

WASHINGTON - Kristine McCown, 32, still struggles with a stutter and stumbles over the pronunciation of some words, but she's hoping lawmakers on Capitol Hill heard her loud and clear last week.

The Fairbury, Neb., woman, who suffered a series of strokes while taking the drug Vioxx in 2002, joined consumer advocacy groups in Washington to urge stepped-up regulation of drug companies by the Food and Drug Administration.

They see an opportunity for change this year because the system under which user fees are collected to fund drug safety oversight must be reauthorized by Congress or expire in September.

The consumer groups contend that the FDA bows too often to pressure from the industry to speed approval of new drugs.

They have identified changes they would like, including: more funding for the FDA; better monitoring of drugs after they have been released for widespread public consumption; and more transparency in testing by requiring companies to release information on all of their studies of new drugs.

Pharmaceutical companies aren't so keen on implementing sweeping changes to the current system of approving and regulating drugs.

Alan Goldhammer, of the Pharmaceutical Research and Manufacturers of America, said the industry already has taken steps to address patient concerns. He praised the current FDA oversight.

"There's a very delicate balance between appropriate studies and requiring so many studies that it would delay introduction into the marketplace of a drug designed to really provide a public health benefit," Goldhammer said.

McCown said years of speech and physical therapy helped her make some progress but that effects of her strokes linger.

Constant migraines make it difficult to concentrate and will plague her for the rest of her life. She said she has "lost her math" and can't help her 11-year-old daughter with homework. She has trouble keeping her balance and has fallen many times, breaking legs, ribs and wrists.

She began taking Vioxx for shoulder pain but then suffered a couple of minor strokes.

She said doctors discounted the idea that her symptoms represented strokes because she was only 27 and did not have other risk factors. They told her to keep taking Vioxx, because stroke was not considered a possible side effect of the drug, she said.

Then she suffered a massive stroke. Merck & Co., the maker of Vioxx, later voluntarily recalled the drug due to an increased danger of stroke or heart attacks.

Even if she had known about the potential side-effects, McCown said she likely would have taken Vioxx, but she believes she could have been properly diagnosed.

McCown visited the offices of several Nebraska lawmakers in Washington .

Her congressman, Adrian Smith, R-Neb., expressed support for protecting consumers and said some changes may be in order. But he also cited a need to not slow the approval of new drugs.

Rep. Lee Terry, R-Neb., could be the first Nebraska congressman to vote on the issue, because he is a member of the House committee expected to consider any legislation on it.

Terry said he would look into what McCown and others are seeking. He said he also hears strong arguments from the other side that overly restrictive regulations could hold up release of important drugs, such as those used to battle different types of cancer.



