Maurice Hinchey NEWS

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HINCHEY SAYS INACTION ON NEURONTIN LINK TO SUICIDES IS MORE EVIDENCE OF FDA FAILURE

KINGSTON, NY - U.S. Representative Maurice Hinchey (NY-22) today sent a letter to Food and Drug Administration Acting Commissioner Lester Crawford, calling for a thorough examination of the link between the prescription drug Neurontin and suicide. Hinchey said the FDA's failure to act on this matter reaffirms his belief that the agency is not fulfilling its duty to protect public health and safety.

"It is becoming increasingly clear to me that the U.S. Food and Drug Administration has lost its way," said Hinchey. "This agency, whose sole mission is to protect the public's health, has become more concerned with making life easier for drug manufacturers. This is another example of the Bush Administration placing its neoconservative ideology above statutory mandates."

Over the past six months, Hinchey has been examining the FDA's unsolicited intervention into private state lawsuits on behalf of drug companies or medical device manufacturers that are being sued by individuals harmed by their products. He was successful in passing an amendment to the FDA appropriations bill that would help put an end to this practice. The bill passed the House in July and is awaiting action in the Senate.

Hinchey's work on this matter came to the attention of Andrew Finkelstein, an attorney in Newburgh, NY, who subsequently wrote to Hinchey about his recent experience with the FDA. Finkelstein had a client who twice attempted suicide soon after being prescribed Neurontin, an anti-seizure drug that is also widely prescribed by doctors for many unapproved uses like pain, migraines and bipolar disorder. Finkelstein's client, a Newburgh man diagnosed with bipolar disorder, had never exhibited suicidal tendencies before going on Neurontin.

While it is not illegal to prescribe drugs for "off-label" uses, the practice depends on clear communication between drug manufacturers and doctors and patients about possible side effects. Marketing a drug for off-label uses *is* illegal and Pfizer pleaded guilty to marketing Neurontin for unapproved uses earlier this year. The settlement, however, did not require any change in the drug's labeling.

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Finkelstein conducted a survey about the possible link between Neurontin and suicide. When he brought the results of his research to the FDA, the agency's Neurontin safety officer responded that an "imminent health hazard" might exist. The FDA requested a follow-up conference call with the law firm and several FDA officials. During that call, the agency told Finkelstein that his firm had the "world's most important data set" on the issue of psychiatric adverse events and Neurontin.

Despite this strong initial reaction, the FDA then inexplicably ceased looking into the matter, suggesting that Finkelstein's law firm should conduct further analysis. Finkelstein responded that his law firm wasn't equipped or qualified to perform this type of analysis and continued to ask the FDA to do so, to no avail. On May 17, 2004 Finkelstein & Partners filed a citizen petition with the FDA asking the agency to require that Neurontin's label reflect the number of known suicides among the drug's users. This is one of only four such petitions filed this year by someone other than a drug or medical device manufacturer. Still the agency has taken no action.

Hinchey discussed his letter to Crawford at a press conference, at which he was joined by Finkelstein, the Newburgh client whose case initiated the attorney's investigation, and family members of a New Jersey suicide victim who was prescribed Neurontin for foot pain.

A copy of the letter is attached.

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