United States Senate
Committee on Finance

Sen. Chuck Grassley · Iowa
Ranking Member

http://finance.senate.gov
Press_Office@finance-rep.senate.gov

Statement of U.S. Senator Chuck Grassley of Iowa
regarding the guest commentary titled "Grassley's War on Cancer Patients"
printed in The Wall Street Journal on Thursday, May 29, 2008

The vicious attack by Dr. Mark Thornton on the May 29 editorial page of the Wall Street Journal against my oversight of the Food and Drug Administration exploits cancer patients for greater drug company profits, and it would result in less information for all patients.

Readers should also know that those in charge of the Wall Street Journal editorial page did not require the author to disclose that he is the Senior Vice President of Product Development at GenVec, Inc., a company that stands to make a lot of money depending on FDA approval of therapies the company is developing for pancreatic cancer, rectal cancer, head and neck cancer, and melanoma.

In his Wall Street Journal piece, Dr. Thornton mischaracterizes and protests my asking the Government Accountability Office to determine if the FDA is carrying out its own policy of requiring follow-up studies on pharmaceutical drugs that have been approved based on surrogate end points. This means that the FDA may approve a drug if the drug achieves something specific like slower tumor growth, controlled glucose levels or lower cholesterol, separate from whether the drug will help a patient live a longer or healthier life. Surrogate end points are a valid way for the FDA to approve drugs. The FDA's policy to follow up on such approvals is designed to provide additional information about a drug's performance for anyone who is using or considering a particular drug.

In recent years, many leaders in the field of medicine, including the Institute of Medicine, the New England Journal of Medicine, and the Journal of the American Medical Association, have concluded that the FDA's post-market surveillance of pharmaceuticals is inadequate and needs reform. My own scrutiny found the same in many cases. The diabetes drug Avandia lowers blood sugar levels but has also been found to increases the risk of a heart attack. The drug Vytorin lowers cholesterol but does not improve a person's cardiovascular health. My recent request for an independent review of the FDA's performance with follow-up studies on surrogate end point approvals is not part of a conspiracy to slow the approval of cancer drugs, as suggested by a drug company doctor. It is an effort to strengthen post-market surveillance by the FDA, to make the relationship between the FDA and drug makers less cozy as there's been too much collaboration in addressing post-market concerns, and to see the FDA be more

forthcoming with information about drug safety and risks after drugs are on the market and more becomes known about them than can ever be learned from clinical trials or smaller-scale testing.

For cancer patients and others, follow-up studies on drugs approved through the surrogate end point method would give them more information about the drugs they're taking. What's wrong with that? A cancer patient deserves to know if his therapy slows tumor growth but doesn't extend life expectancy. A diabetic deserves to know if his prescription controls glucose levels but increases his risk for a heart attack. A heart patient deserves to know if his medicine lowers cholesterol but doesn't change his cardiovascular condition. The decision to take a particular drug is personal, and people have the right to the whole picture.

Drug makers and drug developers violate the public interest when they work to muzzle the scientific process and fight disclosure of newly emerging information about various pharmaceuticals in order to drive up their sales and profits. Everyone wants new life-enhancing and life-saving therapies. Cancer patients and others deserve to have information in order to weigh the risks, benefits and unknowns for themselves. The FDA is responsible for developing this information and making it available. Congress is responsible for overseeing the FDA's effectiveness, and that work has to continue despite attacks on editorial pages, even those attacks that are discredited by conflicts of interest.