pay a portion of prescription drug costs. On over-the-counter medications, the consumer pays all of the cost. If the FDA gives in to the Health Insurance companies, our costs would increase to \$3,800 - \$4,000 a year. For Seniors on limited, fixed incomes, this could be devastating. Further, attempts by Congress to help Seniors and others pay for prescription drugs would be meaningless.

Without the oversight by a pharmacist or doctor, there would be extremely serious problems. Many drugs are not compatible and have deadly side effects when taken together. Further, antihistamines could trigger Glaucoma, the major cause of blindness. Blood pressure and cholesterol drugs may damage the liver and kidneys. Pharmaceutical firms and doctors strongly recommend periodic blood tests (4 - 6 months apart) to determine liver and kidney function when taking such medications.

Recently, an FDA panel recommended that antihistamines become "over-the-counter." Who are they working for, the people or to satisfy the greed of the Health Insurance companies? Simultaneously, the Health Insurance companies are increasing premiums and reducing coverage. Their motto appears to be "you give—we take."

Your assistance to insure that the FDA does not contribute to a catastrophe by converting commonly used prescription drugs to "over-the-counter" drugs is very much needed.

Sincerely,

  
George A. Miller

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