

As if read into the record

Statement of Senator Charles E. Grassley
Before the United States Senate
Manipulating Science
January 30, 2008

SPEECH ON DRUG SAFETY

Mr. GRASSLEY: Mr. President, last May, Senator Baucus and I began investigating GlaxoSmithKline regarding their diabetes drug, Avandia.

We began this investigation when Dr. Steve Nissen at the Cleveland Clinic published a study in the New England Journal of Medicine.

That study found a link between Avandia and heart attacks.

Shortly after we began our investigation, Dr. Scott Gottlieb, a former deputy commissioner at the Food and Drug Administration, wrote an op-ed in the Wall Street Journal.

In that article, he insinuated that congressional investigators had obtained a copy of the Nissen study before it was published.

Dr. Gottlieb suggested that this action called into question the integrity of both congressional investigators and Dr. Nissen.

Well, congressional investigators did NOT get a copy of the Nissen study until it became public. But you can imagine my surprise when I learned that one of GlaxoSmithKline's own consultants leaked a copy of the study to GlaxoSmithKline weeks before it was published.

The man who did this is Dr. Steven Haffner. He confirmed to my investigators that he faxed a draft of the study to GlaxoSmithKline weeks before it was published.

The New England Journal of Medicine picked Dr. Haffner to peer review the study submitted by Dr. Nissen. That means that Dr. Haffner was supposed to check the study for quality.

He was not supposed to pass it back to GlaxoSmithKline.

Not only did Dr. Haffner breach his agreement with the New England Journal of Medicine to properly peer review the Nissen study, but he violated practically every tenet of independence and integrity held sacred by the major medical journals.

Dr. Haffner told my investigators that GlaxoSmithKline did not ask for an early copy of the Avandia study.

But the question still remains about what the company did once they had the study. Maybe GlaxoSmithKline's executives returned the study to Dr. Haffner.

Or maybe they contacted the New England Journal of Medicine to report this violation of publishing ethics.

I don't know, but I have sent GlaxoSmithKline a letter asking how they behaved after Dr. Haffner leaked the study to them.

But the most troubling aspect of this situation is that the integrity of another aspect of the scientific process is called into question - scientific peer review.

This process ensures that other scientists will judge a study's quality before it is made public and becomes used as a marketing tool.

It is only good quality science that separates modern pharmaceuticals from old fashioned snake oil.

Over the last few years, my investigations have found that the Food and Drug Administration has a very cozy relationship with drug companies.

I have also discovered that drug companies spend big bucks to influence which drugs doctors prescribe.

Finally, I have shown that some drug companies intimidate scientists who speak up about bad drugs. Now it appears that even peer reviewed science is not completely without its own problems.

Before I close, I would like to ask unanimous consent to enter into the record my letter to GlaxoSmithKline.