



IDSA
Infectious Diseases Society of America

JUN 28 2000
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STATEMENT OF FREDERICK P. SPARLING, M.D.

On behalf of the

INFECTIOUS DISEASES SOCIETY OF AMERICA

Before the

FOOD AND DRUG ADMINISTRATION

Part 15 Hearing

About the

Status of Over the Counter Drug Products

June 28, 2000

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Food and Drug Administration Part 15 Hearing
The Status of Over the Counter Drug Products
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Good afternoon. I am Fred Sparling, professor of Medicine and Microbiology and Immunology at the University of North Carolina, Chapel Hill [UNC]. I am representing the Infectious Disease Society of America [IDSA] in my capacity as Chair of IDSA's Public Policy Committee. IDSA represents more than 5,500 physicians, scientists and other health care professionals who specialize in infectious diseases. The Society's mission is to promote and recognize excellence in patient care, education, research, public health, and the prevention of infectious diseases.

My Statement serves as IDSA's initial comments to the Food and Drug Administration's notice concerning the agency's approach to regulating over-the-counter [OTC] drug products. IDSA appreciates the opportunity to testify about this important subject.

IDSA strongly opposes changing the regulations to allow antibiotics to be dispensed OTC without prescription from a physician, primarily because it would increase the risks for additional development of antibiotic resistance. There also could be other adverse effects, including patient misdiagnoses of causes of apparent infections, with resultant poor outcomes.

Antibiotic resistance is a clinically significant problem at present and has been getting worse throughout the world for many years. Indeed, the problem has become sufficiently serious that public media have given much coverage to emergence of antibiotic resistant "super bugs". These problems are particularly severe within hospitals but also increasingly involve common outpatient infections, in part due to shifting care from inpatient to outpatient settings. Patients have been infected with bacteria that were resistant to every available antimicrobial agent and literally could not be treated effectively. Fortunately, the pharmaceutical industry continues to be successful in developing new drugs to treat resistant infections, but we cannot assume that this will always be the case. We must do whatever we can to preserve the effectiveness of currently marketed drugs. Resistant bacteria are contagious. The health of the public depends on your decision.

Allow me to list just a few specific instances for illustrative purposes. The pneumococcus, the most common cause of community-acquired pneumonia and a common cause of middle ear infections in children, meningitis, and other very serious diseases, has gradually become resistant to penicillins and other antimicrobials including macrolides and trimethoprim/sulfamethoxazole. The effectiveness in treating these classic infections is threatened severely. The gonococcus, a common cause of genital infections and a cause of ectopic pregnancy and female sterility, has become resistant to penicillins and tetracyclines and is beginning to become seriously resistant to the fluoroquinolones. The emergence of resistant gonococci and pneumococci was noted first

in areas of the world where antibiotics are freely available without prescription. Many have concluded from these and many other examples that development of resistance is fostered by free availability of OTC antibiotics, because this leads to use of subtherapeutic antibiotic concentrations and/or abbreviated courses of therapy, both of which favor emergence of resistance. Any move to allow similar OTC distribution of antibiotics and antimicrobials in this country would undermine the public health safeguards that we currently have in place to protect our citizens and place us on par with lesser developed nations in this area. This would be a serious step backwards.

There are many other examples of similar problems. For instance, resistance of the bacteria that commonly cause otitis media [a middle ear infection] in small children has increased dramatically in recent years, and many believe this to be the result of inappropriate use of antibiotics to treat non bacterial upper respiratory infections. Over prescription of antibiotics by physicians both in the office and in the hospital is recognized to be a problem. Many societies [including IDSA] are working to develop better guidelines and educational strategies to limit antibiotic use to those situations where they really are necessary. The U.S. Senate currently is considering methods to help educate physicians so as to limit the inappropriate use of antibiotics. If we accept that over prescription of antibiotics leads to emergence of resistant bacteria, then anything that liberalizes the uninformed use of antibiotics for non-indicated conditions would aggravate the problem. Self-diagnosis by the citizenry would not enable distinctions between viral and other non-bacterial infections that cause similar syndromes and would inevitably lead to self-medication with antibiotics when antibiotics are not needed. This, in turn, would increase pressures for emergence of resistant bacteria.

It could be argued that antibiotics would be approved for OTC use only for syndromes for which good algorithms for treatment exist, and in which diagnosis is relatively simple such as urinary infection or diarrhea. However, inappropriate use because of misdiagnosis still would be expected. OTC antibiotics might be restricted to only certain uncommon classes of drugs, such as the currently approved neomycin/bacitracin for topical use, reasoning that this would be unlikely to cause problems of resistance to more commonly used antimicrobials. However, this would not prevent emergence of resistance to commonly used drugs, for the reason that genes for resistance to different types of drugs are commonly carried on single mobile genetic elements, or may result from a single mutation in an efflux pump. Treatment with a single drug therefore may result in resistance to multiple drugs. The only safe policy is to restrict as much as possible the use of all antibiotics to situations where informed evidence suggests they are needed.

We urge you not to approve further OTC distribution of any antibiotic or antimicrobial agent for topical or oral use in humans without clear and convincing evidence that such a policy would not result in selection for resistance to these or other antimicrobial agents, or in an increased incidence of important misdiagnoses or other adverse effects. The ethical decision is to say no to the proposal.

Thank you for your attention and help.