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To The United States Senate Committee on Health, Education,  
Labor and Pensions

Re: Fluoroquinolone Toxicity Syndrome (FTS)

Dear Senators,

Serious adverse reactions to fluoroquinolone antibiotics (FQs) have been reported in medical journals and to the FDA since the 1980s. Although the FDA has increased the warnings on these drugs (Levaquin, Cipro, Avelox, Floxin, Norfolk, Factive), my analysis of FDA data shows that reports continue to climb in number. As of February 2014, approximately 45,000 individual cases of fluoroquinolone toxicity have been reported to be FDA. And, as studies have proven, the FDA receives reports of only 1%-5% of the actual numbers of adverse reactions that occur.

I have been following these medications for 16 years and have evaluated in person or by telephone consultation more than 400 people injured by FQs. In 2001, I published an article, *Peripheral Neuropathy with Fluoroquinolone Antibiotics*, in the *Annals of Pharmacotherapy*. This article described 45 cases of severe neurological symptoms such as tingling, numbness, burning pain, twitching, and/or severe weakness. Moreover, 93% of the subjects sustained injuries to other vital systems: agitation, impaired cognitive function, intractable insomnia, hallucinations, psychosis, acute manic episode, joint or muscle pain, or tendon rupture. In many cases, toxicities also involved the cardiovascular and gastrointestinal systems, skin, and sight or hearing. Overall, the majority of my subjects experienced toxicity to multiple body systems. Hence my coining the term Fluoroquinolone Toxicity Syndrome.

Of greatest concern, the majority of my cases had lasted more than 1-2 years and were ongoing. These severe, long term reactions occurred in a generally young and healthy population. The average patient age was 42, many of them athletes. In fact, top athletic organizations now warn athletes to avoid treatment with FQs.

Because of the impaired healing seen in severe FTS patients, we have long suspected genetic injury from FQs. These drugs were designed to injure the genetic structure of bacteria and thereby kill them, and they are very efficient in doing so. However, testing was never performed to ensure that FQs did not also injure human DNA. A recent study using high performance liquid chromatography with mass spectrometry has demonstrated that FQs do indeed injure human DNA. Further study on this must now be undertaken.

There is no doubt that fluoroquinolones are important medications that help many thousands of people each year, but the indiscriminate prescribing of these highly potent, "big gun" antibiotics for everyday minor infections such as sinusitis, sore throats, or bladder infections is unnecessary and medically negligent. Medical authorities have repeatedly denounced the overuse of FQs. In my 40+ years in pharmacovigilance, FQs surpass Vioxx and thalidomide in the degree of permanent harm done.

FDA warnings currently describe many of the adverse effects of FQs. Recently the FDA has finally acknowledged that FQs can cause *permanent* injury. However, FDA warnings do not adequately describe the FTS syndrome, so doctors do not consider FTS and instead waste valuable time and expense testing for rare neurologic or rheumatologic disorders, meanwhile discounting or dismissing patients who are suffering severely from FTS. The warnings must be improved and the word about FTS must be spread nationally and worldwide. It can start with you. If you still doubt what I have written here, please examine the extensive literature on FQs toxicity beginning with the articles cited below.

Jay S. Cohen M.D. has been a faculty member at the University of California, San Diego, for three decades and has published more than 20 articles on drug safety in leading medical journals. Based on his articles and books, the FDA chose him as the keynote speaker at a FDA conference in 2004. He has debated FDA officials on drug safety strategies at conferences for the American Society for Clinical Pharmacology and Therapeutics and at the Drug Industry Association. His work has been highlighted in major newspapers and magazines including the New York Times, Newsweek and others. During the anthrax scare of 2001, Dr. Cohen's article on FQs and his appearance on National Public Radio led the CDC to withdraw its recommendation for Cipro for treating anthrax exposure in favor of other, safer antibiotics.

**Important Articles on FTS:**

Sincerely  
Jay S. Cohen M.D.

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