

Subject: OTC Anthihistimines Testimony

Sandy,

We spoke a few weeks ago and you invited me, on behalf of our organization to submit testimony and comments on Wellpoint's petition and the Advisory Hearing on May 11. My hope is that we may still be included as offering testimony in the brief 5 minute segments on May 11.

RxHealthValue is a coalition of consumer groups, health care providers, labor, employers, insurers, pharmacy benefit managers and individuals whose mission is to improve access to health improving drugs. Members include: Organizational Members: AARP,

Academy of Managed CarePharmacy,
AdvancePCS Health Systems, Inc
AFL-CIO,
AFSCME,
Alliance for Community HealthPlans (not-for-profit health plans),
American Academy of Family Physicians,
American Medical GroupAssociation,
Blue Cross/Blue ShieldAssociation (48 Blue Plans),
Caremark Inc.
DaimlerChrysler
FamiliesUSA,
Ford Motor Company,
General Motors,
GTE Corporation,
Kaiser Permanente,
Lahey Clinic,
Managed Health Care Association,
Marriott Corporation
Midwest Business Group onHealth,
National Consumers League,
National Council of SeniorCitizens,
National Institute of HealthCare Management,
Schneider Institute for Health,
Service Employees International Union,
United Automobile Workers,
US West/Verizon
Washington Business Group on Health,

Individual Members

Stuart Altman, Ph.D., BrandeisUniversity;Alain Enthoven,Ph.D., GraduateSchool of Business, Stanford University
Christine K. Cassel, MD, Chair,Department of Geriatrics, Mt. Sinai Hospital/School of Medicine;Arnold Milstein, MD, William M.Mercer, Inc., Ira Ockene, MD, University of Massachusetts MedicalCenter

RxHealthValue supports Wellpoint's bringing this petition before the FDA and the FDA acting in a timely manner. As a general policy, RxHealthValue supports conversion of prescription drugs to OTC only in those cases when : · low side effect profiles, · labeling which is understandable at a reasonable reading level, · the condition is easily diagnosed by the patient and treated with the OTC product, and · the use of the product or the medical condition do not require on-going medical management such as diagnostic procedures, lab tests or assessments requiring the technical expertise of a physician · the condition treated is a chronic condition (as opposed to acute) · the benefit/risk ratio is of net benefit to the patient ·

no potential harm to the patient, and · low potential for misuse and abuse

The experience in Canada, Australia and New Zealand provides compelling evidence of years of appropriate understanding and use of 2nd generation antihistamines based on labeling offered by the manufacturers. We recommend that the FDA consider reviewing the post-marketing surveillance data from these nations.

Please feel free to call with any questions at:

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