DRUG SAFETY

Mr. GRASSLEY. Mr. President, I wish to speak for a short period of time on another issue that I have been working on.

Yesterday, the Journal of the American Medical Association published a study on the diabetes drug Avandia. This study concluded Avandia significantly increases the risk of heart attacks, a subject that Senator BAUCUS and I have been investigating for some months. You will remember that it was back in May that a study in the New England Journal of Medicine first alerted the public of an increased risk of heart attacks from Avandia.

When that study was published, Senator BAUCUS, chairman of the Senate Finance Committee, and I raised concerns that the drugmaker had sought to silence a critic who voiced apprehension about Avandia back in 1999. Remember, this is 8 years ago. At the time, SmithKline Beecham manufactured Avandia. The company later merged with Glaxo Wellcome to form today's GlaxoSmithKline.

According to the Wall Street Journal, GlaxoSmithKline said the allegations that the company silenced critics of Avandia were ''absolutely false.''

Today I would like to discuss some internal company communications that suggest otherwise. The person who first blew the whistle about cardiovascular problems with Avandia was Dr. John Buse. He was a professor at the University of North Carolina.

Shortly after Avandia came on the market, back in 1999, Dr. Buse began warning his colleagues at medical meetings that the drug might be dangerous.

How did this company respond when this professor brought up these issues? In an e-mail dated June 25, 1999, two company executives discussed ways to silence Dr. Buse. I would like to read parts of the e-mail. One executive wrote of a plan to ''write him a firm letter that would warn him about doing this again . . . with the punishment being that we will complain up his academic line and to the CME granting bodies that accredit his activities.''

CME stands for continuing medical education. I will come back to that in just a second.

In response, another company executive e-mailed back, proposing to sue Dr. Buse and launched a media offensive promoting Avandia.

Based on this e-mail exchange, it seems to me that at least two drug company officials did attempt to silence a critic. In fact, Dr. Buse stopped making any critical statements about Avandia shortly after this e-mail exchange. Scientists should be able to raise issues related to public health and safety in a free and uncensored manner, not the way they do things in China. And when these scientists are suppressed, we ought to consider that a very serious problem. The reason why is because the scientific process will take care of itself. If scientist Grassley has a suggestion and you think it is crazy, you are a scientist, my work can be reviewed by you and it has to stand the test of peer review. So I think it is a very good process, and if we just let it go on, it will show whether this scientist or that scientist is right or wrong.

The scientific process, if suppressed, I say, is a very serious problem. But more important in this whole process, the American public loses. Instead of Avandia being more critically examined for safety, it was heavily marketed and became what experts have called the best selling diabetes drug in America. It has been reported to me that this huge volume of sales may have resulted in 60,000 to 100,000 heart attacks from 1999 until the year 2006—that is about 20 a day—from the users of Avandia.

What happened to the company executives who sought to attack Dr. Buse for voicing his scientific opinion? Based on the information I have received to date, nothing has happened to these corporate executives.

Let me return to the issue of continuing medical education. In the e-mail exchange I quoted, the two company officials discussed complaining about Dr. Buse to the accrediting bodies of continuing medical education. Every year, medical professionals must get continuing medical education credits to stay current in their profession. The continuing medical education companies and the doctors who teach the classes are supposed to be independent of drug companies that fund the courses. But I think we now know what we have often suspected: Continuing medical education courses often are not independent at all. In fact, the drug companies have a lot to say about what goes on in these courses and who gets paid to teach them.

In April, the Finance Committee staff released a report on pharmaceutical company support of continuing medical education. Drug companies pour about $1 billion every year into continuing medical education, and the report noted that some educational courses have become veiled forms of advertising.

Of course, this also ties in to last week's introduction of the bill I submitted called the Physicians Payments Sunshine Act. I introduced that bill with Senator KOHL, who is chairman of the Aging Committee, because Americans have a right to know how the drug companies are using money to try to shape the medical field. The bill requires drug and device companies to report payments and other gifts they give to doctors, bringing a little transparency to the practice of companies such as GlaxoSmithKline. I hope to see more of my colleagues sign on to this legislation. I cannot spotlight every instance where a drug company goes after an independent scientist with a stick, as they did with Dr. Buse, but together we can splash some sunlight on the financial carrots drug companies use to try to shape doctors' behavior.

Before I yield the floor, I ask unanimous consent to have the e-mails I referred to printed in the RECORD.

There being no objection, the material was ordered to be printed in the RECORD, as follows:

From: Tachi Yamada
To: William D Claypool
CC: David M Stout, Jean-Pierre Garnier
Subject: Re: Avandia Renegade
Date: 06/25/1999 19:15:33 (GMT–05:00)

BILL: I spoke to both JP and David Stout today about this situation. I doubt that speaking to his chairman about him will do much good—in fact if he's as bad as he seems to be, his chairman probably already has doubts about him. In any case, I plan to speak to Fred Sparling, his former chairman (they are actively looking for his replacement) as soon as possible. I think that there are two courses of action. One is to sue him for knowingly defaming our product even after we have set him straight as to the facts—the other is to launch a well planned offensive on behalf of Avandia so that the listeners begin to understand at the very least that there are two sides to this story. I suspect that the latter approach would be preferred—it wouldn't look good for SB to be at war with a KOL.

TACHI.

William D Claypool on 25–Jun–1999 12:23
CLINICAL RESEARCH AND DEVELOPMENT
To: Tachi Yamada
Subject: Avandia Renegade

TACHI: At Avandia Day today, mention was made of John Buse from UNC who apparently has repeatedly and intentionally misrepresented Avandia data from the speaker' dais in various fora, most recent among which was the ADA. The sentiment of the SB group was to write him a firm letter that would warn him about doing this again (he will be speaking next at a major European congress in Stockholm in July) with the punishment being that we will complain up his academic line and to the CME granting bodies that accredit his activities. There was brief mention of a law suit but this was reserved for a later approach. The question comes up as to whether you think this is a sensible strategy, whether you know any of the principals at UNC (I don't), and whether we have other avenues to ensure his accuracy in the future (we don't really do too much work at UNC to make any threats)? I imagine that Paul Wadkins is too new in post for us to ask him to exert any influence on our behalf at his new institution.

Any thoughts?

Thanks.

BILL.

Mr. GRASSLEY. I yield the floor, and I suggest the absence of a quorum.

The PRESIDING OFFICER (Mr. CASEY). The clerk will call the roll.

The assistant legislative clerk proceeded to call the roll.

Mrs. MURRAY. Mr. President, I ask unanimous consent that the order for the quorum call be rescinded.

The PRESIDING OFFICER. Without objection, it is so ordered.

VA WAIT TIMES

Mrs. MURRAY. Mr. President, I rise today, after two days of testimony by General Petraeus and Ambassador