



Elizabeth Hart <eliz.hart25@gmail.com>

RE: Request for information re adverse experience reporting / possible conflicts of interest [SEC=UNCLASSIFIED]

Elizabeth Hart <eliz.hart25@gmail.com>

Wed, Apr 20, 2011 at 4:19 PM

To: "SUTER, James"

Cc: Bea Mies, Jenni Mack, Heather Yeatman, Sally

James, re your email below....

Is there any progress yet on your response to my questions, which was promised last week?

Also, in regards to my question as to why the APVMA boldly marks responses to adverse experience reports '**COMMERCIAL-IN-CONFIDENCE**'. I have heard anecdotal reports that pharmaceutical companies also demand that pet owners who are reimbursed for medical expenses after their pets experience adverse events after vaccination, or other veterinary product use, be bound by confidentiality agreements which gag them from discussing the matter openly.

Of course, it's difficult to find evidence of this, given the secrecy involved.... However, recently I discovered evidence on a Facebook page set up by pet owner Judy Schor. Judy is in the US and her dog Peaches suffered serious skin inflammation after a rabies vaccination.

If you are a member of Facebook, you can access the page here: <http://www.facebook.com/media/set/fbx/?set=a.1274778556713.2042916.1447415540>

Judy provides details of her experience in the attachment - 'Pet's Health Crisis'. Judy notes that Peaches underwent many vet visits and invasive tests, and she kept trying different vets to find a solution. One of the specialists consulted asked when Peaches had last been vaccinated but was not willing to suggest a relation between the vaccine and the skin condition. Judy finally found a senior veterinary specialist willing to acknowledge the likelihood of a Type III hypersensitivity response to some component of the rabies vaccine - see attachment - 'Penn Vet Medicine'. Approximately \$US12,000 was expended on diagnosis and treatment for Peaches' skin condition.

Also see attached a copy of correspondence from Fort Dodge Animal Health to Judy and her husband offering some compensation, and which also demands that the terms **"are to be held confidential, and shall not be disclosed to any person or entity under any circumstances other than to explain the factual circumstances giving rise to the claim in response to a direct enquiry from any State or Federal regulatory body..."** Judy and her husband did not accept Fort Dodge's offer. (I have Judy's permission to forward on the correspondence attached.)

I strongly suspect pharmaceutical companies in Australia may also have similar confidentiality caveats in place for their dealings with pet owners who report adverse events after the use of veterinary products. **Do you have any knowledge about this James?**

It is very alarming to discover the degree of secrecy involved with the reporting of adverse experiences. It seems it is the aim of pharmaceutical companies and government regulators (such as the APVMA) to keep these matters under wraps. Certainly this secrecy does not encourage confidence in the transparency and effectiveness of the adverse experience reporting system.

Can you please let me know when you will be able to respond to my questions?

Thanks
Elizabeth

[Quoted text hidden]

3 attachments



Pet's Health Crisis.pdf
25K



Penn Vet Medicine.doc
107K



Fort Dodge Confidentiality.doc
172K

