

# Attachment #3

Subject: Re: [ ]  
Date: 4/17/2003 9:40:05 AM Eastern Daylight Time

From: [ ]

>>> [ ] 04/17/03 08:38AM >>>

Dear DR

Was the information which DR Wagner (Genentech) relayed to your concerning the number of girls with TS using Nutropin Depot and any adverse conditions, the same registry you had repeatedly referred to as a registry you could obtain this information from namely NCGS?

\* Yes, I believe the information came from the NCGS registry.

Was any explanation given, as to why the long delay for their response to our previous inquiries?

\*\*There was no explanation for the long delay. I am fairly certain that it just seemed like too much trouble to the first two people I requested this from. One was about to leave the company; the other simply supplied the number of cases of diabetes reported in girls with Turners (2) but did not supply the info by product nor the number of Turner girls treated with Depot. I am not sure whether this was laziness (because that was the immediately easy info to retrieve), honest misunderstanding of my request, or ignorance of the availability of the specific info (because for most purposes of the registry the products are considered interchangeable). I don't think it was intentional withholding of info known to the people I talked to.

They relayed to me, from the onset, that no such information was available. They had no way of knowing for what subgroups of persons the drugs were being prescribed for. The only way they would have any knowledge for what a prescription was being used for, was when an adverse reaction occurred and a doctor informed them of the circumstances.

This is sort of true and sort of not true. The NCGS registry is funded by Genentech but maintained by an independent corporation. It is not a "company database" in the sense that they consider the info proprietary corporate secrets. The primary users of the database are prescribing doctors (i.e., those who submit the data). The most common uses of the database are related to responses to GH treatment; for instance, I might ask the NCGS whether any children with growth failure due to inflammatory bowel disease have been treated with GH and how well they responded, or I might ask what average mg dose is being used in Turner girls in the 12-14 year old age range.

The people you talked to might have been lying to you of course, but it seems more likely to me that the people who deal with patient and public complaints or inquiries are not the same people who are familiar with the contents of the database and must be constrained to a very limited number of legally approved answers to people's questions. Only a limited number of Genentech employees have access to the NCGS registry and many might not even know about it or what specific info was collected in it. They can claim that it is in fact not Genentech info at all since it is maintained by an independent corporation and most Genentech employees have neither the knowledge of it nor access to it.

I'm still following up on receiving a printout of all adverse reactions to Nutropin Depot reported to CDER. Am I correct in my recollection of our conversation regarding Genentech, that DR Wagner stated to you that their had seen one other reported case of Type1 diabetes reported from the use of GH, but the GH was not the Nutropin formulation?

\*\*That is my recollection also: two cases of type 1 diabetes in Turner girls, one on Depot ( ) and one on either Nutropin or Nutropin. The database had records of 66 Turner girls treated with Depot, and hundreds of Turner girls treated with other GH products. Around the world thousands of Turner girls have been treated with various GH products over the last 20 years. As you may recognize, these numbers are not large enough to prove that the diabetes risk is not slightly increased by GH treatment, nor do they prove that the risk of the different products is the same. They simply prove that the vast majority of Turner girls treated with any GH product do not get diabetes during treatment.

Thanks again for your assistance. [ ]

\*\*\*You're welcome.