Attorneys File Flurry of Cases Following FDA Advisory Panel Finding on Decongestants

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Body

Johnson & Johnson and Procter & Gamble were among the companies hit with a flurry of class action lawsuits in New York, Florida and Louisiana federal courts over their sale of over-the-counter decongestants, following a finding by an FDA advisory panel that phenylephrine, an ingredient in many allergy and cold medicines, is ineffective as a nasal decongestant.

And the attorneys who filed the lawsuits include Darren Kaplan, a partner at Kaplan Gore in New York, who represents a plaintiff, Sandra Yousefzadeh . Yousefzadeh's filing says she purchased two packages of 24 tablets of Sudafed based on defendant Johnson & Johnson Consumer Inc.'s representation that Sudafed PE was an effective nasal decongestant.

"There is good case law in the Eastern District of New York having to do with FTCA preemption," Kaplan said about the federal law that regulates medication labeling. "There is almost complete preemption in that area, which would ordinarily preclude state law claims of the type that I'm alleging, however, I do believe I will be able to thread the needle with these claims."

William "Bert" McBride, a shareholder at Trenam in Tampa, is a class action expert who is not involved in the lawsuits. He said litigators will be keeping their eyes on this case and those that could be filed in other jurisdictions.

The decongestant is contained in at least 250 products that were worth nearly $1.8 billion in sales last year.

"These are some heavy hitters when it comes to total sales," McBride said. "There will be a significant amount of litigation due to the dollar values that are likely involved in this that could ultimately result in some significant settlements or judgments, should plaintiffs get past some initial hurdles."

'Will Probably Turn Into an MDL'

The dispute, in these cases, dates to a Food and Drug Administration advisory panel that agreed in the majority this week that phenylephrine, a common decongestant ingredient used in many over-the-counter medicines, is ineffective.

And so far, the lawsuits are not limited to just one product and one defendant.

The first class action surfaced by Law.com Radar was filed by a plaintiff, Kristin DePaola , who sued a defendant, Procter & Gamble Co., over her "purchase of ineffective and worthless (or, certainly worth less) over-the-counter drugs," which include DayQuil Severe and NyQuil Severe Cold & Flu.

"If the science is in fact true and right, these lawsuits are probably going to be in every state," said Scott Jeeves, an attorney who specializes in class actions at the Jeeves Law Group in Tampa who is not involved in the matter. "So they will probably turn into an MDL at some point."

Meanwhile, instead of the U.S. District Court for the Middle District of Florida like DePaola's lawsuit, another plaintiff, Steve Audelo , sued Johnson & Johnson and Procter & Gamble in the Northern District of Florida. And, Audelo argued in the complaint that the news on Tuesday should not have come as a surprise to the defendants.

Jason Richards, a partner at Aylstock, Witkin, Kreis & Overholtz, who represents Audelo, said since 2007, there have been several additional large clinical trials have been conducted regarding the efficacy of phenylephrine, such as two in 2009 and one in 2015, that had similar findings.

"Studies show that phenylephrine is no more effective than a sugar pill, yet these companies have made billions in profits from these products," Richards said. "Our lawsuit seeks to hold these pharmaceutical companies accountable and get reimbursement for consumers who were wrongfully deceived."

There have also been filings in additional states, including New Jersey and Illinois.

Moving forward, the FDA will likely in the months ahead have to decide whether to essentially ban the ingredient, phenylephrine, from liquid and tablet cold remedies. The result of the ban could be the pulling of hundreds of products containing it from store shelves.

Jill Okun, a partner at Porter Wright in Ohio who specializes in class actions and is not involved in the matter, said there could still be a claim without a recall but there would be several challenges, including that many customers are repeat customers, who may have believed that the product was effective in prior usages.

"This is a race to the courthouse," Okun said. "The FDA opinion came out two days ago. Who knows what's going to come out of this, but plaintiff lawyers like to be the first one and if it turns out to be something big like an MDL, they could become lead counsel."

Classification

Industry:
Over-the-counter Drugs (89%), Lawyers (79%), Drug Labeling (72%)

Subject:
Suits & Claims (93%), Litigation (92%), Negative Business News (90%), Class Actions (90%), US Federal Government (89%), Lawyers (79%), Law & Legal System (79%), Common Cold (78%), Sales Figures (78%), US State Government (77%), Government Bodies & Offices (72%), Drug Labeling (72%), Influenza (50%)

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