PROSTAGLANDIN LASH GROWTH PRODUCTS PREMATURELY AGE THE APPEARANCE OF USERS.

Allergan clinical trials minimized the reported risk of using Latisse by not identifying side effects.

BEVERLY HILLS, CA, USA, March 18, 2021 /EINPresswire.com/ -- BEVERLY HILLS, CALIF.—March 18, 2021. In detailed analysis to be published in the medical journal, Dermatologic Surgery, and available online now, authors Kenneth D. Steinsapir, MD, and Samantha M.G. Steinsapir establish that Allergan investigators made study design choices for the bimatoprost ophthalmic solution 0.03% (Latisse, Allergan Inc., Dublin, Ireland) clinical trials for eyelash growth that reduced the likelihood of identifying side effects. Allergan investigators eliminated frontal facial photographs that would have revealed upper eyelid volume loss with the sustained use of the bimatoprost. These investigators used an unproven method for assessing changes in iris (eye) color. An Allergan investigator characterized the reliability of the method as “less-than-perfect.” Allergan studies supplied to the FDA did not find evidence of eye color change or loss of upper eyelid volume, paving the way for FDA approval of Latisse (bimatoprost ophthalmic solution 0.03%) for eyelash growth.

Bimatoprost ophthalmic solution was first developed for treatment of glaucoma and FDA approved in 2001. Bimatoprost is a prostaglandin analog (PGA); one of a group of compounds developed in the past twenty years for the treatment of glaucoma, a common eye condition associated with elevated eye pressure and a leading cause of blindness. These drugs have changed how glaucoma is treated. Darkening of eye color is common, occurring in as many as 77% of those receiving PGA drops. Hazel eyes are the most prone to show changes in eye color. These changes are thought to be permanent. In 2004, loss of upper eyelid volume, called prostaglandin associated periorbitopathy (PAP) was first reported and is now documented to occur in 50 to 60% of glaucoma patients using PGA drops.

Patients using PGA drops for eye pressure were noted to have thicker, longer, and darker eyelashes. This led Allergan investigators to study the use of bimatoprost ophthalmic solution 0.03% for cosmetic eyelash enhancement. The drop was applied once per day to the base of the upper eyelashes. The initial study found a profound improvement in eyelash thickness, length, and darkness. It also found that 42% of patients experienced stinging and burning of the eyelid margin upon application of bimatoprost. In the initial published report, the Allergan investigators stated that after the study they choose not to use eyes open, frontal facial photographs of study participants. Only so-called superior eyelash view photographs were used. Those feature the

closed eyelids with the eyelashes fanned out below. No explanation for this choice was offered. This decision prevented the detection of changes in eyelid volume that are only seen in frontal photographs with the eyes open. This choice was replicated in subsequent Allergan clinical trials, the basis for FDA approval for bimatoprost for eyelash growth in 2008. Proven methods of detecting eye color change had been developed for the study of PGA drops for glaucoma using high resolution iris photographs. Allergan clinical trials for bimatoprost did not use any photography to assess changes of eye color. Since FDA approval, there have been 127 post-marketing reports of eye color change.

“Users of bimatoprost for lash growth are not currently monitored for upper eyelid volume change by their prescribing physicians,” notes Dr. Steinsapir, who advocates that individuals who choose to use these products should be carefully monitored for volume loss and eye color change. He further states: “With glaucoma, we are saving vision, but those using prostaglandin serums for eyelash and now also eyebrow growth, are trading permanent, premature aging of the eye area for thicker, longer, and darker lashes that only persist while the product is being used.” He calls for more consumer educations, stronger black box warnings for Latisse, and resumption of FDA enforcement to prevent manufacturers from selling over-the-counter eyelash and eyebrow serums that contain prostaglandin analogs to unsuspecting consumers.

Reference: Steinsapir, Kenneth D. MD; Steinsapir, Samantha M.G. Revisiting the Safety of Prostaglandin Analog Eyelash Growth Products, Dermatologic Surgery: February 22, 2021 - Volume Publish Ahead of Print - Issue -doi: 10.1097/DSS.0000000000002928

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