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Maker of Botox Settles Inquiry

By NATASHA SINGER

[Allergan](#), the maker of [Botox](#), agreed on Wednesday to pay \$600 million to settle charges that it illegally promoted and sold the drug through 2005 for unapproved uses like treating headaches.

That settlement, the latest in a continuing Justice Department crackdown on off-label drug promotion by pharmaceutical companies, comes with an unusual postscript. In recent months, the [Food and Drug Administration](#) has been seriously weighing approval of Botox for treatment of chronic migraines, a remedy that has been cited as beneficial in new studies and which was ratified last month in Britain.

The charges of illegal marketing cover the first half of this decade, before the F.D.A.'s review.

The settlement also represents the latest in a series of prominent deals by drug makers to resolve criminal and civil allegations, and it closely follows news that the federal government has expanded [an investigation](#) into the overseas practices of several big pharmaceutical companies involving suspected bribery of foreign officials.

In this case, the government's civil complaint said that Allergan had "illegally, vigorously and, without any thought to the possible negative health effects to which it subjected patients, promoted" Botox for uses that had not been deemed safe and effective by the F.D.A.

The company developed and put in place a wide-ranging marketing program, according to the complaint, that included paying kickbacks to doctors to induce them to prescribe Botox for conditions — like pain and severe spasms in the limbs of children with [cerebral palsy](#) — not included in the drug's label.

Federal prosecutors also accused the company of teaching doctors how to get reimbursement from [Medicare](#) and [Medicaid](#) for off-label uses by putting in the codes for an approved treatment.

Allergan denied the kickback and fraud allegations, Caroline Van Hove, a spokeswoman for the company, wrote in an e-mail, calling the claims totally unproven civil accusations.

In the settlement, Allergan agreed to plead guilty to one criminal misdemeanor charge and to pay \$375 million to the government for misbranding Botox, through promotions for unapproved uses.

Additionally, Allergan agreed to pay \$225 million to resolve civil charges that it had caused false claims to be submitted to Medicare, Medicaid and other government health programs, although the company denied those allegations.

“With cases like this one, we hope to put an end to the practice in the pharmaceutical industry known as off-label marketing,” Sally Quillian Yates, the United States attorney for the Northern District of Georgia, said in a phone interview Wednesday.

Her office and other government agencies began investigating the company’s marketing efforts in 2007 after a whistle-blower filed a lawsuit in Atlanta. “When pharmaceutical companies ignore the F.D.A.’s approval process and market their drugs for off-label indications,” she said, “they remove the safety net and assurance of efficacy provided by the F.D.A.’s rigorous review.”

Once the F.D.A. has approved a drug for a particular use, doctors are permitted to prescribe that drug for other conditions when they deem it medically appropriate. But it is illegal for pharmaceutical companies to market drugs for unapproved uses.

In a statement Wednesday, Allergan said it agreed that its marketing from 2000 to 2005 had resulted in the use of Botox for unapproved uses, including the treatment of [headache](#), pain, [spasticity](#) and juvenile cerebral palsy.

During the time period covered by the settlement, the F.D.A. approved Botox as a treatment for four medical conditions — [crossed eyes](#), [involuntary blinking](#), involuntary [neck muscle contractions](#) and excessive [underarm sweating](#). It was also approved for the cosmetic use of smoothing [vertical wrinkles](#) between the eyebrows.

Karen Riley, a spokeswoman for the F.D.A., said she could not comment specifically on the agency’s pending review of Botox as a potential [migraine](#) treatment.

Allergan has also entered into a five-year corporate integrity agreement with the government under which the company will be required to publish information about its payments to doctors. The agreement also required Allergan to drop its First Amendment

lawsuit against the F.D.A., in which it had claimed free speech protections when giving doctors information about unapproved uses of Botox. Five whistle-blowers will be awarded a total of \$38.7 million out of the settlement.

A news release from the Justice Department on Wednesday said that Allergan had “made it a top corporate priority to maximize sales of Botox” for unapproved uses.

“This is part of a departmentwide and administrationwide effort to really crack down on health care fraud,” Tony West, assistant attorney general for the civil division of the Justice Department, said in a phone interview Wednesday.

Last year, for example, Eli Lilly pleaded guilty to one misdemeanor charge and paid \$1.41 billion to settle criminal and civil charges that it had improperly marketed an antipsychotic drug for elderly patients with dementia.

Also last year, Pfizer paid \$2.3 billion to settle criminal and civil charges that it had illegally marketed the painkiller Bextra and other products. In April, AstraZeneca agreed to pay \$520 million to settle federal investigations into the marketing of Seroquel, a schizophrenia drug; in settling, the company denied charges that it had marketed the drug for unapproved uses.

The Justice Department contended that Allergan’s promotions included paying doctors \$1,500 each to listen to presentations on off-label uses and sending sales representatives to visit specialists who would not ordinarily administer Botox for any of the approved applications.

Medicaid paid about \$76.5 million for Botox treatments from 2002 to 2006, much of it for unapproved uses of the drug, according to the government’s civil complaint. The complaint cited an Allergan presentation from 2004, for example, indicating that 86 percent of Botox treatments reimbursed by Medicaid were for children, primarily for cerebral palsy, an unapproved use, the complaint said.

Several years later, the F.D.A. issued a public advisory saying that it had received reports of serious medical problems — including hospitalization and death — related to the use of botulinum toxin drugs like Botox, particularly in treating severe spasms in children with cerebral palsy. Last year, the agency required all botulinum toxins to carry “black box” labels warning that the drug can spread from the injection site, with the potential to cause difficulties breathing or swallowing.

