

# THE DRINNON LAW FIRM PLLC

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RE: *Avandia MDL Litigation Update*

Dear Client:

As always, we hope this status letter finds you well. A significant amount of activity has occurred since our July 8, 2010 letter to you regarding the Avandia litigation.

## **First Trial Postponed**

To begin, the Avandia case previously scheduled for trial this month has been continued. Judge Cynthia Rufe previously entered an order setting the trial for October 5, 2010. However, Defendant GlaxoSmithKline filed for a continuance, which was granted by Judge Rufe on September 15, 2010. A new trial date has not been rescheduled.

Although the new trial date is yet to be determined, the first case currently scheduled to be tried within the federal MDL is *Burford v. SmithKline Beecham Corporation*. This case was selected by the Plaintiffs' Steering Committee, and the Defendants will be allowed to designate the subsequent case for trial.

As a result of the continuance, other pre-trial rulings have been postponed as well. Among the most significant of these rulings will be the Court's decision pertaining to the parties' expert witnesses who have been designated to testify at trial. The Defendants have objected to, among other things, the admission of testimony by Plaintiffs' designated experts Judy Melnick, M.D., Allan D. Sniderman, M.D., Joshua Septimus, M.D., Peter Rost, M.D. and Stephen S. Lippman, M.D. The Plaintiffs have a significant objection pending, requesting the Court to exclude testimony of any defense expert which relies on the so-called Record Study conducted by Glaxo. As discussed below, the FDA's recent ruling on the Record Study may have some impact upon the Court's decision.

## **FDA Ruling**

Apart from the trial proceedings, you may recall from the last status report that the FDA was scheduled to have an open debate on July 13-14, 2010 to

determine whether Avandia would remain on the market in the United States. The debate took place and, while the FDA ultimately voted to allow Avandia to continue to be sold in the United States – with some severe restrictions – the decision was not without controversy. Moreover, European regulators voted to ban the sale of Avandia in Europe.

The FDA advisory panel convened in July and, after reviewing the safety risks of the drug, voted on whether GlaxoSmithKline (“Glaxo”) should be allowed to continue selling Avandia. The votes of the advisory panel were as follows:

- Twelve votes to remove Avandia from the market
- Ten votes to continue sales of Avandia, but with a revised warning label and possible sales restrictions
- Seven votes to continue sales with additional warnings, and
- Three votes to keep Avandia on the market without any additional warnings or restrictions

Subsequent to the panel’s recommendations, however, it was discovered that David Capuzzi, an endocrinologist who has been a professor at Thomas Jefferson University in Philadelphia (where Glaxo is headquartered), earned \$3,750 as a speaker for Glaxo in 2009. It was also later reported that Capuzzi had earned \$8,000 from Glaxo in 2008 for similar speaking engagements. This had *not* been disclosed to the FDA prior to the convention of the advisory panel, and Capuzzi was one of the panelists who defended Avandia during the debate. Ultimately, the FDA referred the matter to the Health and Human Services Office of Inspector General. To date, we are unaware of any findings or ruling by the Inspector General.

Following the panel’s recommendations and the disclosure of the Capuzzi conflict, the FDA issued its ruling. Although Glaxo will be allowed to continue marketing Avandia in the United States, the FDA’s latest restrictions are severe. In addition to the “black box” warnings already in place, in order to prescribe Avandia to new patients, doctors now will have to (i) certify that the patient has tried and failed on other medicines before they prescribe Avandia, and (ii) the doctor must warn patients about heart attack risks. Patients will have to sign a document saying that they understand the risks before receiving a prescription for Avandia.

In addition, the FDA ordered Glaxo to halt a study that it was conducting, in which Glaxo was attempting to compare Avandia to Actos, a drug manufactured by competitor Takeda Pharmaceutical Co. The FDA also ordered

Glaxo to reanalyze the company-funded "Record Study," because the FDA found that the Record Study was flawed and that Glaxo may have undercounted the number of heart attacks among people taking Avandia. Glaxo had conducted and funded the Record Study on its own, and has relied on the results to tout the safety of Avandia.

It would seem reasonable that the FDA's criticism of the Record Study would be taken into consideration by the Court in conducting its analysis of whether to allow defense expert testimony. Clearly, the FDA regards the Record Study as flawed, which should cause the Court to seriously question its reliability as a basis for allowing expert testimony at trial.

As for the restrictions issued against Glaxo regarding Avandia, even those experts who have vigorously argued for a total ban on Avandia sales seem pleased with the outcome. Dr. Steven Nissen, speaking of the FDA actions, was quoted in the *Wall Street Journal* as saying "I think it's a reasonable course of action. It will limit 99% of its use." A copy of the *Journal* article is enclosed for your review.

<http://online.wsj.com/article/SB10001424052748703384204575509832210269228.html>

As you may recall Dr. Nissen first came under fire with the medical community in 2007 when he published his findings about the efficacy of Avandia in the *New England Journal of Medicine*. Since coming under attack in 2007, the *Wall Street Journal* reported that Glaxo's Avandia sales have fallen from over \$2 billion to less than \$500 million worldwide.

### Settlements

In the letter we sent to you last July, we mentioned that there had been media reports of settlements by Glaxo with various groups of state lawsuit plaintiffs. However, the terms and amounts of the purported settlements have not been confirmed, and the media reports have been somewhat vague. Until we are able to confirm through reliable sources the terms of the reported settlements, we remain cautious in assuming the accuracy of the reported amounts. We will continue to monitor news of settlements and, if and when we are able to confirm the terms thereof (as they may be subject to confidentiality provisions), we will provide you with that information.

As we have pointed out in previous correspondence to you, the most important challenge concerning an Avandia personal injury case involves the question of whether or not there is sufficient scientific evidence to prove that

Avandia causes heart attacks, strokes, death and/or cardiovascular disease. In addition, scientific evidence in a pharmaceutical case necessarily revolves around the medical symptoms and conditions experienced by each individual or their loved ones which makes detailed medical records important. With your continued help in acquiring medical records, we will be able to support our scientific theories as best we can, which we hope will in the end hold GSK accountable for putting their profits over your safety and the safety of your loved ones.

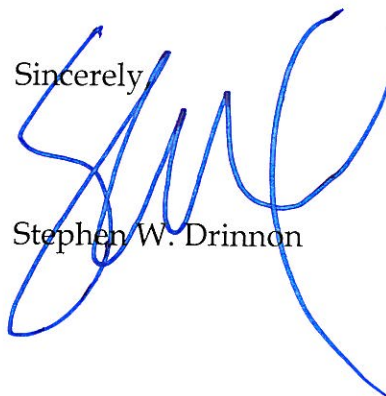
### Safeguarding Records

As we always remind you, it is important that you not destroy any files or documents in your possession related to Avandia. This includes emails (either from you or to you), information from WebPages that you may have visited, blogs you may have written or read, or any other electronic information. If you have any questions on what you need to keep, please contact our office. Moreover, in the unfortunate event that you have to declare bankruptcy, please make sure to bring your Avandia claim to the attention of your bankruptcy attorney. Failure to disclose your case as an asset in bankruptcy proceedings can have serious consequences.

Please feel free to contact attorney Philip Green with any questions you may have. Additionally, you are welcome to call me at any time or my paralegal, Roxana Murray. If we are unavailable, leave a message and we will get back to you promptly.

We appreciate your continued patience and the confidence you have expressed in our firm to handle your Avandia claim. Your claim is very important to us. As always, we are glad to hear from you when you have a change in circumstances, change in contact information, or simply questions. Also, please remember to keep us informed of any significant changes in your condition and to make certain that we have current contact information for you and current contact information for a close friend or relative. We may at some point be required to contact you with short or little notice and if we are unable to do so, the value of your case could suffer dramatically.

Sincerely



Stephen W. Drinnon