

The “Disclaimer Statement” - FDA’s Mantra of Irresponsibility

We have all seen this statement. It is on supplement labels and at the bottom of any product that may state a structure or benefit claim for its use. The verbiage we are talking about is **“this statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease”**. Just exactly what does this statement mean- that the product doesn’t work? That it hasn’t been studied? What do you think about when you read this? Essentially, we are dealing with FDA’s mantra of irresponsibility.

History of the “Disclaimer Statement”

Usher in the Bill Clinton Years and we can find the [Dietary Supplement Health and Education Act](#) (DSHEA) of 1994 where the “Disclaimer Statement” first appears. Because of a manufacturing glitch and the notorious “tryptophan” scare where hundreds of people became ill from contaminated tryptophan supplement pills, a task force was engaged subsequent to this tragedy whereby it was recommended that FDA maintain tighter control of the supplement and health claim industry. It was out of the DSHEA Act that the “Disclaimer Statement” emerged.

Enter the Industry Lobbying

The [industries](#) became heavily involved in the passage of the DSHEA Act and claimed that supplements could be taken off the market if the act were passed in the format the task force had advised thus scaring the public that they might lose their right to buy nutraceuticals. The voices of the industry grew stronger and the words of the DSHEA act became softer. This created a division between how drugs and supplements or health claims were treated.

The stricter regulations the task force had recommended for the FDA gave way to the allowance of “structure and function” claims for health products. Drugs would still have to follow FDA’s regulatory pathway which included animal testing, clinical trials, pre-marketing evaluations, safety protocols, etc. while structure and function claims would be allowed. Health claims of any other nature need be followed by the “Disclaimer Statement” the same as structure and function claims.

What are Structure and Function Claims?

A [structure/function](#) claim describes the role of a substance intended to maintain the structure or function of the body. This type of claim is not required to have FDA approval but still requires

the “Disclaimer Statement”. A health claim, on the other hand, needs to go through the rigors of the FDA and be authorized by them before it can legally be present on the label or be used in advertising of any health care treatment, and then, it also must carry the “Disclaimer Statement”.

It is a signal to consumers that they must determine for themselves if a therapy is effective or not and essentially FDA's way of showing a lack of responsibility for any claim made that bears this “disclaimer statement”. For example, it is ok to say that vitamin C supports a healthy immune system but not ok to say that vitamin C cures colds. Or, a product promotes healthful cholesterol levels but not that it lowers it.

Does a Disclaimer Statement Mean You Can't Trust the Claim?

No. A disclaimer statement only means the information was not provided to the FDA for evaluation of the safety and effectiveness of the claim being made. The claim may be backed up by animal or human studies and very well may be true but has not gone through the expensive rigors of FDA evaluation in a manner that a pharmaceutical drug would go through.

On the other hand, making any claim without evidence or oversight opens the door for charlatans to misuse information and fool an unwitting public. Even so-called “qualified health claims” supported by clinical evidence must be accompanied by the “Disclaimer Statement” leaving it up to the consumer to determine the level of evidence present to verify the claim being made. Basically the “Disclaimer Statement” is FDA's way of taking no responsibility for the claim, true, or not.