FTC/FDA Cease and Desist Letters to Companies Touting Diabetes Cures: Is the FTC Testing the Limits of Its Civil Penalty Authority?

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As they often have done in the past, the FTC and the FDA issued joint cease and desist letters last week to 10 companies suspected of making unproven health claims – in this instance, claims that dietary supplements treat or cure diabetes. The FTC and the FDA join forces on such letters in order to deliver a strong and consistent message that unsubstantiated health claims are illegal under the laws enforced by both agencies.

The FTC warned that the claims do not appear to be supported by competent and reliable scientific evidence, in violation of the FTC Act. The FDA warned that the products are being marketed as drugs that could cure, treat, mitigate, or prevent disease, but are not generally recognized as safe and effective for the marketed uses and not approved by the FDA. As such, the products are misbranded and illegal under the Food Drug and Cosmetic Act (FD&C Act). The letters demanded that the companies cease and desist from making unsubstantiated claims within 15 days.

Deceptive Claims under the FTC Act

To be sure, these letters are noteworthy for companies making diabetes-related claims, but their importance is not necessarily limited to that. Advertisers should pay attention more broadly to the FTC section of the letters, as it may signal the FTC testing its authority to seek penalties under Section 5(m)(1)(B).

In particular, in describing how and why the claims violate the FTC Act, the letters cite to cases holding that unsubstantiated disease claims ***of various types*** are unlawful, and appear to be styled as so-called Section (5)(m)(1)(b) letters laying the groundwork for civil penalties – similar to letters the FTC has sent companies making allegedly unsubstantiated claims that their products are made from bamboo. In general, the FTC has limited authority to obtain civil penalties. However, Section (5)(m)(1)(b) of the FTC Act authorizes the agency to seek penalties when the FTC has (1) previously determined in a litigated administrative proceeding that a practice is unfair or deceptive (2) issued a final cease and desist order with respect to such practice, and (3) put a company on notice of this fact (such that it has "actual knowledge) via warning letter.

It's not clear yet whether the FTC will actually seek civil penalties based on these letters. But if it does, it would be testing the limit of its authority under Section 5(m)(1)(b). That's because the law arguably contemplates that the "final cease and desist order" cited in a Section 5(m)(1)(b) letter be

more specific to the practice being warned about than the potpourri of health cases cited in these current letters. Put another way, to confer "actual knowledge" on the companies, the cited cases should address unsubstantiated diabetes claims, not wholly different health claims about heart disease, cancer, erectile dysfunction, etc. Indeed, the language of Section (5)(m)(1)(m) and precedent from the bamboo cases support this narrower reading. Top FTC officials have called for more frequent and aggressive use of the FTC's Section 5(m)(1)(b) authority, and this appears to be a move in that direction.

Misbranding Under the FD&C Act

The FDA section of the letters doesn't break new ground, but it does provide a helpful gauge for risk and a reminder about the importance of context.

Companies marketing supplements and foods to people with diabetes or pre-diabetes should review the claims cited in the letters to help assess risk of their current marketing. For example, some letters cite to claims that clearly exceed the bounds of structure function claims, e.g., claiming that the ingredients or products produced quantifiable improvements in fasting blood sugar, A1C levels, and reduced blood pressure as well as risk of heart attacks. However, other letters cite to claims that many marketers may think fall more squarely on the structure-function side of the line, e.g., "promote healthy glycemic response" and "supports healthy glucose tolerance." In addition to product labels and websites, the letters also cite to claims on social media – including testimonials dating as far back as 2018 – and to Amazon store fronts.

As is standard, the letters cite to specific claims, but it's important to also consider the broader context. When marketing diabetes-related products, it's risky to position any product as the fix for a condition that likely requires medication along with constant dietary discipline and monitoring. Even if the product claims are substantiated and within structure-function limitations, the context of positioning the product as one part of an overall diabetes management plan is key to managing risk.

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We will closely monitor developments in these matters, as well as the agencies' future use of warning letters and sources of legal authority, and post updates as they occur.

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