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TECHNOLOGY

Technology: Abbott's $1.6 billion global settlement illustrates government's commitment to health care fraud enforcement

Abbott now has to put extensive internal controls in place to ensure this doesn't happen again

BY JESSE WITTEN

Last month, the government obtained one of the largest settlements ever in a health care fraud matter, as Abbott Laboratories agreed to pay $1.6 billion to settle allegations that it unlawfully marketed its drug, Depakote. The global settlement, announced on May 7, included a criminal guilty plea and the settlement of numerous civil cases. Furthermore, the Office of Inspector General of the Department of Health and Human Services (OIG) and Abbott have entered into a five-year corporate integrity agreement (CIA), which will regulate Abbott's prospective conduct.

The government's investigation reportedly began in 2007, when a whistleblower contacted the Virginia attorney general's office and shortly afterward filed a complaint under the *qui tam* provisions of the False Claims Act in the Western District of Virginia. Three additional *qui tam* lawsuits were subsequently filed by others against Abbott. The ensuing investigation reportedly involved witness interviews in 26 states and the production of more than one million documents.

On May 7, Abbott pled guilty to a misdemeanor for promoting Depakote for non-FDA-approved, or "off-label," uses. Although physicians may prescribe drugs for off-label use, federal law only permits pharmaceutical manufacturers to market drugs for approved uses. In its guilty plea, Abbott admitted that between 1998 and 2006, it promoted Depakote as a treatment for schizophrenia and behaviors associated with dementia, but the FDA had only approved the drug to treat epileptic seizures and biopolar mania and to prevent migraine headaches.

Abbott directed its off-label promotional activities toward nursing homes with residents suffering from dementia. Abbott admitted to maintaining a specialized sales force to market the drug in nursing homes, instructing sales representatives to explain how nursing homes could use Depakote to avoid having to comply with laws designed to prevent unnecessary use of medications in nursing homes, offering rebates triggered by increased Depakote use and programs to train pharmacies about using Depakote to treat behaviors associated with dementia.

In addition, according to an agreed statement of facts filed with the plea agreement, Abbott funded two studies on the use of Depakote to treat schizophrenia, and both failed to meet the main goals of the studies. The second study failed to show a statistically significant treatment difference between antipsychotic drugs used in combination with Depakote and the antipsychotic drugs alone. Abbott did not inform its sales force of the study results or publish them for two years while it continued to market Depakote as a schizophrenia therapy.

Abbott agreed to pay a criminal penalty of $500 million and an additional forfeiture of $198.5 million. Under the relevant sentencing statute, Abbott's criminal penalty could be as much as $800 million (twice the gross gain from the unlawful conduct).

Abbott settled civil False Claims Act allegations, asserted in the four *qui tam* actions, that Abbott's unlawful marketing activities caused health care providers that administered Depakote to submit false claims to Medicaid and Medicare. Abbott agreed to pay approximately $561 million to the federal government and $239 million to several states. The four sets of whistleblowers will share $84.1 million from the federal settlement amount and will presumably also receive additional payments out of the state settlements.

Furthermore, Abbott agreed to pay $100 million to 45 states and the District of Columbia to settle a companion consumer fraud case.

The Abbott CIA requires the company to establish and maintain extensive internal controls intended to prevent and detect violations of law. These controls include:

- Maintaining a compliance officer
- Issuing comprehensive written policies and procedures related to marketing activities
- Training employees on the policies

In addition, the CIA obliges Abbott to disclose probable violations of health care laws to the OIG within 30 days of determining that the reportable event has occurred.

The CIA further requires Abbott to establish comprehensive programs to monitor the company's sales representatives and to oversee financial relationships with physicians and other health care professionals. These internal review programs will include auditing speaker programs, observing sales representatives, reviewing records of sales representatives' interactions with physicians and monitoring consultant arrangements, research activities, publication activities and medical education grants. Abbott also will be required to notify Depakote-prescribing physicians of the settlement and CIA

Finally, under the CIA, Abbott must retain an outside auditor to conduct extensive annual audits to ensure Abbott's compliance with pharmaceutical marketing laws and transactions with physicians and other health care providers.

The Abbott settlement is not the first health care fraud settlement to top $1 billion, and it likely will not be the last. In case there remained any doubt, the Abbott settlement vividly illustrates the government's intention to crack down on health care fraud. The government is investigating numerous medical device and pharmaceutical companies in similar matters, and the substantial bounty paid to the whistleblowers in this case will doubtlessly spur others to share their accusations with the government.