Is that Flexibility We See in an FTC Order on Disease Claims?

June 2, 2014

On May 28, 2014, the FTC announced a settlement with the company that sells Lice Shield shampoos, leave-in sprays, and products to be applied to head gear. In the FTC's view, the company did not possess adequate substantiation for claims that the products will prevent or reduce the risk of head lice. Without admitting any wrongdoing, the company agreed to a consent order and to pay $500,000 in monetary relief to settle the allegations. Under the terms of the consent order, the company must possess "at least one adequate and well-controlled human clinical study" for any future claims for entirely preventing head lice or for reducing the risk of or repelling head lice by a specific percentage or amount. The company must also possess "competent and reliable scientific evidence" – although not necessarily human clinical studies – for any future non-quantified claims for risk reduction or repelling head lice.

The consent order appears to reflect some flexibility as compared to other recent FTC orders on disease claims. In a recent settlement involving "genetically customized" dietary supplements, the resulting consent order requires at least *two* adequate and well-controlled human clinical studies for any future claims to treat or prevent diabetes, heart disease, arthritis, or insomnia. Similarly, in a case recently litigated in California, the FTC sought and the court upheld an order requiring at least *two* adequate and well-controlled human clinical studies for any future claims to treat or prevent diabetes or metabolic disorder. Presumably, given the less serious nature of head lice as compared to the diseases at issue in these other cases, the FTC went a little easy on the makers of Lice Shield.

The FTC's case against POM Wonderful involves allegations that the company made deceptive claims for prostate cancer, erectile dysfunction, and heart disease. In that case, the FTC is seeking to require at least *two* adequate and well-controlled human clinical studies for future claims to treat or prevent *any* disease. The outcome of the POM case will no doubt affect future FTC orders on disease claims.