**FDA Advises Restricting Fluoroquinolone Antibiotic Use.**

On July 26, 2016, the US Food and Drug Administration (FDA) approved [changes to the labels](http://www.fda.gov/Drugs/DrugSafety/ucm511530.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery) of flouroquinolone antibacterial drugs for systemic use (i.e., taken by mouth or by injection). The FDA revised the Boxed Warning, the FDA’s strongest warning, to address serious safety issues that may result from the use of fluoroquinolones. In addition, the FDA updated other parts of the drug label including the Warnings and Precautions and Medication Guide sections. This follows a previous [warning issued in May](http://www.fda.gov/Drugs/DrugSafety/ucm500143.htm) regarding limiting the use of fluoroquinolones in certain bacterial infections.

The FDA specifies that fluoroquinolones have serious side effects that outweigh the benefits in the use of conditions, such as **uncomplicated urinary tract infections** (UTIs), in patients for which other treatment options may be effective. The FDA mentions disabling and potentially permanent serious side effects involving the tendons, muscles, joints, nerves and central nervous system. The specialty of urology was not specifically mentioned in the new label changes or the warning; however, the treatment of urinary tract infections and the use of fluoroquinolones is very common in our field. The majority of UTIs treated in urology are complicated and may warrant the use of a fluoroquinolone. However, in this circumstance, one should inform the patient about the side effects of the medication. Uncomplicated infections usually occur in women who do not have anatomical or urological causes and do not have recurrent UTI. All men with UTI are considered complicated. The [Infectious Disease Society of America (IDSA) Guidelines](http://www.idsociety.org/Guidelines/Patient_Care/IDSA_Practice_Guidelines/Infections_by_Organ_System/Genitourinary/Uncomplicated_Cystitis_and_Pyelonephritis_(UTI)/) (1999) recommended trimethoprim/sulfamethoxazole, nitrofurantoin, fosfomycin and pivmecillinam as first-line therapy for uncomplicated UTIs.

The FDA does not comment on the use of fluoroquinolone antibiotics prior to outpatient procedures or the routine use perioperatively. However, due to the side effect warning consider switching to a different antibiotic in surgery or prior to a procedure on case-by-case basis. Consider the need for any antibiotics prior to routine cystoscopy, cystography or urodynamics in low-risk patients. Prostate biopsy has evidence for the use of fluoroquinolone prophylaxis; however, it is recommended that you not prescribe more than 24 hours of the medication to reduce exposure. Regarding prophylaxis for several procedures and surgeries, refer to the [AUA Best Practice Policy Statement on Urologic Surgery and Antimicrobial Prophylaxis](https://www.auanet.org/education/guidelines/antimicrobial-prophylaxis.cfm).

If you do choose a fluoroquinolone for antibiotic therapy and the patient does have symptoms or side effects, the FDA urges you to report that incidence to the [FDA MedWatch](http://www.fda.gov/Safety/MedWatch/) program on their website.



Michael A. Liss, M.D., M.A.S.

Department of Urology

University of Texas HSC San Antonio

AUA Quality Improvement and Patient Safety Committee

AUA Representative to S-FAR