ILLINOIS ATTORNEY GENERAL LISA MADIGAN

PRESS RELEASE

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For Immediate Release
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MADIGAN, PUBLIC CITIZEN, PETITION FDA FOR "BLACK BOX" WARNING REGARDING POTENTIAL ADVERSE EFFECTS OF CERTAIN POPULAR ANTIBIOTICS

Chicago - Attorney General Lisa Madigan, and the Washington, D.C. based non-profit consumer advocacy group, Public Citizen, today announced that to protect the public's health and safety they have petitioned the Food and Drug Administration (FDA) to take action about severe and increasingly frequent tendon disorders caused by certain types of antibiotics.

These antibiotics are in the fluoroquinolone class of antibiotics, which are commonly prescribed for conditions such as gastrointestinal, respiratory and genito-urinary tract infections, and include drugs such as Cipro (ciprofloxacin) and Levaquin (levofloxacin).

Public Citizen today submitted a new Citizen's Petition asking the FDA to strengthen the cautionary advice currently provided on drug labels with the use of a "Black Box" warning, and to make greater efforts to inform health care providers and patients about the potential adverse drug reaction. Madigan today submitted a supplement to her previous petition to the FDA including this new information, and urging the FDA to take necessary action.

Madigan's and Public Citizen's petitions point out that tendon disorders appear to be increasing in frequency as the use of fluoroquinolone drugs increases, and can causeserious problems such as rupture of the Achilles tendon. The petitions state that physicians and consumers alike need to be better informed about this potential adverse side effect through the use of "Black Box" warnings in labeling information, increased warnings to patients, letters to health care professionals, and further review of this class of drugs by the FDA's new Drug Safety Oversight Board.

Madigan's office became interested in this problem after receiving complaints from consumers who suffered from tendon disorders after taking the antibiotic Levaquin. After investigation, Madigan's office took action by submitting a Citizen Petition to the FDA in May 2005. This petition urged the FDA to require manufacturers of the fluoroquinolone class of drugs to:

- Revise drug labeling to strengthen warnings for the potential serious adverse side effect of tendinopathy and tendon rupture;

- Create a "Black Box" warning to reflect the risk and severity of this adverse side effect;
- Require manufacturers of fluoroquinolone antibiotics to issue a "Dear Health Care Professional" letter to inform health care providers about this significant hazard to health and announce the changes in drug package labeling;
- Supplement information provided to patients with bolded warnings about the risk of tendinopathy and tendon rupture; and
- Submit the class of fluoroquinolone drugs for review to the FDA's Drug Safety Oversight Board.

After receiving only a tentative, non-substantive response from the FDA in November 2005 indicating that a decision had not yet been made regarding the petition, Madigan has now collaborated with Public Citizen to strongly encourage the FDA to take prompt action to effectively educate and warn consumers and physicians of these potential adverse side effects.

In August 1996, Public Citizen successfully petitioned the FDA to require that a warning regarding the risks of tendonitis and tendon rupture be included in the package inserts for all fluoroquinolone antibiotics. However, this information, placed in the routine "Warnings" section, has proven to be inadequate, as shown by increased numbers of tendon ruptures related to the use of fluoroquinolone antibiotics. Public Citizen analyzed the FDA Adverse Events database covering the period from 1997 through 2005, and discovered that the incidence of tendon disorders caused by fluoroquinolones appears to be increasing.

"Consumers and physicians have a right to know the adverse effects associated with prescription medicines," Madigan said. "We join with Public Citizen in urging the FDA to take prompt action on these petitions."

"Public Citizen has long advocated adequate disclosure of risks associated with fluoroquinolone antibiotics, and today's petition is our latest effort to implore the FDA to take action to protect consumers," Sidney Wolfe, MD, Director for Public Citizen's Health Research Group, said. "We are pleased to join with Attorney General Madigan on this important initiative."

Consumers taking fluoroquinolone antibiotics should direct any questions or concerns they have about possible adverse side effects to their physicians or other health care professionals.

Medical Director Arnold Widen, M.D. and Health Care Bureau Medical Director, Babs Waldman, M.D. are handling this matter for Madigan's office and Sidney Wolfe, M.D., Director of theHealth Research Group and Jay Parkinson M.D., M.P.H. have worked on this issue for Public Citizen.

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