Biden's Medicaid Fraud Control Unit secures $137,000 for Delaware in national false claims settlement with pharmaceutical company

Wilmington – Delaware Attorney General Beau Biden announced Thursday that Shire Pharmaceuticals will pay Delaware $137,000 as part of a national settlement with state and federal governments to resolve allegations that the company improperly marketed its drugs for off-label uses.

The entire settlement totals $56.5 million for Delaware, the federal government and many other states. The agreement settles charges that Shire, a Pennsylvania-based company, launched marketing campaigns for Adderal XR, Vyvanse, Daytrona, Lialda and Pentasa, promoting the drugs for uses for which they had not received Food and Drug Administration approval. Delaware's $137,000 payment will go to Delaware's Division of Medicaid and Medical Assistance, as reimbursement for previous Medicaid expenses that were incurred as a result of the drugs being used for off-label purposes.

"The misuse of prescription medication is a major public safety issue," Biden said. "Pharmaceutical companies have a responsibility to market their drugs only for uses that have been approved by the FDA, and will be accountable when they attempt to sell their drugs for unapproved uses."

Adderrall XR, Vyvanse and Daytrona are approved by the United States Food and Drug Administration (FDA) for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) and Lialda and Pentasa are approved for the treatment of mildly to moderately

active ulcerative colitis. Specifically, according to the settlement, Shire is accused of:

• Promoting Adderall XR as clinically superior to other ADHD drugs despite a lack of clinical data to support such claims and for the treatment of Conduct Disorder, an indication not approved by the FDA;
• Promoting Vyvanse as preventing certain negative consequences of ADHD and as less abuseble than Adderrall XR or other ADHD medications despite a lack of clinical data to support such claims;
• Promoting Daytrona as less abuseable than pill-based medications despite a lack of clinical data to support such claims; and that Daytrona, a patch applied product, demonstrated difficulty in sticking to the patient's body, making it therapeutically less effective;
• Promoting Lialda for the prevention of colorectal cancer, an indication not approved by the FDA and marketed Lialda as having greater efficacy than other medications, despite a lack of clinical data sufficient to support such a claim;
• Promoting Pentasa for the treatment of indeterminate colitis and Crohn's Disease, indications for which it had not been approved by the FDA.

As a condition for the settlement, Shire has entered into a Corporate Integrity Agreement (CIA) with the United States Department of Health and Human Services, Office of the Inspector General, which will closely monitor the company's future marketing and sales practices.

The settlement resulted from two qui tam lawsuits originally filed by whistleblowers in the United States District Courts for the Eastern District of Pennsylvania and the Northern District of Illinois under the federal False Claims Act and various state false claims statutes.

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