

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville MD 20857

JUN 29 2001 559 PM JUL 10 12:19

Mr. George A. Miller  
10513 Edgefield Drive  
Aldephi, Maryland 20783

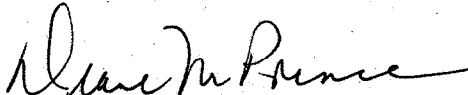
Dear Mr. Miller:

Thank you for your letter of May 15, 2001, addressed to Senator Barbara A. Mikulski regarding your concerns about switching prescription drugs to the over-the-counter medications. Senator Mikulski has asked that we respond to you directly.

Currently, the Food and Drug Administration (FDA or the Agency) has an open docket to receive comments on prescription drugs, namely the antihistamines, such as those you referred to. We are forwarding your letter to docket number 98P-0610 where it will be considered by the Agency.

Thanks again for contacting Senator Mikulski concerning this matter.

Sincerely,

  
Melinda K. Plaisier  
Associate Commissioner  
for Legislation

cc: The Honorable Barbara A. Mikulski  
United States Senate  
Washington, D.C. 20510-2003

Dockets Management Branch, HFA-305  
(#98P-01610)

98P-0610

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BARBARA A. MIKULSKI  
MARYLAND

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(202) 224-4654  
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## United States Senate

WASHINGTON, DC 20510-2003

May 23, 2001

Ms. Melinda Palisier  
Associate Commissioners for Legislation  
Food and Drug Administration  
U. S. Department of Health & Human Svcs.  
5600 Fishers Lane, Room 15-55  
The Parklawn Building  
Rockville, Maryland 20857-0002

Dear Ms. Palisier:

I am writing to request your consideration of the attached correspondence from George Miller. Please respond directly to Mr. Miller and send a copy to Stephanie Sterling of my staff. If you have any questions, please call Ms. Sterling at (202) 224-4654.

Thank you for your assistance.

Sincerely,



Barbara A. Mikulski  
United States Senator

BAM:ss  
Enclosure

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10513 Edgefield Drive  
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May 15, 2001

The Honorable Barbara A. Mikulski  
United States Senate  
709 Hart Senate Office Building  
Washington, DC 20510-2003

Dear Senator Mikulski:

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