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SPECIAL EDITION: INFLAMMATION

Study designs looking at chronic inflammation are attractive for researchers, tricky for marketers

By Hank Schultz, 16-Nov-2015

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Designing a study on a product that can influence inflammation that can subsequently be used directly to support a marketing plan is a delicate operation. It can skirt dangerously close to a disease claim.

Inflammation has been recognized as an underlying aspect of many disease conditions, and so talking about quelling inflammation directly has over the years been treated as a de facto as the sort of claim that might get your product listed as a new, unapproved drug by the Food and Drug Administration.

"During my time at the agency, inflammation was always considered a disease claim," Corey Hilmas, MD, PhD, senior vice president of scientific and regulatory affairs of the Natural Products Association said at an industry event in September in Boulder, CO.

That being said, there have been few warning letters that have cited treating inflammation per se. Taking the extra step of claiming to treating the underlying inflammation that causes a patient's arthritis, Alzheimer's disease or whatever clearly steps over the line. But given FDA's often cited dearth of manpower and competing enforcement priorities, claiming to dampen down chronic inflammation itself seems at the moment seems to be merely standing on the precipice of an illegal disease claim.

Unrestricted research

These fine regulatory distinctions have not restrained independent researchers in the field in any way. Natural products researchers have, for example, been furiously researching the effects of curcumin in quelling chronic inflammation. A cursory search on the Pubmed database maintained by the National Institutes of Health brings up 874 references for 'curcumin and inflammation.' The same is true but even more so for the effects of omega-3 fatty acids and their effects on chronic inflammation. The same search on Pubmed using the terms 'omega-3 and inflammation' brings up 2,332 results.

For researcher Bill Harris, PhD, of the University of South Dakota medical school, (Harris is also the president of OmegaQuant) the issue is not so much the study design as what one chooses to say about it. The "E" portion of DSHEA stands for education, after all, and in Harris's view the research shouldn't be stuffed into a narrow bottle just to satisfy regulators. For instance, a study that Harris conducted recently in conjunction with Ann Skulas Ray, PhD, of Penn State University (more on her later) looked at DPA, the 'third leg' of the omega-3 triangle and its effects on inflammation. *"The associations between RBC n-3 DPA, CRP, and fasting TG may have important implications for the prevention of atherosclerosis and chronic inflammatory diseases and warrant further study,"* the authors wrote.

"It's all about how you market it. What you say about it. You certainly can do the study," Harris told NutraIngredients-USA. "At the end of the day the company will want to use the information in their marketing. They can't say it's for treating disease, but they could say it can reduce inflammatory markets. Inflammatory markers are not disease."

Disease claim handcuffs

Attorney Justin Prochnow, a shareholder in the law firm Greenberg Traurig, was not as sanguine as Harris about a firm's ability to day any study it wants. Certainly there is not stricture against the free flow of ideas in the pure research realm, but the trick is trying to connect those dots with those that appear in a company's marketing plan.

"It's a difficult proposition. The reality is that you are confined to studies about supporting a healthy inflammation response. It is really about inflammation as a result of some stimulus," Prochnow said.

This makes it difficult to use information about an ingredient's effects on chronic inflammation. And in truth, that mimics the ambiguity among researchers as to where chronic inflammation fits in the disease development pathway. It is a causative effect, or an associated condition?

Prochnow said the takeaway for the marketers of inflammation products when planning their research strategy is not much different than for other health conditions that natural products might seek to address. If a company wants to stay on the right side of FDA and FTC, it makes sense to make the study design and the information a company chooses to share about the study match as closely as possible to the planned claim.

"In the inflammation context I would focused on doing a claim on inflammation connected with some input, such as exercise," Prochnow said. This is a similar positioning to that taken by companies marketing immune health ingredients. Those companies have chosen to look at otherwise healthy populations facing some sort of immune health challenge, such as marathon runners or medical students spending sleepless hours studying for board exams.

"It's really important to have whoever is designing the study protocol have a solid scientific background," Prochnow said.

Harris said studies with disease treatment overtones could still be useful if a company confines itself to communicating only certain information about those studies.

"You could say we did a study with our product with these kinds of patients and we found their CRP level wen from this level to that level. We are looking at circulating levels of these biomarkers. We know for example that a higher omega-3 index is correlated with lower levels of these biomarkers. None of that is disease specific.

Inflammation forum

Ann Skulas Ray, PhD and Corey Hilmas, MD, PhD, are among four panelists offering insights in NutraIngredients-USA's online Inflammation Forum, scheduled for broadcast on Thursday. To register, [click here](#) .

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