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Rep. Maurice Hinchey, D-Hurley, right, and attorney Andrew Finkelstein discuss their challenge to the Food and Drug Administration over the drug Neurontin.

Photo contributed

## Hinchey, lawyer seek drug label change

By MATT PEPPE  
Gazette staff writer

Six months after filing a citizens petition to the Food and Drug Administration requesting a label change that warns of the drug Neurontin's risk of suicide, the Finkelstein & Partners law firm is waiting for a response.

Earlier in the year, Finkelstein & Partners, based in Newburgh, notified the FDA during a conference call of its own studies of the risks of suicide for patients taking the prescription drug Neurontin, which is produced by Pfizer.

A client of attorney Andrew Finkelstein attempted suicide soon after being prescribed Neurontin in 2002. The man had been diagnosed with bipolar disorder.

Finkelstein & Partners then placed an advertisement for people to report cases of suicide relating to Neurontin use. The firm received thousands of calls from people who had attempted suicide and families of victims.

The firm claimed to have discovered 400 cases of suicide and several thousand cases of attempted suicide. According to Andrew Finkelstein, the FDA told him the agency was "very concerned," and needed to "regroup."

After not hearing back from the FDA, the firm filed the petition in May and have received no response since.

Finkelstein contacted Rep. Maurice Hinchey, D-Hurley, who had been critical of the FDA's intervention in private state lawsuits to protect drug companies from liability for individuals harmed by their products.

Hinchey worked to pass an amendment to the FDA appropriations bill that takes money from the FDA commissioner's budget and gives it to the budget of the Center for Drug Evaluation Research. The bill, which

passed in the House in July, is pending in the Senate.

The chief counsel of the FDA, Dan Troy, was an attorney for Pfizer before being appointed to the top legal position in the FDA in 2001.

Neurontin, whose generic name is Gabapentin, was approved by the FDA in 1993 for use as a supplement to other drugs to treat epilepsy. Of the \$2.9 billion Neurontin nets annually for Pfizer, only \$200 million comes from uses related to epilepsy.

Pfizer has pleaded guilty to promoting the drug "off-label," encouraging doctors to prescribe Neurontin for depression, nerve pain, bipolar disorder, and other conditions it was never tested to treat.

Pfizer had to pay \$430 million in the fraud settlement earlier this year. The settlement did not require any change in the drugs labeling.

Prescription of a drug for a condition other than what it was approved for is not illegal, but it is illegal for a pharmaceutical company to market the drug in this way.

Andrew Finkelstein is urging the FDA to conduct more research to study the links between Neurontin and suicide.

He stresses that in this case, the cost of allowing Neurontin to continue to be prescribed off-label far outweigh the benefits.

"When people are losing their lives daily, the costs are immeasurable while the benefits are negligible," Finkelstein said.

In early September, Hinchey sent a letter to FDA Commissioner Lester Crawford, imploring him to undertake an extensive examination of links between Neurontin and suicide.

Kevin O'Connell, a spokesman for Hinchey, said the

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congressman has not received any response from the FDA in a long time.

"The FDA is ignoring their main mission, which is to protect public health," O'Connell said.

This will not slow Hinchey's efforts to shed light on the matter. O'Connell said Hinchey will continue to work through the appropriations committee to hold the FDA accountable.

"It is becoming increasingly clear to me that the U.S. Food and Drug Administration has lost its way," Hinchey said in a statement. "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."

The FDA did respond to phone calls and e-mail requests for comment over a period of four days last week.

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