Electronic Mail Message

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Date: 08/31/2001 9:37:48 AM
From: Anne Trontell TRONTELLA
Subject: Answer to Julie's comments on DHE proposal

Julie and Allen,

I believe the compliance targets need to be negotiated between HLR and Derm, with input/review by CDER senior mgt. OPDRA needs to be as quantitative as possible about what various compliance targets may imply in terms of pregnancy exposures. Allen and I need to work together to bring that to closure in terms of modeling contingencies and assumptions and then writing them up.

My reason for highlighting that the goals are not yet finalized is to remind Roche that the numbers are not yet set in stone and that their declaration of certain numbers in the context of protocols doesn't make them a matter of implicit FDA agreement. BTW, 90% tag use and 90% tag component compliance suggests a total compliance with label component of 81% just probabilistically, and that may not be acceptable to FDA.

The suggestion about having different people fill out the sticker is reasonable, but I think it complicates the issue unnecessarily. The primary point of the tag is for physicians to document PPP compliance. The Medguide (a pharmacist compliance issue) is a lesser compliance objective and one we get at least some handle from the Slone instrument. We may also be able to monitor that by other means than the pharmacist survey. I believe we will get better quality data if only one person, the MD, fills out the tag. I don't think it's that critical that the pharmacist get specialty info off the Rx. Roche could give them a list of docs and specialties based on their marketing data.

On a different metric note, I was stunned by the chart audit metric proposal that 3% of Accutane prescribers (the high volume PCPs) prescribe nearly 20% of Accutane scripts. (About $36 million in sales for HLR..) That's more than any dermatologic category. These high volume PCPs sound like they could be "acne mills" and so may deserve highly targeted educational and compliance checks.

BTW, in my opinion the chart audit metric is unacceptable for ethical as well as scientific validity reasons. We should get that message to Roche early next week after we discuss internally.

Anne

>Anne,
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>This is very nice. I had a couple of comments
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>1) What do you have in mind regarding compliance targets? Do you think they should/could be higher?

>2) With regard to your questions 3 & 16 about who would be answering
>which questions on the QT (e.g., re Medication Guides), I'd suggest