

reduces the risk that the result obtained in a single study may be due to chance, or may not lend itself to “generalization due to the uniqueness of the study sample.” *POM Wonderful LLC*, 155 F.T.C. 1, at 81 (Jan. 10, 2013) (quoting expert testimony with approval). Replication also reduces the risk of unanticipated and undetected biases that may lead to flawed conclusions.⁵ Further, it may help guard against the manipulation or falsification of data – issues present in other recent Commission weight loss matters.⁶ While the proposed consent order includes other provisions requiring the retention of underlying study data, that alone may not suffice to prevent bias or the falsification or manipulation of data, as the data itself may not necessarily reveal such deficiencies.

Moreover, in testing weight loss products, replication of results through a second RCT is particularly important, because almost any study purporting to find a product capable of causing substantial weight loss is likely to be novel and unexpected. Thus, from a scientific perspective, replication in this context likely only enhances accuracy.

The two RCT standard adopted in this settlement is consistent with the standard endorsed by those in the expert community for weight loss claims. It is also consistent with Commission precedent, as well as the Commission’s past orders in weight loss matters. Additionally, requiring two RCTs will further our goal of ensuring that our orders in cases like this one are sufficiently specific to be enforced in court.

For the foregoing reasons, we support the consent order in this matter, including its requirement of two RCTs.