

Botox maker to pay \$600M to resolve investigation

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Food and Drug Administration (FDA) Commissioner Margaret Hamburg speaks to reporters during a news conference at the Justice Department in Washington, Wednesday, Sep. 1, 2010, regarding a major settlement with a pharmaceutical company for False Claims Act and off-label marketing violations. Allergan Inc., the maker of wrinkle-smoothing Botox, has agreed to pay \$600 million to settle a years long federal investigation into its marketing of the top-selling, botulin-based drug. (AP Photo/Manuel Balce Ceneta)

(AP) -- Allergan Inc., the maker of wrinkle-smoothing Botox, has agreed to pay \$600 million to settle a yearslong federal investigation into its marketing of the top-selling, botulin-based drug.

The Justice Department and the company said Wednesday in a statement it will plead guilty to one misdemeanor charge of "misbranding," in which the company's marketing led physicians to use Botox for

unapproved uses. Those included the treatment of headache, pain, spasticity and [cerebral palsy](#) in children.

Companies are prohibited from promoting drugs for unapproved, or "off-label," uses.

Allergan said it will pay \$375 million in connection with the plea, which includes the forfeiture of \$25 million in assets. Additionally, the company will pay \$225 million in civil fines - \$210 million to the federal governments and the rest to several states - related to the investigation, although the company denies liability for the civil claims.

Allergan, based in Irvine, Calif., also struck an agreement with the Department of Health and Human Services' Office of the Inspector General that requires the company to submit compliance reports, and to post on its website any payments to doctors, such as honoraria, travel or lodging.

Allergan "paid kickbacks to induce physicals to inject Botox for off-label uses and Allergan also taught doctors how to bill for off-label uses, including coaching doctors how to miscode Botox claims leading to millions of dollars of false claims being submitted to federal and state programs," Assistant Attorney General Tony West said.

Allergan officials will make their first appearance in federal court on Thursday. The settlement is not official until approved by a [federal judge](#).

"The FDA had approved therapeutic uses of Botox for only four rare conditions, yet Allergan made it a top corporate priority to maximize sales of far more lucrative off-label uses that were not approved by the FDA," said Sally Yates, U.S. Attorney for the Northern District of Georgia. "Allergan further demanded tremendous growth in these off-

label sales year after year, even when there was little clinical evidence that these uses were effective."

The investigation was sparked by a whistleblower complaint, officials said, and five whistleblowers will split \$37.8 million of the government's share of the settlement.

Allergan's product sales topped \$4.4 billion in 2009, with Botox accounting for more than \$1.3 billion of that total.

The Justice Department's investigation covered Allergan's marketing of Botox from 2001 through at least 2008.

Wells Fargo analyst Larry Biegelsen said the settlement is a positive for the company's stock because it removes uncertainty.

"We view the settlement as a positive for Allergan as it provides cost certainty ... and eliminates additional related litigation cost," Biegelsen wrote in a note to investors.

In recent years, federal investigators have reached multibillion dollar settlements with Pfizer, Eli Lilly and other drug companies over their marketing practices.

Botox is most famous for its ability to smooth frown lines on aging foreheads, but the drug - introduced in 1989 - is also approved to treat neck spasms, eye muscle disorders and excessive underarm sweating.

Last year the drug won approval to treat spasms in the elbows, wrists and fingers. The drug is also widely used off-label to treat cerebral palsy in children as well as in adults, and Allergan says it is in discussions with U.S. health regulators to approve the use of Botox for children with the neuromuscular disorder.

In guidelines published earlier this year, the American Academy of Neurology endorsed Botox as an "effective and generally safe treatment" for children with cerebral palsy. While the use is not approved by the Food and Drug Administration, the guidelines stated that there are more studies supporting Botox than other movement-disorder drugs.

Botox works by blocking the connections between nerves and muscle, temporarily paralyzing muscles that cause wrinkles as well as certain types of spasms. The drug is a purified form of botulinum, one of the most toxic substances in the world.

As part of the settlement, Allergan agreed to drop a lawsuit against the FDA in which the company pressed for greater leeway to discuss off-label uses with doctors.

The company argued it had a First Amendment right to educate doctors about how to safely use [Botox](#), even for uses that are not currently approved. FDA's rules are designed to stop companies from promoting drugs for uses that haven't been federally confirmed as safe and effective.

Some legal experts speculated that Allergan's lawsuit against FDA was primarily aimed at gaining leverage in its negotiations with the Justice Department, which was a separate matter.

Shares of Allergan rose \$1.86, or 3 percent, to \$63.28.

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