FTC Releases a Second Order Requiring Preservation of Records from Clinical Trials

John E. Villafranco

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The FTC recently announced a settlement with the makers of Nopalea, a fruit drink derived from Nopal or "prickly-pear" cactus. The FTC alleges that the company and two individuals disseminated unsubstantiated claims that Nopalea improves respiration, treats skin conditions, and reduces inflammation and pain, including pain associated with arthritis, fibromyalgia, and other conditions. The company and individuals agreed to follow the terms of a consent order and pay $3.5 million in consumer redress.

For any future, similar claims to treat respiratory or skin conditions, or pain or inflammation, the consent order requires the named parties to possess "human clinical testing." The exact number of clinical studies required is not specified, and presumably one could be enough. This is somewhat surprising given the relatively serious nature of the claims that were at issue. Other recent orders have typically required "*at least two*" clinical studies where claims for conditions, such as arthritis and diabetes, have been at issue. Generally, in the realm of diseases and health conditions, only one trial has been required only where claims were for less serious conditions, like head lice. This new order may represent a compromise among the FTC's Commissioners. While Chairperson Ramirez and Commissioner Brill have supported two-study requirements for an array of claims for diseases and other health conditions, Commissioner Ohlhausen, in the past year, has raised concerns about the feasibility of clinical testing for disease claims and has stated that she is "not willing to support a *de facto* two-RCT standard . . . for food or other relatively-safe products." Commissioner Wright, likewise, has raised concerns and suggested that "a fact-specific inquiry may justify [alternative] specifically crafted injunctive relief in certain cases, such as bans, performance bonds or document retention requirements for underlying study data."

Commissioner Wright appears to have made headway with this new order on "document retention requirements for underlying study data." In addition to requiring "human clinical testing" for certain claims, the order requires the named parties to retain data, protocols, and other records from any clinical testing relied upon for claims. A narrow exception is made only for high-quality peer-reviewed and published studies that were not "conducted, controlled, or sponsored in whole or in part" by the named parties or a manufacturer or ingredient supplier used by the named parties. This is the second FTC order to include such record keeping provisions. The first order, which we discussed in an earlier post, was issued in a case involving claims that a dietary supplement could improve memory and combat cognitive decline in adults. Such record keeping provisions may become a standard feature of any order requiring clinical testing.