



## Statement of the American Urological Association to the Antimicrobial Drugs and Drug Safety and Risk Management Advisory Committees of the U.S. Food and Drug Administration

*Presented by Dr. Tim Averch on November 5, 2015*

My name is Doctor Tim Averch and I am a practicing urologist here today representing the American Urological Association (AUA), an organization that represents nearly 15,000 members who provide urologic patient care in the United States. Our organization has maintained that fluoroquinolones such as ciprofloxacin and levaquin should be available for the uncomplicated UTI in very select patients, specifically not as a first line therapy. It is well noted that urinary tract infections (UTIs) are a common patient infection. Not only are UTIs among the most common type of nosocomial infection but they frequently lead to morbidity. Treatment of an uncomplicated UTI should be efficacious, simple, and low risk. Additionally, we recognize the warnings regarding side effects of these medications needs to be strengthened. There is also a public health risk of bacterial resistance in the patient and in the community microbial reservoir. Antimicrobial usage has had a clear impact on the emergence of resistant bacterial strains. A substantial cause of the emergence of these resistant strains is the over-use (treatment when none is needed and prolonged therapy exposures) of antimicrobial agents for all indications. Data suggesting that fluoroquinolone resistance is rising in areas of high use, supporting the contention that microbial resistance is directly related to repetitive exposure of microbes to unique antimicrobial agents. It is likely that the appropriate use of antimicrobial prophylaxis (indication-specific and of limited duration) would limit these resistance trends.

The AUA supports the use of fluoroquinolones for the treatment of uncomplicated UTIs only as noted previously. We agree that it should not be considered first line unless there is a contraindication or allergy to recommended first line therapies, such as macrolides or sulfa-trimethoprim.

In summary, the AUA believes that the continued use of fluoroquinolones for UTI treatment is warranted only in very particular instances. And we would not want to take it out of the hands of the providers to utilize and use warnings appropriately. Providers must be aware of best practices, in terms of antimicrobial selection and in an effort to decrease bacterial resistance and reduce side effects. Guidance authored by the AUA through published guidelines and best practice statements available in our urologic literature and on the AUA website, provides this information and, therefore, ensures that antibiotic use remains beneficial for both patient and public health. We make ourselves available to provide additional support or answer questions as necessary. Thank you for your attention.