



Health Claims: The Claim Substantiation Dossier

by *Risa Schulman, Ph.D.*

In this three-part series, we've been focusing on the process of designing health claims, including the elements of taking good science and using it well, capturing the science and the claims it can support by writing it down, and involving a multidisciplinary team to bring unity to the way the message is designed and used by all the departments involved in the launch. In this last installment, we'll take a deep dive into the last step: creating a claim substantiation dossier.

Writing a claim substantiation dossier is an opportunity to create a comprehensive guiding resource that serves a number of important purposes. First, it provides solid, written documentation of substantiation for claims defense—a very real necessity in this regulatory climate—and the peace of mind that comes with having it at the ready. It also serves as a go-to reference for all the departments involved in labeling, writing marketing pieces, designing message points, pitching at trade shows, etc., ensuring a consistent and strong overall product presentation. Lastly, having the state of the science described provides a jumping-off point for planning new research, products and business development. An added benefit for ingredient suppliers: a modified version can serve as an outstanding value-add for customers, presenting the ingredient's story and potential powerfully, reassuring them of its validity, and providing them a resource for their own substantiation that goes beyond journal abstracts.

So how does the document actually look? If you've gathered the scientific substantiation and have been writing it down, and have designed your claims with the input of the various interests on the launch team, you have your raw materials well in hand. The dossier should be designed in such a way that it clearly lays out the pertinent information. For example, it should:

Name the exact ingredient/food/extract that is the subject of the dossier.

Define the intake level to which the claims pertain, as derived from literature.

List the claim(s) and categories of claims (e.g. heart health and energy claims for the same ingredient) and

all wording variations, as derived from the literature and the input of the team, taking into account an analysis of current thinking, the regulatory climate, public opinion and competitive positioning.

Provide pertinent scientific background on the ingredient, the health area it is affecting or the specific value-adds of the ingredient.

Cite and detail the papers that substantiate the claim(s), summarizing them concisely while also in context, and with the necessary detail to understand the specific substantiation.

Include the full spectrum of the literature, including epidemiological, intervention, pharmacokinetic, dose response, animal and in vitro studies describing mechanism, as well as meta-analyses, reviews articles and case studies.

The ideal person to write the dossier should have a good working knowledge of science, regulatory and marketing; barring that, it can be a jointly produced document. Another note: the Dossier should be viewed as a dynamic document. New research or regulatory twists should be incorporated and distributed on a periodic basis.

The clarity and effectiveness that comes with the completion of a claim substantiation dossier in this way shines through in how the team works with, talks about and sells the product. A little effort early in the product development process pays off long term. □

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