



APUA

ALLIANCE FOR THE PRUDENT USE OF ANTIBIOTICS

Chief Executive Officers

Stuart B. Levy, President
Thomas F. O'Brien, Vice President
Kathleen T. Young, Exec. Director

Board of Directors

Stuart B. Levy, Chairman
Harris A. Berman
Barbara Shattuck Dubow
Ellen L. Koenig
Morton A. Madoff
Bonnie Marshall
Thomas F. O'Brien
Arnold G. Reinhold
Philip D. Walson
Fred B. Wilcon

Scientific Advisory Board

Jacques F. Acar, France
Werner Arber, Switzerland
Fernando Baquero, Spain
Michael L. Bennish, USA
Jose Ramiro Cruz, Guatemala
Iwan Darmansjah, Indonesia
Julian Davies, Canada
Stanley Falkow, USA
Walter Gilbert, USA
Herman Goossens, Belgium
Sherwood L. Gorbach, USA
Ian M. Gould, Scotland
George Jacoby, USA
Janusz Jeljaszewicz, Poland
Calvin M. Kunin, USA
Yankel Kupersztuch, USA
Joshua Lederberg, USA
Stephen A. Lerner, USA
Donald E. Low, Canada
Leonardo Mata, Costa Rica
Richard P. Novick, USA
Jorge Olarte, Mexico
Maria Eugenia Pinto, Chile
Vidal Rodriguez-Lemoine, Venezuela
Theodore Sacks, Israel
José Ignacio Santos, Mexico
Mervyn Shapiro, Israel
K. B. Sharma, India
Atef M. Shibl, Saudi Arabia
Ewe Hui Sng, Singapore
Tze-ying Tai, China
Thelma E. Tupasi, Philippines
Anne K. Vidaver, USA
Frantisek Vymola, Czech Republic
Fu Wang, China
Bernd Wiedemann, Germany

Headquarters

APUA
75 Kneeland St.
Boston, MA 02111, USA

Telephone: 617-636-0966
Fax: 617-636-3999
Email: apua@opal.tufts.edu
Website: www.APUA.org

Dockets Management

(HFA 305)
FDA
June 1, 2000

To whom it may concern:

We are writing in response to the federal register notice, docket no. 00N-1256 (Over the Counter Drug Products). APUA is concerned about any proposed slackening of regulations regarding antibiotic prescription requirements. We are opposed to any movement of the FDA toward considering antibiotics for over the counter sales. Our position is that antibiotics should be held as a specialized, more regulated class of protected drugs because of their special nature.

Promoting uncontrolled access will lead to decreased effectiveness of these important weapons in the global battle against reemerging infectious diseases. In the developing world, without antibiotic controls there are several countries where pneumococcal resistance has reached 50-75%. The World Health Organization has passed a resolution stating that antibiotic resistance is a global crisis and that its 125 member countries should adopt antibiotic prescription regulations. The CDC has sent out alerts to physicians about the increasing rates of resistance. The American Medical Association, American College of Physicians and the Infectious Disease Society of America have all designated antibiotic resistance among the top five current public health threats.

In light of the national and world-wide alarm about antibiotic resistance, for all of the above reasons, we suggest that the FDA clarify in its OTC approach that **antibiotics are a protected class which should be categorically excluded because uncontrolled access for individuals will endanger society.**

Antibiotics are different from other drugs in that each dose of antibiotic not only treats the individual, but also often affects the family, the community and the environment with which the patient comes in contact. Among pharmaceutical agents, antibiotics are unique because they impact entire populations of bacteria. Once selected, resistant bacteria are shed, excreted and otherwise spread among people and into the environment where they become part of a common microbial pool, infecting and associating with man, animals and plants.

Use of antibiotics has a broad environmental impact since they disrupt the microbial balance by killing off natural, susceptible, competing bacteria making up the skin and intestinal flora, leaving resistant strains to propagate. While this may be a necessary societal cost when the antibiotic treatment is necessary, unnecessary or misuse of antibiotics will result in unnecessarily shortening the life of these agents for other members of society. The easing of access to antibiotics will contribute to the continuing onslaught of the bacterial world and will lead to the emergence and spread of multiresistant bacteria.

Allowing over the counter antibiotic access would not only increase unnecessary antibiotic use, but also result in patients inadvertently exacerbating the resistance problem by failing to follow the required regimens. Over the counter use would not allow for the provider education needed to encourage appropriate consumer use. Whenever bacteria are exposed to subtherapeutic levels of an antimicrobial drug, they tend to develop protective mechanisms in order to survive. By failing to take a prescription for the specified time, or by stockpiling unused drugs for later use, patients will facilitate the bacteria's development of adaptive mechanisms of resistance against an antibiotic.

00N-1256

CH 47

APUA's position is that strong prescription and other regulatory requirements are needed to encourage appropriate use of antibiotics in human and veterinarian medicine and to forestall the continuing build up of resistant bacteria in the environment, health facilities and the community. Major medical associations and several regulatory groups are acknowledging antibiotic resistance as public health crisis. Given the current problem it is inappropriate for any proposed FDA framework to suggest any easing of antibiotic access.

APUA and other concerned scientific, clinical and consumer groups look to the FDA to provide leadership in maintaining strict regulation of antibiotics for both animal and human uses. We would appreciate the FDA's strong commitment to use its authority to curb this major global public health problem. Thank you.

Sincerely,

Kathleen T. Young
Executive Director APUA

Cc: Stuart Levy, MD, President APUA