

## A PATIENT REPORTED OBSERVATION

*submitted for Network News by Cynthia Chauhan following the FDA Guidance Conference on Patient Reported Outcomes, February 23-25, 2006*

It has been my privilege to sit with you for two days observing and learning from how you as professionals view, interpret, relate to my reality. You are all obviously bright, well-intentioned, altruistic people who are concerned about patient wellbeing and I thank you from the bottom of my heart not just for myself but for all patients. I have watched you struggle with concepts and fight for opportunity and recognition.

I know a lot about struggling, fighting for opportunity, and claiming recognition. I happen to be a patient with multiple diagnoses related to each other only by the fact that they share my body and inform my life experience. They include two cancers, glaucoma, asthmatic bronchitis, idiopathic neuropathy and a few others. But you get the picture.

I want to respond to and perhaps invite you to reframe some of the issues I have watched you address and shy away from.

First of all, I do understand this is a conference about drug labeling and how to incorporate what the patient says s/he experiences as a result of using that drug in the labeling. You name that patient experience symptoms and you have spent a great deal of time differentiating or arguing against differentiating symptoms from HRQL much less QOL.

I understand the need for partializing in problem solving as long as one holds onto the knowledge that the whole is equal to and perhaps greater than the sum of its parts. In that context, I do not think symptoms can be separated from those two things, HRQL and QOL in the real world.

The symptoms with which I live, some illness induced, some drug induced, are real parts of my every day life and they do affect my quality of life. They affect how I go about my life and the expectations I can reasonably set on myself and others. However, it is equally important to note that the quality of my life affects my tolerance for many of those symptoms. So, an appropriate use of Jeff's hot flashes perceiver would be to use it to help women look at and consider what is going on in their external and internal environments when they do and do not notice the flashes.

Different symptoms affect me to different degrees, and something you did not address is that the hypothetical possibility of symptoms also affects me and choices I make about medications. I know you said that you deal in realities, by which I understand you to mean concrete and quantifiable, not hypothetical situations but hypotheticals do impinge on patients' realities. For example, I use a drug called bimatoprost in my left eye to forestall blindness from glaucoma. I have had sapphire blue eyes all of my life. One of the side effects of bimatoprost in blue-eyed people is turning of the iris to brown. On one level, it's a no-brainer that I will take the drug because going blind is worse than having a brown eye. On another level, there is emotional distress associated with potentially losing what has been a positively defining aspect of self. The eye color change may not qualify as a PRO but the distress does and it affects quality of life. I use this example to urge you to consider and be wary that you do not lose the whole person in your quest to give patient reported outcomes free-standing autonomy but understand they are an artificially extricated part of a complex whole.

On the other hand, I get seriously nauseated and somnolent when I take one of my pain medicines and experience cognitive deterioration when I take one of the others so that I will tolerate a great deal of pain before I resort to the medications because while they provide primary symptom control, their concomitant symptom inducement seriously compromises my quality of life.

Symptoms and quality of life are inextricably intertwined for the patient. If I were to do your balloon cartoon, I would put a large balloon for QOL holding a smaller inset balloon for HRQL holding yet a smaller one for symptoms. Or perhaps I would show multiple smaller balloons of symptoms attenuating and distorting the other balloons as they do our lives.

In your quest to differentiate and honor symptoms, I caution and urge you not to validate the ancient Indian tale of the nine blind men who sought to describe an elephant by each touching one part of the elephant. They did come up with interesting creative descriptions and observations which each held to as inviolably true. But, in fact, those observations did not translate to the reality of the elephant. No matter how much it wiggles, an elephant's tail is never a snake.