International Serious Adverse Events Consortium

On September 27, 2007 seven pharmaceutical companies announced they have formed the International Serious Adverse Events Consortium. The results from Their first study will be released in about a year which will include Stevens Johnson Syndrome. The article states they have DNA samples from at least one pharmaceutical firm on Stevens-Johnson Syndrome and a related skin condition known as toxic epidermal necrolysis. There has been much controversy and speculation as to the agenda of this group within the SJS support group communities, with good reason! Below is the link to the article that appeared In the Wall Street Journal, and a response from Wyatt Buchanan, SJS patient. The SJS Foundation has not been contacted by the consortium.

http://online.wsj.com/article/SB119085484716840809.html?mod=googlenews_wsj

Below is a letter written by Wyatt Buchanan

Ms. Corbett- Dooren,

I am writing an open letter to you for consideration of publishing in the Wall Street Journal

As an SJS sufferer and on behalf of the many worldwide SJS/TENS sufferers I am deeply concerned with the announcement yesterday by Abbott Labs, Glaxo Smith Kline, Johnson & Johnson, Pfizer, Roche Sanofi-Aventis and Wyeth at. al., announcing a two year study looking to establish a genetic casual link to SJS/TENS.

This is problematic on multiple levels. This announcement smacks of an attempt by these companies to avoid product liability. If the problem with their medications is genetic and has nothing to do with their product they have an argument for a release form liability for the problem lays with the patient not their medications.

When company's which are involved in litigation over their product liability, such as the company's noted above, fund research which could allow them to disallow claims because of a genetic predisposition and whose findings no one else will have a chance to monitor, or have input into, this constitutes a serious conflict of interests.

"A person has a conflict of interest when the person is in a position of trust which requires him/her to exercise judgment on behalf of others (people, institutions, etc.) and also has interests or obligations of the sort that might interfere with the exercise of his/her judgment, and which the person is morally required to either avoid or openly acknowledge".

The American Bar Association specifies as part of a general rule on conflict of interest

that

"A lawyer shall not represent a client if the representation of that client may be materially limited by the lawyer's responsibilities to another client or to a third party, or by the lawyers own interests, unless: 1) the lawyer reasonably believes the representation will not be adversely affected, and 2) the client consents after consultation". ABA 1999

The news article states that they have already selected their focus to be "tissue samples housed in two Britain-based academic institutions, and information and DNA samples from at least one pharmaceutical firm". Who are these institutes and do they get their research monies from any of the companies named? Most of these research institutes are universities whose entire medical/biological departments are funded by large pharmaceutical companies. Often the "studies" you hear about coming from these universities are preparatory studies for the release of a new drug that pharmaceutical company is going to release in the near future.

Here are the caveats form just five popular drugs currently on the market. "Side effects may include unpleasant taste, headache, drowsiness and dizziness"," Common side effects are headache, indigestion, back pain, muscle aches, flushing, and stuffy or runny nose." "Sudden decrease or loss of vision in one or both eyes", "can cause serious muscle problems that can lead to kidney problems, including kidney failure.", "side effects include headache, constipation, diarrhea, gas, upset stomach and stomach pain, rash, and muscle and joint pain". "Certain sexual side effects may occur such as impotence and loss of sexual desire, women should not handle (redacted) due to the potential of a specific birth defect. Can they really blame genetics for all of this? Especially since by their own statement they causally link the last drug mentioned to a specific birth defect.

Drug company's not adequately validating their own data or under reporting their own data results has lead to many drugs being pulled form the market. Are we too simply to accept the drug company's assertions? Will the overworked, under-funded agencies responsible for monitoring these findings challenge these findings or accept them Carte Blanche as they historically have?

The two-year test data they propose of subjects in Brittan could never be a broad enough sampling base to state conclusively that any one genetic marker is capable of producing SJS in the whole spectrum of people. This does not take into account social cultural or environmental differences between people groups on different continents. It does not take into account the differences between classes of drugs that although similar vary significantly in formulation (I.E. Celebrex, Vioxx and Bextra, all Cox 2 inhibitors, 2 pulled and later readmitted with black box warnings and one pulled completely). Where was the FDA when this occurred?

Further the human genome and its interaction to various chemical substances is not sufficiently known to make the kind of broad and sweeping categorizations that they propose.

The Muscular Dystrophy Association with BILLIONS of dollars in funding for nearly 30 years have not found the cure for any of the neuron- muscular diseases, let alone find one single medicine that addresses each one of the genetic predispositions for such. If this International Serious Adverse Events Consortium, using the limited study they propose, can isolate one gene and say that this gene predisposes all patients possessing this gene to trigger SJS when exposed to any of the medicines they manufacture then they will have done in 2 years on millions what the MDA has not been able to do in 30 years on billions. This is preposterous because the advanced state of genetic research has not made those kinds of quantum leaps in understanding yet.

I therefore place a challenge before these drug companies funding this study, if they wish to preserve the integrity of this study, that firs;, they utilize only those institutes they do not fund either directly or indirectly, to do this study and further that they disallow their own data form the mentioned pharmaceutical company in the article.

To preserve the integrity of the study and its conclusions this research must be done in the most open and transparent way by universities and research facilities which do NOT get their funding from endowments by any of those company's. Failure to do this is a conflict of interest of the first order.

Secondly, if they persist on moving forward and doing this without these kinds of adequate controls then the SJS community and the National Trial Lawyers Association should immediately call upon the US FDA and the National Institutes of Health to invalidate their findings and conclusions. You simply can not put foxes in charge of the chicken coop and say they chickens have nothing to worry over. This type of conflict of interests is akin to police investigating the police, the Republicans investigating the Republicans or the Democrats investigating the Democrats.

Lastly, I propose that the SJS Foundation and the worldwide SJS community petition for representation from all stakeholders affected by this study. Unless there is a mutual representation from responsible government authorities, genetic medical experts form the legal community, independent research universities as well as those directly affected by this syndrome there can be no impartial findings in this matter.

They could say what they want and there will be no one to stop them.

Respectfully,
Wyatt Buchanan
NY
Diagnosed SJS suffer since 2002