

## Label Testing: Molehills from Mountains

In the recent discussions of label comprehension testing in the prescription to nonprescription switch process, most of the recommended actions have pointed toward, at some point, one large comprehension study. Here is an alternative line of thinking.

As in all good research, label comprehension testing depends heavily on the objectives that are set. Since every product is different, every switch is different, so it is risky to generalize. Given that, however, there appear to be three objectives that recur. They are:

1. Can consumers correctly decide whether the proposed OTC is appropriate for their use? (Self-selection)
2. Do consumers who are likely to use the new product understand the labeling directions for use, indication, etc.? (Comprehension)
3. Are those who definitely should not use the product aware of their non-candidacy status after reading the label? (Warning Comprehension or Heeding)

It is possible to address these issues in one large study or in two or three smaller ones. There will be instances in which a different population is needed to address each of them. There have been instances in which one or more of them are unnecessary.

With respect to self-selection, it seems clear that, with a cholesterol-lowering product, for example, the question of whether consumers can appropriately self-select is a crucial one, while in smoking cessation (and other symptomatic conditions), it is of much less relevance and may not need to be addressed.

Comprehension probably is needed in all switch cases, but comprehension among those who might actually use the product makes more sense than comprehension in a general population sample. Assuming appropriate self-selection criteria are met, it is probably wise to test comprehension within this group.

Note that it is relatively easy to address the self-selection and comprehension criteria in one study. Those who appropriately self-select can be asked the

comprehension questions. Those who do not appropriately self-select, either the ones who could use but say that they could not, or the ones who should not use but say they could, can be asked why, and even asked the comprehension questions if it seems logical to do so.

The warning objective is somewhat different, because warnings should be tested among those to whom the warning applies. In this testing, it may make sense to ask "would you use" rather than "could you use," because the objective is to determine what percent of an "at risk" group may use the product if it is switched. It is also vital to understand why these consumers respond as they do.

In warning studies, any percentage saying they would use the product is an indication of problems. Warning testing is one area where a control group – a comparator label – makes especially good sense. The comparator is an already approved label, existing in the marketplace, which contains the wording of the warning on the proposed switch product. It is blinded in the testing, so that the brand name does not influence results. By randomizing the "at risk" consumers into Test and Control cells, one can benchmark the percent who say "they would use" to a product that already exists. The reason this is vital is that consumers like to please interviewers in this type of testing situation, so a number of "false positives" are expected.

While label warnings can be tested in the one, big label comprehension study, it is probably wiser to test warnings separately, since the questions and populations differ so much. There also will be cases where it is wiser (and "cleaner") to test self-selection and comprehension separately.

To sum up, it is important to sort out the information needed, set the appropriate objectives, and conduct the number of separate "label comprehension" studies that make the most sense in a given switch situation.

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