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PHARMACEUTICAL COMPANY ALLERGAN AGREES TO PLEAD GUILTY AND PAY $600 MILLION TO RESOLVE ALLEGATIONS OF OFF-LABEL PROMOTION OF BOTOX®

Settlement is the Fifth Largest Amount Paid by a Single Defendant in a Pharmaceutical Off-Label Marketing Case and Largest Settlement in History for the Northern District of Georgia

ATLANTA, GA – Sally Quillian Yates, United States Attorney for the Northern District of Georgia, today announced that pharmaceutical manufacturer Allergan Inc., headquartered in Irvine, California, has agreed to plead guilty and pay $600 million to resolve its criminal and civil liability arising from the company's unlawful promotion of its biological product, Botox®, for uses not approved as safe and effective by the Food and Drug Administration (FDA). The resolution includes a criminal fine and forfeiture totaling $375 million and a civil settlement with the federal government and the states of $225 million.

United States Attorney Yates said, "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 FDA. 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 FDA approval process ensures that pharmaceutical companies market their medications for uses that are proven to be effective, and this case demonstrates that companies that fail to comply with these rules face criminal prosecution and stiff penalties."

Under the Food, Drug and Cosmetic Act (FDCA), a company in its application to the FDA must specify each intended use of a biological product. After the FDA approves the product as safe and effective for a specified use, any promotion by the manufacturer for other uses – known as "off-label" uses – renders the product misbranded.

United States Attorney Yates announced the filing of a Criminal Information in the Northern District of Georgia today against Allergan for unlawfully promoting Botox® for headache, pain, spasticity and juvenile cerebral palsy – none of which were approved by the FDA - from 2000 to 2005. Allergan has agreed to plead guilty to a criminal misdemeanor for misbranding Botox® in violation of the FDCA.

Botox®, a prescription biological product containing botulinum toxin type A, a purified neurotoxin, was FDA approved in 1989 to treat strabismus (crossed eyes) and blepharospasm (involuntary eyelid muscle contraction). In 2000 and 2004, approval was given to treat cervical dystonia (involuntary neck muscle contraction) and primary axillary hyperhidrosis (excessive underarm sweating), respectively. In 2010, approval was given to treat adult upper-limb spasticity.

According to the Criminal Information, Allergan aggressively promoted Botox® as a treatment for headache, pain, spasticity, and juvenile cerebral palsy from 2000 to 2005. The Criminal Information alleges that Allergan exploited its on-label cervical dystonia (CD) indication to grow off-label pain and headache (HA) sales. In 2003, Allergan developed the "CD/HA Initiative" as a "rescue strategy" in the event of negative results from its headache clinical trials to ensure continued expansion into the pain and headache markets. As part of this initiative, Allergan claimed that cervical dystonia was "underdiagnosed" and that doctors could diagnose cervical dystonia based on headache and pain symptoms, even when the doctor "doesn't see any cervical dystonia."

The Criminal Information also alleges that Allergan's off-label marketing tactics included calling on doctors who typically treat patients with off-label conditions. In 2003, Allergan doubled the size of its reimbursement team to assist doctors in obtaining payment for off-label Botox® injections. Allergan held workshops to teach doctors and their office staffs how to bill for off-label uses, conducted detailed audits of doctors' billing records to demonstrate how they could make money by injecting Botox®, and operated the Botox® Reimbursement Hotline which provided a wide array of free on-demand services to doctors for off-label uses. Allergan also lobbied government healthcare programs to expand coverage for off-label uses, directed physician workshops and dinners focused on off-label uses, paid doctors to attend "advisory boards" promoting off-label uses, and created a purportedly independent online neurotoxin education organization to stimulate increased use of Botox® for off-label indications.

In a plea agreement with the United States, Allergan will pay a criminal fine of $375 million, which includes forfeiting assets of $25 million. Allergan's guilty plea and sentence is not final until accepted by the U.S. District Court.

"This global resolution marks the end of an investigation that exemplifies what can be accomplished when there is cooperation between law enforcement agencies sharing information and working together," said United States Attorney Yates. "Allergan's

unlawful marketing activities first came to light when two whistleblowers, a doctor who was an Allergan consultant and a Botox® sales representative, filed a False Claims Act complaint against Allergan here in Atlanta. Our investigation continued to expand after two more whistleblower complaints were filed against Allergan in the District of Massachusetts and the District of Maryland and were transferred to Atlanta where our investigation was underway. The second complaint was filed by two former Allergan employees in the Botox® reimbursement division, and the third by an Allergan sales representative. In Atlanta we will thoroughly and aggressively investigate whistleblower claims and bring those who have violated the law to justice."

In a separate civil settlement agreement, Allergan has agreed to pay an additional $225 million to the federal government and the states to resolve claims that its unlawful marketing practices caused false claims to be submitted to government health care programs such as Medicare, Medicaid, TRICARE, and to the Federal Employees Health Benefit Program, the Department of Veterans' Affairs and the Department of Labor's Office of Workers' Compensation Programs. The civil settlement addresses allegations that from 2001 through at least 2008, Allergan promoted Botox for off-label indications that were not medically accepted and therefore not covered by federal healthcare programs, made unsubstantiated and misleading statements about the efficacy of Botox® for off-label indications, instructed doctors to miscode Botox® claims for uncovered indications using inappropriate diagnosis codes to ensure payment by government healthcare programs, and provided inducements to doctors to inject more Botox®. The federal share of the civil settlement amount is $210,250,000, and Allergan will pay up to $14,750,000 to states that opt to participate in the agreement.

The civil settlement resolves three lawsuits filed under the *qui tam*, or whistleblower, provisions of the False Claims Act, which allow private citizens to bring civil actions on behalf of the United States and share in any recovery. The three cases, all pending in the Northern District of Georgia, are *United States ex rel. Amy M. Lang & Charles Rushin v. Allergan, Inc.*, Civ. No. 1:07-1288-WSD; *United States ex rel. Cher Beilfuss & Kathleen O'Connor-Masse v. Allergan, Inc.*, Civ. No. 1:08-1883-WSD; and *United States ex rel. Albert E. Hallivis v. Allergan, Inc.*, Civ. No. 1:09-2817-WSD.

Allergan has also executed a Corporate Integrity Agreement (CIA) with the Department of Health and Human Services, Office of Inspector General (HHS-OIG). The five-year CIA requires, among other things, that the board of directors (or a committee of the board) annually review the company's compliance program and certify its effectiveness; that certain senior executives annually certify that their departments or functional areas are compliant, that Allergan send doctors a letter notifying them about the settlement, and that the company post on its website information about payments to doctors, such as honoraria, travel or lodging. Allergan is subject to exclusion from federal health care programs, including Medicare and Medicaid, for a material breach of the CIA and subject to monetary penalties for less significant breaches.

Brian D. Lamkin, Special Agent in Charge, FBI Atlanta, said: "This was a complex investigation that required much in terms of investigative resources in order to conduct the many interviews and document reviews needed to get us where we are today. The FBI, through its vast experience investigating Health Care Fraud, is not only able to provide such resources, but is also able to recognize which circumstances need those resources the most. The off-label marketing tactics employed by Allergan was one of those aforementioned circumstances."

"Some pharmaceutical companies take advantage of our healthcare system by getting their drugs approved by the FDA for one health condition, then heavily promoting it for numerous unrelated conditions. Drug companies have an obligation to patients and physicians to market prescription medicine in accordance with law and FDA regulations," said Special Agent in Charge Derrick L. Jackson, Health and Human Services, Office of Inspector General, Atlanta Region. "HHS/OIG will continue to protect the public against drug companies that falsely promote drug products and cause false claims to be submitted to Federal Health Care programs."

"Today's settlement sends a clear message that the Government will not tolerate any company that attempts to increase profits by violating laws designed to protect the American public," said David W. Bourne, Special Agent in Charge, Miami Field Office, Food and Drug Administration Office of Criminal Investigations.

"Federal employees and indeed the American taxpayers deserve health care providers and suppliers, including drug manufacturers, that meet the highest standards of ethical and professional behavior," said Patrick E. McFarland, Inspector General of the U.S. Office of Personnel Management. "Today's settlement once again reminds the pharmaceutical industry that it must observe those standards and reflects the commitment of federal law enforcement organizations to pursue improper and illegal conduct that places health care consumers at risk."

"The FDA exists to assure that drugs marketed to the American people are safe and effective," said Dr. Margaret Hamburg, Commissioner, Food and Drug Administration. "The 'off-label' promotion of drugs threatens public health and the role of the FDA, which has served our country well and has protected Americans from unsafe and ineffective drugs."

Allergan markets Botox® for its approved cosmetic use under the trade name Botox® Cosmetic. Botox® Cosmetic has its own FDA-approved label and drug code. The resolution announced today does not address Botox® Cosmetic.

The criminal case is being prosecuted by Assistant United States Attorneys Randy Chartash and Douglas Gilfillan, and DOJ Office of Consumer Litigation Attorney Josh Burke. The civil settlement was reached by Assistant United States Attorneys Sally B. Molloy, Christopher J. Huber, Amy Berne, and DOJ Commercial Litigation Branch Trial

Attorney Edward C. Crooke. Assistance was provided by representatives of the HHS Office of Counsel to the Inspector General; the Center for Medicare and Medicaid Services; FDA's Office of Chief Counsel; and the National Association of Medicaid Fraud Control Units.

This case was investigated by the FBI, the FDA's Office of Criminal Investigation, and the HHS-OIG. Investigative assistance was provided by the Office of Personnel Management Office of Inspector General, TRICARE Program Integrity, the Department of Veterans' Affairs Office of Inspector General, and the Department of Labor Office of Inspector General.

For further information please contact Sally Q. Yates, United States Attorney, through John Horn, First Assistant U.S. Attorney, U.S. Attorney's Office, at (404) 581-6335. The Internet address for the HomePage for the U.S. Attorney's Office for the Northern District of Georgia is www.justice.gov/usao/gan.