MYASTHENIA GRAVIS
FOUNDATION OF AMERICA, INC.

"Black Box" Warning for Cipro® (ciprofloxacin) and Avelox® (moxifloxacin)

Bayer HealthCare, manufacturers of Cipro® and Avelox®, have issued an announcement that they have been directed by the US Food & Drug Administration (FDA) to place the following boxed warning on the product labeling for these drugs:

Warning:
Fluoroquinolones, including AVELOX®/CIPRO®, may exacerbate muscle weakness in persons with myasthenia gravis. Avoid AVELOX®/CIPRO® in patients with known history of myasthenia gravis (see Warnings and Precautions).

The Warnings section in the product labeling within each package of Cipro® goes on to say:
Exacerbation of Myasthenia Gravis: Fluoroquinolones, including CIPRO, have neuromuscular blocking activity and may exacerbate muscle weakness in persons with myasthenia gravis. Postmarketing serious adverse events, including deaths and requirements for ventilatory support, have been associated with fluoroquinolone use in persons with myasthenia gravis. Avoid CIPRO in patients with known history of myasthenia gravis.

The Information for Patients section in the product labeling says:
"…fluoroquinolones like CIPRO may cause worsening of myasthenia gravis symptoms, including muscle weakness and breathing problems. Patients should call their healthcare provider right away if they have any worsening muscle weakness or breathing problems." (There are similar statements in the Avelox® product labeling.)

Although worsening of muscle weakness in MG following administration of a fluoroquinolone antibiotic was reported almost 30 years ago, this is the first time that the FDA has required that a specific warning about this risk be placed on the labeling information for these drugs. (Another antibiotic with a specific warning for MG is Ketek® (telithromycin), which has also been associated with sometimes fatal worsening of MG.) The FDA action in requiring these warnings resulted from reports submitted to their MedWatch Safety Information and Adverse Event Reporting Program. The FDA receives and evaluates reports about possible drug-related adverse events that are voluntarily submitted to the MedWatch program.

Submission of MedWatch reports is particularly important in identifying adverse drug reactions in rare diseases such as MG. Reactions that are specific for rare diseases are not discovered during the clinical trials performed to get new drugs approved because patients with such diseases are ineligible to participate in most drug trials. Also, because these adverse reactions occur in isolated cases, and many things can cause worsening in MG, it can take a long time for individual physicians to see enough such reactions to recognize a pattern pointing to a specific medication. Anyone can submit a MedWatch report - physicians, nurses, pharmacists, patients, even family members - and information about how to submit a report and submission forms can be found on the MedWatch website (http://www.fda.gov/Safety/MedWatch/default.htm) or by running an Internet search on "MedWatch."