

# **We Were Listened to and Heard!**

Comments from FDA Advisory Committee meeting Nov. 5, 2015

Andrea Siani attended and gave testimony at the Joint Advisory Committee Meeting in Washington DC on November 5, 2015 regarding dangerous Fluoroquinolone side effects and the need for disclosure. She is a concerned citizen who is seriously suffering side effects after being prescribed fluoroquinolone antibiotics for a relatively minor infection. She has a B.S. degree in Biochemistry and has worked in community health for her entire career including teaching, being on community health councils and as a director of a non-profit community health program.

The medical community is not aware of the serious side effects of this class of broad spectrum fluoroquinolone antibiotics.

This handful of quotes from the Advisory Committee members, 21 medical professionals from across the country, summarize the serious need for education, disclosure and education.

"Business as usual is not acceptable"

"Misuse has to be addressed immediately"

"Education is important for the physicians"

There is "uncertainty about the safety"

The label "does not provide sufficient guidance for practitioners"

They need a "more user friendly Medication Guide with language easier for practitioners and patients to identify symptoms."

For "second line of defense only"

"FQAD-legitimate warning for this"

"Relying on the labeling alone is too passive"

"We have to act now"

"Need to extend who is at risk"

"Remarkable testimony today"

"No first line of defense use"

"Black box should be expanded-highlighted-raise alarm"

There are "serious safety concerns-(FQ) a flawed tool-needs red flags-BIG red flags"

"The black box does not look serious to me."

"REMS for judicious use of FQ need education process. Risk of disability needs to be added"

"Thank you to the press and patients"

"Learned a lot today"

**It is clear that we were listened to and heard!**

We were listened to and heard at the Joint Advisory Committee meeting. A vote was taken and recommendations shared. The votes were nearly unanimous that the labeling on these antibiotics was inadequate. The three most common uses of these drugs include UTI infections, Sinus/bronchial infections and COPD.

**Protect yourself and request safer alternatives whenever you are prescribed an antibiotic.**