One-A-Day Keeps the Plaintiff's Lawyers Away: FDA Determinations on Disease Claims Preempt Class Action Allegations

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A California court recently dismissed, in part, a consumer class action against labeling and advertising claims for twenty different Bayer One-A-Day multivitamins. The plaintiffs had alleged that the claims, "supports heart health" and "supports immunity" – which Bayer used for many of the products – were impermissible disease claims. The court rejected these allegations. It found, first, that FDA has determined that such claims are permissible, non-disease "structure/function" claims. It pointed to FDA guidance providing that similar claims, such as "helps maintain a healthy circulatory system" and "supports the immune system," are permissible structure/function claims. The court, next, found that, under an express pre-emption provision in the federal Food, Drug, and Cosmetic Act, a litigant cannot upset FDA's prior determination. The FDCA pre-emption provision provides that state law cannot impose a labeling requirement that conflicts with or adds to FDA requirements. In contrast to its holding regarding the heart health and immunity claims, the court refused to dismiss allegations against the claim, "supports physical energy." The difference is that while the plaintiffs challenged the substantiation for the energy claim, they did not allege that the claim was an impermissible disease claim.

The lawsuit, which was filed with the support of the Center for Science in the Public Interest, is a clear winner for industry. The specter of a court finding that a clear structure/function claim, like "supports heart health," is a disease claim loomed large and could have affected the types of claims that dietary supplement and food companies choose to make. This decision, we hope, will discourage future litigants from picking fights over what is and isn't a disease claim. We wonder, too, if this decision or others like it could eventually affect the FTC's position on disease claims. In 2010, the FTC began including in many of its orders specific requirements for any future claims that a food or supplement "treats, prevents, or cures any disease." With the duty to enforce the new provisions, the FTC effectively entered the business of disease claim determination. The FTC orders neither define what constitutes a disease nor refer to FDA regulations on the matter. An open question, thus, has been how exactly is the FTC defining what is and isn't a disease claim? And, should the FTC really be the agency making such determinations?

Jennifer Rodden, a law clerk with Kelley Drye & Warren, assisted in the drafting of this post.