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ConAgra's Petition For Whole Grain/Diabetes Claim Draws Opposition

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Experts and competitors raise doubts about a **ConAgra Foods Inc.** citizen petition that seeks FDA approval of a qualified health claim linking consumption of whole grains and reduced risk of type 2 diabetes.

Though any authorized claim likely would include a disclaimer softening the stated health benefit, ConAgra's request may test how far FDA is willing to bend on a QHC, in the wake of a recent First Amendment case that rejected the agency's handling of a separate QHC.

ConAgra in January petitioned FDA for the ability to claim that consuming three daily servings - 48 grams total - of whole grains may reduce the incidence of type 2 diabetes. According to 2010 data from the Centers for Disease Control and Prevention, diabetes affects 25.8 million Americans and about 79 million citizens aged 20 years or older are prediabetic.

Since type 2 diabetes “is a leading health problem for adults in the U.S., dietary strategies that incorporate increased consumption of whole grains and whole grain products are likely to have a significant and substantially positive public health outcome,” the food company said in its Jan. 25 petition.

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Omaha, Neb.-based ConAgra markets packaged foods including *Orville Redenbacher's* popcorn and *Chef Boyardee* pasta that tout whole grain content. The company likely foresees a sales boost from the ability to claim its foods help reduce diabetes risk, though any firm could use the QHC if FDA approves ConAgra's petition.

ConAgra acknowledged it expects increased consumption of whole grains to come with the authorization of such a QHC, but declined to estimate an amount.

The Whole Grain Story

Kellogg Co., a packaged foods competitor that plays up the bran rather than whole grain content in *Raisin Bran* cereal and other high-fiber products, sees problems with ConAgra's definition of whole grain in the proposed QHC.

Unlike refined grains, whole grains have an intact outer layer of bran. ConAgra defines whole grains as having the starchy endosperm, germ and bran in the same proportion as in the original grain, and possibly containing additional bran and germ.

However, in a comment posted on FDA's website June 15, Kellogg points out a meta-analysis of whole grain studies omitted from ConAgra's petition found a more pronounced reduction in type 2 diabetes risk when bran and germ were considered whole grains independently.

“There is almost no credible evidence to suggest an independent relationship” between type 2 diabetes and whole grain, unless the definition of whole grain includes bran, Kellogg says. “To approve a qualified health claim as ConAgra has proposed, without any reference to bran, germ or cereal fiber, would not accurately reflect the scientific evidence.”

In October 2011, Battle Creek, Mich.-based Kellogg funded a roundtable discussion among food and nutrition experts on “filling America's fiber intake gap.” Among the concerns raised was that consumers often are misled by the unclear distinction between whole grain and fiber content.

While an inverse relationship appears to exist between intake of whole grains and risk of conditions such as cancer, heart disease and type 2 diabetes, “recent research suggests that not all whole grains exert the same effects,” according to a summary of the roundtable meeting published May 30 in the *American Society for Nutrition's Journal of Nutrition*.

Definition, Maybe

General Mills Inc. backs the authorization of a QHC for whole grain and reduced risk of type 2 diabetes, but unlike both ConAgra and Kellogg, opposes a definition of whole grain that would allow additional or separate brand and/or germ.

"Without a specified level of whole grain, the addition of bran or germ in a product could cause the amount of whole grain to vary and for a product to be mostly added bran or germ," General Mills says in a May 11 comment.

"This approach will not guarantee a consistent or dietarily significant whole grain contribution," adds the Minneapolis firm, which has a marketing campaign highlighting the whole grain content and benefits of breakfast cereals such as *Cinnamon Toast Crunch*, *Lucky Charms* and *Wheaties*.

FDA's February 2006 draft guidance on whole grain label statements does not include additional bran or germ in its definition of whole grain.

Other stakeholders wholly support ConAgra's petition. The North American Millers' Association says an authorized QHC would help align packaged food labeling with public health messages, such as the Department of Agriculture's 2010 dietary guidelines recommendation that whole grains make up at least half of all grain consumption.

The comment period for ConAgra's petition closed May 11, and FDA has until Oct. 23 to notify the company of its decision.

A Question Of Fiber Content

Hope Warshaw, a diabetes expert who consults with food and nutritional companies through Hope Warshaw Associates, says many claims about whole grains may be misleading, since fiber content is more meaningful from a health perspective.

"I've actually evolved to using the expression 'fiber-filled whole grains' as a way to differentiate," said Warshaw, who participated in Kellogg's fiber roundtable.

"If we're going to promote whole grains, then it should be whole grains that are a good or excellent source - as defined by FDA - of dietary fiber. But that's hard to do when you're writing for a consumer," she added.

FDA already allows health claims for soluble fiber from certain foods and reduced risk of cancer and coronary heart disease.

In 2009, General Mills ran afoul of the approved claim for soluble fiber and heart disease reduction with cholesterol-lowering claims for *Cheerios* whole grain oat cereal, eliciting a warning letter from FDA ("*FDA Cheerios Warning Signals Tougher Stance On Health Claims Enforcement*" - "*The Tan Sheet*," May 18, 2009).

General Mills' comment on ConAgra's petition notes that fiber is one healthy component of whole grain, though "when the

effect of fiber is controlled for, the benefit of whole grain on reducing risk for chronic disease still remains significant."

The Center for Science in the Public Interest's Bonnie Liebman points out the proliferation of foods trumpeting whole grains typically tells consumers little about a product's percentage of whole grain content.

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By requesting a QHC based on an absolute amount of whole grain consumption rather than a percentage, ConAgra may not actually move the ball forward on replacing typically low-fiber refined grains in consumer diets, said Liebman, CSPI's nutrition director.

Waiting On A Disclaimer

CSPI prefers marketers stick to using full health claims, backed by significant scientific agreement, and generally opposes QHCs, arguing that disclaimers and ambiguous language mislead consumers ("*Trade Groups Defend Qualified Health Claims Following Critical GAO Report*" - "*The Tan Sheet*," Oct. 20, 2008).

The agency has come under fire from industry attorneys in recent years for authorizing overly restrictive and essentially unusable QHCs that highlight FDA's doubt regarding the evidence for a claimed health benefit.

After a federal court in February ordered the agency to reformulate a green tea/cancer QHC that sponsor **Fleminger Inc.** said violated its First Amendment right to make truthful statements about green tea research, some industry observers suggested a door could be opening for a more liberal QHC regime ("*Nutrition Market Shifting From Supplements To Whole Foods - Experts*" - "*The Tan Sheet*," Apr. 9, 2012).

Attorney Anthony Pavel says following the Fleminger decision, FDA's preferred language in past QHCs such as "FDA does not agree" may be scrapped in favor of disclaimers closer to "There is limited scientific data to support the claim."

"That is still providing an accurate assessment of the information, but it is not poisoning the well for consumers by having FDA say 'we don't agree,'" said Pavel, a partner with K&L Gates in Washington.

Ultimately, he said the strength of the whole grain QHC will depend on the scientific data ConAgra provided in support of its petition.

Liebman points out that the studies in the petition do show whole grain’s positive effects on blood glucose and insulin

levels - surrogate endpoints for diabetes risk - in short-term scenarios, though several other studies on chronic effects show no benefit.

“The bottom line is, the evidence is not persuasive that whole grains lower the risk of diabetes,” she said. 