Inspections, Compliance, Enforcement, and Criminal Investigations

May 7, 2012: Abbott Labs to Pay $1.5 Billion to Resolve Criminal and Civil Investigations of Off-Label Promotion of Depakote

Food and Drug Administration
Office of Criminal Investigations

U.S. Department of Justice Press Release

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Company Maintained Specialized Sales Force to Market Drug for Off Label Purposes; Targeted Elderly Dementia Patients in Nursing Homes

WASHINGTON – Global Health Care Company Abbott Laboratories Inc. has pleaded guilty and agreed to pay $1.5 billion to resolve its criminal and civil liability arising from the company's unlawful promotion of the prescription drug Depakote for uses not approved as safe and effective by the Food and Drug Administration (FDA), the Justice Department announced today. The resolution – the second largest payment by a drug company – includes a criminal fine and forfeiture totaling $700 million and civil settlements with the federal government and the states totaling $800 million. Abbott also will be subject to court-supervised probation and reporting obligations for Abbott's CEO and Board of Directors.

"Today's settlement shows further evidence of our deep commitment to public health and our determination to hold accountable those who commit fraud," said James M. Cole, Deputy Attorney General. "We are resolute in stopping this type of activity and today's settlement sends a strong message to other companies."

The FDA is responsible for approving drugs as safe and effective for specified uses. Under the Food, Drug and Cosmetic Act (FDCA), a company in its application to the FDA must specify each intended use of a drug. A company's promotional activities must be limited to only the intended uses that FDA approved. In fact, promotion by the manufacturer for other uses – known as "off-label" uses – renders the product misbranded.

Abbott has pleaded guilty to misbranding Depakote by promoting the drug to control agitation and aggression in elderly dementia patients and to treat schizophrenia when neither of

these uses was FDA approved. In an agreed statement of facts filed in the criminal action, Abbott admits that from 1998 through 2006, the company maintained a specialized sales force trained to market Depakote in nursing homes for the control of agitation and aggression in elderly dementia patients, despite the absence of credible scientific evidence that Depakote was safe and effective for that use. In addition, from 2001 through 2006, the company marketed Depakote in combination with atypical antipsychotic drugs to treat schizophrenia, even after its clinical trials failed to demonstrate that adding Depakote was any more effective than an atypical antipsychotic alone for that use. Illegal Promotion of Depakote to Control Agitation and Aggression in Dementia Patients.

The FDA approved Depakote for only three uses: epileptic seizures, bipolar mania and the prevention of migraines. The FDA never approved the drug as safe and effective for the off-label use of controlling behavioral disturbances in dementia patients. In 1999, Abbott was forced to discontinue a clinical trial of Depakote in the treatment of dementia due to an increased incidence of adverse events, including somnolence, dehydration and anorexia experienced by the elderly study participants administered Depakote.

Abbott trained its sales force to promote Depakote to health care providers and employees of nursing homes as advantageous over antipsychotic drugs for controlling agitation and aggression in elderly dementia patients because Depakote was not subject to certain provisions of the Omnibus Budget Reconciliation Act of 1987 (OBRA) and its implementing regulations designed to prevent the use of unnecessary medications in nursing homes. Exploiting the fact that certain OBRA provisions did not yet apply to Depakote, Abbott sales representatives stated that by using Depakote, nursing homes could avoid the administrative burdens and costs of complying with OBRA.

Abbott's off-label promotion of Depakote was multifaceted. The company entered into contracts that provided long-term care pharmacy providers with payments of rebates based on increases in the use of Depakote in nursing homes serviced by the providers. In addition to using its sales force to promote the drug to health care providers and employees of nursing homes, Abbott created programs and materials to train the pharmacy providers' consultant pharmacists about the off-label use of Depakote to encourage them to recommend the drug for this unapproved use. Under these contracts, Abbott paid millions of dollars in rebates to the pharmacy providers.

"Not only did Abbott engage in off-label promotion, but it targeted elderly dementia patients and downplayed the risks apparent from its own clinical studies," said Acting Associate Attorney General Tony West. "As this criminal and civil resolution demonstrates, those who put profits ahead of patients will pay a hefty price."

Illegal Off-Label Promotion of Depakote for Schizophrenia

In the agreed statement of facts, Abbott also admitted that from 2001 through 2006, the Company misbranded Depakote by marketing the drug to treat schizophrenia. Abbott funded two studies of the use of Depakote to treat schizophrenia, and both failed to meet the main goals established for the study. When the second study failed to show a statistically significant treatment difference between antipsychotic drugs used in combination with Depakote and antipsychotic drugs alone, Abbott waited nearly two years to notify its own sales force about the study results and another two years to publish those results. During this time, Abbott continued to promote Depakote off-label to treat schizophrenia.

"Today's settlement demonstrates our continued scrutiny of the sales and marketing practices of pharmaceutical companies that put profits ahead of patient health," said U.S. Food and Drug Administration Commissioner Margaret Hamburg, M.D. "The FDA will continue its due diligence and hold pharmaceutical companies accountable for marketing practices that undermine the drug approval process."

Criminal Plea

Today's global resolution has criminal, civil and administrative components. First, Abbott has pleaded guilty to a criminal misdemeanor for misbranding Depakote in violation of the FDCA. Under the plea agreement, Abbott will pay a criminal fine of $500 million, forfeit assets of $198.5 million, and submit to a term of probation for five years. In addition, Abbott will also pay $1.5 million to the Virginia Medicaid Fraud Control Unit. As a condition of probation, Abbott will report any probable FDCA violations to the probation office, its CEO will certify compliance with this reporting requirement, and its board will report annually on the effectiveness of the company's compliance program. In addition, Abbott agrees that during the term of probation, the company will not compensate sales representatives for off-label sales, will ensure that continuing medical education grant-making decisions are not controlled by sales and marketing, will require that letters communicating medical information to healthcare providers be accurate and unbiased, and will have policies designed to ensure that clinical trials are approved by the company's medical or scientific organizations and published in a consistent and transparent manner. Abbott's guilty plea and sentence are not final until accepted by the U.S. District Court for the Western District of Virginia.

"As the agreed statement of facts filed in court today demonstrates, Abbott promoted Depakote to control behaviors in elderly dementia and schizophrenia patients without significant evidence of its effectiveness for that use, and even after clinical data established that it was not effective," said Timothy Heaphy, U.S. Attorney for the Western District of Virginia. "The resolution announced today includes a self-policing mechanism by which Abbott's board of directors will monitor compliance with the law and report any violations, as well as a period of probation and court supervision. We credit Abbott's acceptance of responsibility and encourage other pharmaceutical companies to impose the similar mechanisms to prevent off-label marketing, which damages health care consumers."

Civil Settlement

Under the civil settlement, Abbott has agreed to pay $800 million to the federal government ($560,851,357) and the states ($239,148,643) that opt to participate in the agreement to resolve claims that its unlawful marketing and illegal remuneration 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 broader allegations by the United States that from 1998 through 2008, Abbott unlawfully promoted Depakote for unapproved uses, including behavioral disturbances in dementia patients, psychiatric conditions in children and adolescents, schizophrenia, depression, anxiety, conduct disorders, obsessive-compulsive disorder, post-traumatic stress disorder, alcohol and drug withdrawal, attention deficit disorder and autism. .

Some of these unapproved uses were not medically accepted indications for which the United States and state Medicaid programs provided coverage for Depakote. The United States contends that this promotion included, in part, making false and misleading statements about the safety, efficacy, dosing and cost-effectiveness of Depakote for some of these unapproved uses, and claiming use of Depakote to control behavioral disturbances in dementia patients would help nursing homes avoid the administrative burdens and costs of complying with OBRA regulatory restrictions applicable to antipsychotics.

The civil settlement also covers allegations that Abbott offered and paid illegal remuneration to health care professionals and long term care pharmacy providers to induce them to promote and/or prescribe Depakote and to improperly and unduly influence the content of company sponsored Continuing Medical Education programs, in violation of the Federal Anti-Kickback Statute. The claims settled by the civil agreement are allegations only and there has been no determination of liability, except to the extent that Abbott has admitted facts in the civil settlement agreement or in the criminal plea and agreed statement of facts filed in the criminal action.

The civil settlement resolves four lawsuits pending in federal court in the Western District of Virginia 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. As part of today's resolution, the whistleblowers will receive $84 million from the federal share of the settlement amount.

Corporate Integrity Agreement

In addition to the criminal and civil resolutions, Abbott 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 Abbott's board of directors review the effectiveness of the company's compliance program, that high-level executives certify to compliance, that Abbott maintain standardized risk assessment and mitigation processes, and that the company post on its website information about payments to doctors. Abbott 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.

"As a result of OIG's joint investigation with our federal and state partners, Abbott Laboratories will enter one of the pharmaceutical industry's largest settlements and pay $1.5 billion for unlawfully promoting its drug Depakote, including to nursing home patients with dementia," said HHS Inspector General Daniel R. Levinson. "Our integrity agreement will hold Abbott accountable for preventing future violations of federal health care laws and FDA requirements, which will protect federal programs, taxpayers and our most vulnerable patients."

A Multilateral Effort

The criminal case is being prosecuted by the U.S. Attorney's Office for the Western District of Virginia and the Civil Division's Consumer Protection Branch. The civil settlement was reached by the U.S. Attorney's Office for the Western District of Virginia and the Civil Division's Commercial Litigation Branch. Assistance was provided by representatives of the HHS Office of Counsel to the Inspector General; the Center for Medicare and Medicaid Services (CMS) and Office of the General Counsel, CMS Division; FDA's Office of Chief Counsel; and the National

Association of Medicaid Fraud Control Units.

"Crimes involving the misbranding of drugs for financial gain will not be tolerated," stated Richard Weber, Chief IRS Criminal Investigation. "The special agents of IRS Criminal Investigation will use all their investigative tools, including the use of asset forfeiture statutes, to combat financial crimes and hold corporations accountable for their actions."

This matter was investigated by the Virginia Attorney General's Medicaid Fraud Control Unit; the Internal Revenue Service - Criminal Investigation; the FDA - Office of Criminal Investigation; the Defense Criminal Investigative Service; the Health and Human Services - Office of Inspector General; the West Virginia State Police; the Office of Personnel Management - Office of Inspector General; the Department of Veterans' Affairs Office of Inspector General; the Department of Labor - Office of Inspector General; and TRICARE Program Integrity.

This resolution is part of the government's emphasis on combating health care fraud and another step for the Health Care Fraud Prevention and Enforcement Action Team (HEAT) initiative, which was announced in May 2009 by Attorney General Eric Holder and Kathleen Sebelius, Secretary of HHS. The partnership between the two departments has focused efforts to reduce and prevent Medicare and Medicaid financial fraud through enhanced cooperation. One of the most powerful tools in that effort is the False Claims Act, which the Justice Department has used to recover more than $7.4 billion since January 2009 in cases involving fraud against federal health care programs. With the settlement announced today, the Justice Department's total recoveries in False Claims Act cases since January 2009 will exceed $10.2 billion. During this same time, the department has secured $3.9 billion in criminal fines, forfeiture, disgorgement, and restitution relating to violations of the FDCA.