

NEW JERSEY FEDERAL COURT DISMISSES EYE-DROP SUIT FOR LACK OF ARTICLE III STANDING

A New Jersey federal court recently dismissed a putative consumer class action on grounds that the plaintiffs failed to allege an injury sufficient for Article III standing. *Cottrell v. Alcon Labs., Inc.*, No. 14-5859 (D.N.J., order entered March 24, 2016.) The case will likely have a significant impact on future consumer class actions in the drug and medical device industry, as defendants have bolstered support for attacking speculative damages claims in the context of purported class actions alleging unfair trade practice act violations. The decision, handed down by The Hon. Freda L. Wolfson, rejects “unsupported conclusion[s] regarding alleged loss” based on pricing theories that are purely hypothetical.

The defendants were manufacturers and distributors of U.S. Food and Drug Administration (FDA)-approved prescription eye drop medications sold as fluids in plastic bottles. The complaint alleged that the plastic tips on the bottles dispensed larger-than-necessary drops of medication, causing plaintiffs to pay inflated costs because of the “wasted” glaucoma treatment. The court had previously held that the plaintiffs lacked standing, reasoning that absent allegations plaintiffs were promised a specific number of doses or drops, their “theory of loss was too conjectural.” The court gave the plaintiffs the opportunity to cure the defects in their complaint. They responded by citing numerous articles and studies commenting on eye-drop volume and potential cost savings of smaller drops.

The court said such evidence missed the point: “The flaw in relying on these opinions is that they do not specifically address or discuss Defendants’ pricing model as to the ophthalmic medications at issue... Plaintiffs have not pled any basis for alleging that the way Defendants price their products will take into account the drop sizes. Rather, Plaintiffs and these authors resort to hypothesizing what manufacturers would do if tip dispensers were made smaller.” Noting that the plaintiffs’ theory of unfair overcharging was insufficient to confer Article III standing, the court found that the plaintiffs’ claims were based on the faulty premise that hypothetically redesigned bottles dispensing smaller drops would

Shook offers expert, efficient and innovative representation to clients targeted by litigation and regulation. By partnering with companies to navigate the complex operational, technological and regulatory challenges of today’s global business environment, we are able to manage emerging threats and overcome potential obstacles at every step in the decision-making process.

For more information about this issue of the Drug and Device Bulletin, please contact:



Lori McGroder
Partner | Kansas City
816.559.2290
lmcgroder@shb.com



Jim Muehlberger
Partner | Kansas City
816.559.2372
jmuehlberger@shb.com

For more information about our Pharmaceutical and Medical Device Practice, please contact:



Madeleine McDonough
Partner | Washington, D.C.
202.639.5600
mmcdonough@shb.com

DRUG AND DEVICE BULLETIN

APRIL 12, 2016

ABOUT SHOOK

Shook, Hardy & Bacon is widely recognized as a premier litigation firm in the United States and abroad. For more than a century, the firm has defended clients in some of the most significant national and international product liability and mass tort litigations.

Leading pharmaceutical and medical device companies rely on Shook to advance their business interests in the courtroom and beyond. More than 100 Shook attorneys are involved in the defense of product liability, commercial, intellectual property, and other litigation specifically for pharmaceutical and medical device manufacturers. We also help them prepare for state and federal regulatory changes, respond to government charges and investigations, or engage in strategic influence initiatives to improve the political climate in which they operate.

Our lawyers handle various enforcement and rulemaking proceedings in addition to advising on risk and compliance matters in connection with the manufacture, sale and promotion of products; clinical trials; approval pathways; labeling; safety; facility and product registration; facility inspections; custom holds; and product withdrawals and recalls. We also work with clients to establish and maintain effective corporate compliance programs, including legal risk assessments, internal investigations and record-keeping audits.

cost less—a conclusion the “Court has no way of knowing ... particularly since the pricing of pharmaceuticals is complex and multi-factored.” And the plaintiffs could not base standing on their “disagreement with how Defendants designed their bottles,” a design “specifically approved by FDA in a medical context.”

The implications for cases brought under consumer protection statutes is clear: Claims based on hypothetical products and prices and conjectural injuries are insufficient to confer Article III standing and subject to successful attack at the motion to dismiss stage.

Shook Partners [Lori McGroder](#) and [Jim Muehlberger](#) represented Allergan, Bausch & Lomb and Valeant.

The choice of a lawyer is an important decision and should not be based solely upon advertisements.

