

FTC Judgment Adds to Growing Number of Medical Food Regulatory Actions

[Kelley Drye](#)

March 11, 2014

The Federal Trade Commission announced recently that it obtained a \$2.2 million judgment against Wellness Support Network, Inc., and its two principals. The company claimed that its products, Diabetes Pack and Insulin Resistance Pack, could treat diabetes, insulin resistance, and various metabolic disorders. The FTC alleged that although Wellness Support Network touted their products as a “nutritional breakthrough” and referenced “Nobel Prize Winning Technology,” the company lacked substantiation for its claims and was in violation of Section 5 of the FTC Act.

The permanent injunction prohibits Wellness Support Network from making diabetes and related treatment claims absent competent and reliable scientific evidence, defined as two adequate and well-controlled clinical studies. As readers of this blog know, the two-study standard is currently an issue on appeal in the POM Wonderful case.

Although the [FTC’s press release](#) describes Diabetes Pack and Insulin Resistance Pack as dietary supplements, they were actually promoted on the Wellness Support Network websites as [medical foods](#), a unique category of food products that is designed to address a nutritional deficiency created by a disease. Wellness Support Network claimed that diabetes was the result of key nutrient deficiencies.

The medical foods category is a growing area in the already robust functional foods market but it also is receiving unprecedented regulatory attention not limited to this FTC matter. Last August, FDA updated its [draft medical foods guidance](#), incidentally specifying therein that types 1 and 2 diabetes are not conditions for which a medical food may be marketed. In addition, FDA has issued four warning letters regarding medical food claims over the course of the last year, constituting one-third of all medical food warning letters ever issued.

The lesson for marketers is that the functional foods and health claims environment continues to evolve. Although it doesn’t appear that the FTC targeted Wellness Support Network because it billed its product as medical foods, this action evidences the agency’s continued enforcement on health claims and the imposition of the controversial two-study substantiation standard on a medical food product. Further, FDA’s medical food warning letters signal that the agency intends to regulate via enforcement to prohibit what it deems inappropriate disease claims.