Quote from FDA: *In God We Trust, but everyone else bring data!*

Actually this quote is fictitious, but a good illustration that FDA can respond and make decisions only on data (good data).

**Labeling, Label Expansion, Label Changes:**

**Labeling:** FDA will limit any drug label according to the trial data that was provided to them.

**Examples:**

If a clinical trial was done involving a new drug as part of a combination, and the results were positive, the label can only describe use of the agent as part of the combination.

If a clinical trial was done involving a new drug as a sole agent, and the results were positive, the label can only describe use of the agent as a sole agent.

If a clinical trial was done involving patients in a second or third line setting, and the results were positive, you can label the drug only for second or third line use.

In other words, the label exactly reflects how the drug was studied in the clinical trial. Many things can change the effectiveness and safety of a drug.

**Label Expansion:** Drug companies often get new drugs approved in second or third line settings at first, and then do additional clinical studies to eventually/hopefully achieve first line use. This is a type of label expansion. Drug companies also do additional clinical trials to get the drug approved for different types of cancer. This is another type of label expansion.

**Label Changes:** As experience is gained in the use of any agent after it is approved (remember clinical trials only involve small subsets of the total population), new information about the drug is commonly added to a drug label. This information can be good or bad news about the drug. All this information is in the package insert.