PATIENT SAFETY BLOG

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Contact Lens Recall Spurs Lawsuit

In two recent decisions, the FDA determined that the eyes have it. And that's not a positive outcome.

In November, the agency issued a class I recall of Avaira Toric Soft Contact Lenses, manufactured by CooperVision. (Class I is the most serious of the FDA's graduated scale; see below for a description.) Last week, the feds issued the same recall for another of CooperVision's products, the Avaira Aquaform Sphere Soft Contact Lens.

These lenses, the agency determined, put users at risk of serious eye injury because of silicone oil residue. Initial symptoms of the problem include hazy or blurry vision, discomfort and corneal abrasions. If you use either of these products, visit CooperVision's website to see if the lot number on your lens package is included in the recall. If you don't have the number, or if you simply want to exercise caution, cease using the lenses immediately and call your eye doctor.

According to AboutLawsuits.com, a class action lawsuit was filed last month by stockholders against CooperVision. They allege that CooperVision's parent company artificially inflated its stock value by minimizing problems with the contact lenses and failing to take sufficient steps to make sure the public was aware of the initial recall.

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The website says that the FDA came down on the company in October for failing to provide detail about the lenses' problems and for issuing its own recall of the Toric lenses in August in a manner so secretive as to leave consumers unaware of the risk. The company expanded the recall in November, and the increased visibility prompted the stock to decline.

In what certainly looks bad even if it's legitimate, the company's chief executive officer and chief financial officer sold off millions of dollars in company shares despite their awareness of the growing problem with the contact lenses, according to the lawsuit. Then, the claim says, they boosted expectations for 2011 revenues by minimizing the recall, artificially inflating the value of the company's stock.

Here's a primer on the FDA's approach to recalling suspect, deficient or dangerous products. "Recalls are actions taken by a firm to remove a product from the market," according to its website. "Recalls may be conducted on a firm's own initiative, by FDA request, or by FDA order under statutory authority."

A **Class I recall** denotes "a situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death."

A **Class II recall** denotes "a situation in which use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences" or when "the probability of serious adverse health consequences is remote."

A **Class III recall** denotes "a situation in which use of or exposure to a violative product is not likely to cause adverse health consequences."

Market withdrawal occurs when "a product has a minor violation that would not be subject to FDA legal action. The firm removes the product from the market or corrects the violation. For example, a product removed from the market due to tampering, without evidence of manufacturing or distribution problems, would be a market withdrawal."

A **Medical device safety alert** is issued when "a medical device may present an unreasonable risk of substantial harm. In some case, these situations also are considered recalls."

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