



Statement

of the

American Medical Association

to the

Subcommittee on Health
Committee on Energy and Commerce
U.S. House of Representatives

**Re: Promoting the Development of Antibiotics and
Ensuring Judicious Use in Humans**

Presented by:
Sandra Adamson Fryhofer, MD, MACP, FRCP
Member, AMA Council on Science and Public Health

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Good morning Chairman Waxman, Chairman Pallone, Ranking Member Shimkus, and members of the Subcommittee. My name is Sandra Adamson Fryhofer, MD, MACP, FRCP, and I am a member of the Council on Science and Public Health (CSAPH) of the American Medical Association (AMA). I am a general internist engaged in private practice in Atlanta, Georgia, and a Clinical Associate Professor of Medicine at Emory University School of Medicine. I am pleased to be able to testify today on behalf of the AMA. The AMA commends the Subcommittee for its continued focus on the important issue of promoting the judicious use of antibiotics in humans.

Overview

Antibiotic resistance has been a major public health concern for many years. The problem has continued to increase in prevalence with bacteria. Resistance is a complicated phenomenon that involves the environment and the patient, as well as the microbe. Thus, resistance may arise as a result of therapy or as a result of a previous exposure to a given drug or its analog, or may be intrinsic to the microbe itself. Additionally, resistance is found not only in the hospital environment but also in the community setting and in long-term care facilities, with some hospital outbreaks directly traceable to resistant bacteria introduced from the community.

The AMA believes that the problem of increasing antibiotic resistance is an important public health concern. In order to preserve the utility of these important drugs for the future, it is critical that we manage this problem collaboratively and consider all possible areas for intervention. The AMA believes that a multi-faceted approach is needed comprised of: (1) reducing the inappropriate use of existing antibiotics to preserve their clinical utility; (2) incentivizing the research and development pipeline in order to create novel antibiotics for clinical use; and (3) developing and implementing alternative interventions to reduce dependence on antibiotics. The following testimony focuses to a large degree on the first of these approaches, namely the inappropriate or overuse of antibiotics by physicians.

Reducing inappropriate use

AMA efforts in reducing inappropriate use have focused on three issues: (1) educating primary care physicians on the importance of reducing the inappropriate use of antibiotics in their patients; (2) informing patients about the public health impact of increasing antibiotic resistance; and (3) reducing the inappropriate use of antibiotics in animal agriculture.

AMA policy urges physicians to educate patients about their antimicrobial therapy, the importance of compliance with the prescribed regimen, and the problem of antimicrobial resistance. It also urges that physicians and physicians-in-training are educated continuously about the appropriate prescribing of antimicrobial agents and encourages the use of multidisciplinary and cooperative antibiotic resistance management programs (*H-100.973 Combating Antimicrobial Resistance through Education*). The AMA and physician organizations comprising the AMA's Federation of Medicine are acutely aware of the profession's role in reducing inappropriate antibiotic use and for many years have taken aggressive steps to support judicious use of antibiotics in clinical practice. For example, the use of critical last-resort and new antibiotics, (e.g., vancomycin, streptogramins, linezolid) is monitored, restricted, and controlled by hospital infection control committees. Likewise, procedures to limit or contain the spread of resistant organisms have been actively developed and implemented. In 2005, the AMA supported the Centers for Disease Control and Prevention's (CDC) Campaign to Prevent Antimicrobial Resistance in Healthcare Settings and disseminated information on the campaign to its medical specialty society members and provided links for downloading materials from the CDC website.

Existing data indicate that control strategies implemented in hospitals have reduced the incidence of resistant bacteria. Additionally, optimal selection, dose, and duration of treatment are helping to prevent the development of antibiotic resistance in bacteria. Adjusting hospital antibiotic formulary practices reduces the incidence of specific resistant bacteria, but ongoing surveillance is necessary to guard against the emergence of other resistant bacterial strains. Improved surveillance provides critical information on the emergence and epidemiology of new resistant strains, and the genotypic basis of such resistance, as well as data on appropriate therapeutic options. Studies are now showing that such efforts along with education-based methods are changing the prescribing habits

of physicians. Significantly, cooperation between infection-control specialists, infectious disease specialists, clinical pharmacists, and the microbiology laboratory provides useful real time information pertaining to antibiotic choice and dosing for prescribing physicians.

Antibiotic resistance in the community remains problematic. It continues to manifest, for example, through the appearance of community-acquired methicillin-resistant *Staphylococcus aureus* (CA-MRSA), which has received significant media attention in recent years. Additionally, the use of antibiotics for the treatment of pediatric acute otitis media has not subsided despite the issuance of a “watchful waiting” guidance from the American Academy of Family Physicians (AAFP) and the American Academy of Pediatrics (AAP) almost six years ago. Thus, continued outreach on specific situations where inappropriate antibiotic use still occurs is required.

The AMA has used (and continues to use) various communication tools to increase education and outreach to primary care physicians in private practice on the topic of antibiotic resistance. For example, the AMA has sponsored educational conferences, developed and disseminated educational tools (e.g., a special patient page in the *Journal of the American Medical Association*) and treatment algorithms (including a recent tool on CA-MRSA), and issued scientific reports on specific aspects of antibiotic resistance. The AMA has also supported and publicized primary care practice recommendations with respect to appropriate use of antibiotics. These include a series of “Principles for Appropriate Antibiotic Use” developed by the American College of Physicians in 2001 for adult patients, and several pediatric guidelines that were published more than a decade ago. In particular, the AMA collaborated with the California Medical Association Foundation to move its state-specific Alliance Working for Antibiotic Resistance Education (AWARE) practice guidelines compendia to a national level. The AWARE compendia summarizes and incorporates practice guidelines from multiple authorities on appropriate antibiotic use for several conditions into two easy-to-read documents: one covering pediatric guidelines and the other covering adult guidelines.

The AMA-convened Physician Consortium for Performance Improvement (PCPI) is a national physician-led initiative dedicated to improving patient health and safety. More than 170 members comprise the PCPI, including national medical specialty societies, state medical societies, the American Board of Medical Specialties, health care professional organizations, federal agencies, individual members and other groups interested in improving the quality of care. The PCPI identifies and develops evidence-based clinical performance measures and measurement resources that enhance quality of patient care and foster accountability and promotes the implementation of relevant clinical performance improvement activities. Recognizing the importance of improving the quality of care with respect to judicious antibiotic prescribing, the PCPI has begun to look at developing performance measures that consider this issue.

For example, a performance measure set was developed in consultation with the American Academy of Pediatrics, American Academy of Otolaryngology Head and Neck Surgery Foundation, and the Centers for Medicare and Medicaid Services for the

management of pediatric patients with acute otitis externa and acute otitis media with effusion. The measure set focused in part on avoidance of inappropriate use of systemic antimicrobial therapy. Pediatric patients 2 years and older with diffuse uncomplicated acute otitis externa should generally be managed with topical preparations. Similarly, acute otitis media with effusion in pediatric patients 2 months through 12 years of age usually resolves spontaneously. Systemic antibiotics do not have long-term efficacy and are not recommended for routine management. The measure is derived from the percentage of patients with these diagnoses who were not prescribed systemic antimicrobial therapy unless documentation of medical reason(s) for prescribing systemic antimicrobial therapy was evident. A measure set on adult sinusitis is in the early stages of development for 2010.

Recognizing that the abuse of antibiotics is commonplace in the developing world, the AMA worked with the World Medical Association (WMA) to develop the WMA's 2008 Declaration and Policy Statement on antibiotic resistance. This statement provided targeted policy guidance to: (1) federal governments; (2) national medical associations; and, (3) practicing physicians.

Finally, a primary reason that physicians prescribe unnecessary antibiotics to patients is the patient's desire to receive the antibiotic. Accordingly, the AMA has engaged in several efforts to educate patients and the public on the importance of appropriate antibiotic use. The AMA also has sponsored media briefings on infectious disease topics with a focus on antibiotic resistance, and along with the American Academy of Family Physicians, the AMA participated in the launch of the CDC's "Get Smart" campaign. This campaign targeted the public to educate them on the negative impact of antibiotic resistance on public health as well as individual health and wellness and explained why physicians should not prescribe antibiotics for the common cold. The ultimate goal of the "Get Smart" campaign was to promote appropriate antibiotic use in the community. At the launch of "Get Smart" in 2003, the AMA acknowledged the importance of the campaign and the AMA's unique position to not only increase knowledge and awareness of appropriate antibiotic use among the public and physicians, but also to stimulate appropriate dialogue between patients and their physicians.

It is clear that inappropriate antibiotic use in medical settings, coupled with liberal prescribing practices, previously contributed to the increase in antibiotic resistance. It is also now clear that attention to this issue has improved clinical decision-making on the appropriate use of antibiotics in human medicine. However, we must remain aware that whenever antibiotics are used, the threat for selection of antibiotic-resistant bacteria persists. Such strains of bacteria may enter the human health care system and be amplified and perpetuated. Accordingly, all avenues by which resistant strains can enter the human health care system remain relevant, including the use of antibiotics in food animals. AMA policy states our opposition to the use of antibiotics at non-therapeutic levels in agriculture, or as pesticides or growth promoters, and urges that non-therapeutic use in animals of antibiotics (that are also used in humans) should be terminated or phased out based on scientifically sound risk assessments (*H-440.895 Antimicrobial Use and Resistance*).

The AMA believes that pilot programs examining the impact of eliminating the use of antibiotics in animal husbandry are appropriate. Such an approach would provide data on how farmers can best adapt to changes in agricultural techniques, and would identify best practices for the gradual elimination of the use of antibiotics in agriculture. In order to affect the change necessary to eliminate inappropriate use in animal husbandry, the AMA participated in the FDA's process to develop their draft Guidance for Industry, "Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to their Antimicrobial Effects on Bacteria of Human Health Concern." The AMA has also supported different legislative initiatives to curtail such use, including H.R. 2400, the Strategies to Address Antimicrobial Resistance Act, and H.R. 1549/S. 619, the Preservation of Antibiotics for Medical Treatment Act.

Incentivizing new research and development

The improvement in managing antibiotic resistance within the medical community stems in large part from significant changes in physician prescribing behavior and the aggressive implementation of judicious use and critical "last resort" policies within medical facilities. However, these policies may create a disincentive for research and development of novel antibiotics. Pharmaceutical companies are reluctant to invest in developing a new antibiotic only to be confronted with stringent use paradigms dictated by clinical management strategies, as necessary as they are. Thus, innovative incentives must be developed to foster continued research and development of novel antibiotics to ensure that these important tools to combat infectious diseases remain available for future generations of physicians. The urgency of this situation has been highlighted by a major effort from the Infectious Diseases Society of America. Their first initiative was the call-to-action titled "Bad Bugs, No Drugs," released in 2004 and supported by the AMA. This white paper is now being followed by the "10 by '20" initiative. The goal of this initiative, launched in May of 2010, is to create incentives for manufacturers to develop 10 new antibiotics by 2020. The AMA will be considering endorsement of the "10 by '20" initiative at its June 2010 Annual Meeting.

Reducing dependence on antibiotics

As antibiotic resistance continues to be a problem and the antibiotic pipeline remains stagnant, we should also examine innovative ways to reduce our dependence on antibiotics. As mentioned above, rigorous infection control strategies implemented in hospitals have been successful in limiting the spread of resistant organisms. The development of new vaccines against pathogens with clinically important levels of resistance should be encouraged (e.g. *E. coli*) even as we promote the use of existing vaccines. Of particular note, in the era of increasing antibiotic resistance in *Streptococcus pneumoniae* (pneumococcus) strains, it is disappointing that immunization rates against pneumococcus remain low in adults.

Conclusion

While significant improvements have occurred with respect to judicious use of antibiotics in medical facilities and in physician prescribing behavior, antibiotic resistance remains a major public health problem. Continued vigilance and education to maintain appropriate prescribing practices in physicians, proper use behaviors in patients, and improved surveillance for emergence of resistance are all necessary. The continued use of antibiotics that have a human health impact in animal husbandry remains a major public health problem. Also of particular concern is stagnation in the development of novel antibiotic agents; new processes are necessary to incentivize the research and development of new, clinically important antibiotics.

The AMA recognizes that antibiotic resistance must be controlled through judicious use of antibiotics by health care professionals and will continue to encourage the federal government, the World Health Organization, the World Medical Association, and the International Federation of Pharmacists to promote more effective education on the appropriate use of antibiotics. The AMA will continue to support physicians in their efforts to educate their patients about antibiotic therapy, the importance of compliance with the prescribed regimen, and the problem of antibiotic resistance. The AMA will also continue to educate physicians and physicians-in-training about the appropriate prescribing of antibiotics while encouraging the implementation of multidisciplinary and cooperative antibiotic resistance management programs that include participation of infectious disease physicians, infection-control specialists, microbiology laboratory personnel, and clinical pharmacists.