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PHARMACEUTICAL COMPANY ALLERGAN PLEADS GUILTY; SENTENCED TO A PAY A TOTAL OF $375 MILLION

Allergan's Guilty Plea and Sentencing Resolves Criminal Allegations That it Unlawfully Promoted "Botox" for Headache, Pain, and Spasticity

ATLANTA, GA – United States Attorney Sally Quillian Yates today announced that Allergan, Inc. pleaded guilty and was sentenced to pay $375 million to resolve its criminal case arising from its unlawful marketing and promotion of its biologic product, Botox® Therapeutic ("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.

United States Attorney Sally Quillian Yates said of the case, "The FDA approval process is designed to help protect the public, and when a manufacturer puts potential profits and sales ahead of the approval process, they risk paying a bigger price. At the time of the offenses, Allergan knew that there was insufficient clinical evidence for the wide range of claims the company was promoting and pushing with doctors. We hope other companies are paying close attention to what can happen if they don't follow the rules and rush towards making profits."

Botox® is a prescription biological product containing botulinum toxin type A, a purified neurotoxin. Under the Food, Drug and Cosmetic Act ("FDCA"), a company must specify each intended use of a biologic product in an application submitted to the FDA. After the FDA approves the product as safe and effective for a specified use, any promotion by the manufacturer for any other uses – known as "off-label" uses – renders that product misbranded.

According to United States Attorney Yates and the information presented in court: Allergan pleaded guilty today for promoting Botox® between 2000 to 2005 for headache, pain, spasticity, and juvenile cerebral palsy – none of which were FDA approved uses during that period. The FDA approved BOTOX for limited therapeutic uses in that period: strabismus (crossed eyes) and blepharospasm (involuntary eyelid muscle contraction), cervical dystonia (involuntary neck muscle contraction) and primary axillary

hyperhidrosis (excessive underarm sweating).

According to the evidence, Allergan made it a top corporate priority to maximize sales of Botox for so-called "off-label" uses, such as headache, pain, and spasticity. 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 teams that assisted doctors in obtaining reimbursement for such 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 neurotoxin education organization to stimulate increased use of Botox® for off-label indications.

Although all of the approved uses for Botox in 2000-2005 were relatively rare, Allergan exploited its on-label cervical dystonia ("CD") indication to grow off-label headache ("HA") and pain 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 headache market. As part of this initiative, Allergan marketed Botox® for headache and pain by claiming 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 Company has signed a plea agreement admitting its guilt to a criminal misdemeanor for misbranding Botox in violation of the FDCA. Under the plea agreement, Allergan will pay a criminal fine of $350 million and forfeit assets of $25 million. Allergan's guilty plea and sentence was accepted today by U.S. District Court Judge Orinda D. Evans in Atlanta.

The criminal plea and sentence is part of a global resolution of criminal and civil allegations. Allergan has also signed a civil settlement agreement in which the company agrees 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 headache and pain using inappropriate diagnosis codes to ensure payment by government healthcare programs, and provided inducements to doctors to inject more Botox®.

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 guilty plea and sentence announced today does not address Botox® Cosmetic.

Allergan has also executed a Corporate Integrity Agreement ("CIA") with the Department of Health and Human Services (HHS) Office of Inspector General. 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.

The criminal case is being prosecuted by Assistant United States Attorneys Randy Chartash and Doug Gilfillan, and DOJ Office of Consumer Litigation Attorney Josh Burke.

This matter was investigated by the Federal Bureau of Investigation, the FDA's Office of Criminal Investigation, and the HHS Office of Inspector General. 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, or Charysse L. Alexander, Executive Assistant United States Attorney, through Patrick Crosby, Public Affairs Officer, U.S. Attorney's Office, at (404) 581-6016. 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.