# Abbott Settles Marketing Lawsuit

###### By [MICHAEL S. SCHMIDT](http://topics.nytimes.com/top/reference/timestopics/people/s/michael_s_schmidt/index.html?inline=nyt-per) and [KATIE THOMAS](http://topics.nytimes.com/top/reference/timestopics/people/t/katie_thomas/index.html?inline=nyt-per)   New YORK TIMES

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WASHINGTON — The pharmaceutical company [Abbott Laboratories](http://topics.nytimes.com/top/news/business/companies/abbott_laboratories/index.html?inline=nyt-org) said on Monday that it had reached an agreement with the federal and nearly all state governments to pay $1.6 billion in connection with its illegal marketing of the anti-seizure drug Depakote.

The settlement comes as the Justice Department and the states have increased scrutiny of the sales and marketing practices of pharmaceutical companies, particularly in cases in which they market drugs for uses that are not approved by the [Food and Drug Administration](http://topics.nytimes.com/top/reference/timestopics/organizations/f/food_and_drug_administration/index.html?inline=nyt-org).

Last year, GlaxoSmithKline, the British drug company, [agreed to pay $3 billion](http://www.nytimes.com/2011/11/04/business/glaxo-to-pay-3-billion-in-avandia-settlement.html) to settle civil and criminal investigations into its sales practices for several drugs, including the diabetes drug [Avandia](http://topics.nytimes.com/top/news/health/diseasesconditionsandhealthtopics/avandiadrug/index.htm?inline=nyt-classifier). In 2009, [Pfizer paid $2.3 billion](http://www.nytimes.com/2009/09/03/business/03health.html) to settle similar charges. Several other pharmaceutical companies have also reached multimillion-dollar settlements over their practices.

Abbott illegally marketed the drug for schizophrenia and agitated dementia, even though it was approved only for treatment of seizure disorders, or mania associated with bipolar disorder and migraines, according to a media release from the Justice Department.

Doctors may prescribe drugs for any purpose, but pharmaceutical companies are prohibited from promoting drugs for conditions that are not approved by the agency.

According to the Justice Department, Abbott admitted to setting up a “specialized sales force” that marketed Depakote in nursing homes to control agitation and aggression in aging patients with dementia, even though there was no evidence that it was safe and effective for such use.

The company trained its sales representatives to promote Depakote to nursing homes as a way to sedate patients without running afoul of a federal law intended to prevent overuse of certain medications.

“Abbott sales representatives stated that by using Depakote, nursing homes could avoid the administrative burdens and costs of complying with” the law, according to the Justice Department [news release](http://www.justice.gov/opa/pr/2012/May/12-civ-585.html).

From 2001 to 2006, Abbott marketed the drug for use along with antipsychotic drugs to treat schizophrenia, even though the company’s clinical trials showed that taking Depakote was not more effective than using the antipsychotic drugs.

The company said in a [news release](http://www.abbott.com/news-media/press-releases/abbott-reaches-settlement-agreement-on-depakote.htm) that it had been under investigation for four years in connection with sales that dated back to 1998.

As part of the agreement, Abbott said that it would pay $800 million to resolve civil cases brought by federal and state authorities, $700 million in criminal penalties and $100 million to states in connection with consumer protection matters.

The company will also plead guilty to one misdemeanor charge of misbranding for violating the Food, Drug and Cosmetic Act. The agreements include several conditions the company must meet to show it is properly marketing the drug.

“We are pleased to resolve this matter and are confident we have the programs in place to satisfy the requirements of this settlement,” Laura J. Schumacher, the general counsel for Abbott, said.. “The company takes its responsibility to patients and health care providers seriously and has established robust compliance programs to ensure its marketing programs meet the needs of health care providers and legal requirements.”

Abbott’s actions were particularly egregious because they aimed at older patients with dementia, “people who didn’t have the ability to engage in informed consent,” said Reuben Guttman, the lawyer who represented Meredith McCoyd, a former Abbott sales representative who was the lead whistle-blower in the case. The four whistle-blowers are to share $84 million in federal rewards and $22 million for state-level claims, Mr. Guttman said.

He called on the federal government to bring drug companies to task in a more meaningful way than simply fining them hundreds of millions of dollars — penalties that often amount to only a small percentage of their profits.

“To me, what happened here was a train wreck, and when you have train wrecks in this country, you investigate,” Mr. Guttman said.

Shares of Abbott rose 10 cents to close at $62.51 on Monday. Abbott set aside $1.5 billion in the third quarter last year to cover the costs of the anticipated settlement.

**Federal report on stent procedures finds potential fraud**

**Investigators question whether doctor's relationship with stent maker encouraged unnecessary medical procedures**

December 06, 2010|By Tricia Bishop, The Baltimore Sun

While Dr. Mark Midei was allegedly implanting unnecessary cardiac stents in hundreds of patients at a Towson hospital, stent manufacturer Abbott Laboratories was paying for crab and barbecue feasts at his Monkton home and building a business strategy around the Maryland cardiologist's high output, according to a federal report being released today.

Abbott, a $30 billion-a-year, Chicago-based pharmaceutical firm, ranked Midei among its top-volume doctors in the Northeast and made plying him with research money and "VIP trips" part of its business plan in late 2008 — about the time Midei's usage of Abbott-brand stents soared, the report said.

The 170-page document contains the findings of a months-long investigation by the U.S. Senate Committee on Finance into allegations of inappropriate and potentially harmful cardiac procedures performed by Midei at St. Joseph Medical Center. It calls the case "a clear example of potential fraud, waste and abuse," noting that St. Joseph billed government and private insurers more than $6.6 million for the procedures.

Committee Chairman Sen. Max Baucus also raised concerns in a statement that "this could be a sign of a larger national trend of wasteful medical device use." Similar allegations have been made against cardiologists in at least three other states and elsewhere in Maryland.

"Hospital patients expect their care to be based on medical need, not profits," the Montana Democrat said. "This report sets forth alarming evidence that patients at St. Joseph's Medical Center received unnecessary and potentially harmful stent implants time and again — a pattern that is shocking, disturbing and shameful.

"Doctors should not be performing invasive medical procedures patients don't need, and taxpayers certainly shouldn't be paying for these wasteful and improper implantations."

The Senate report includes dozens of e-mails, letters and other documents, subpoenaed by the committee, that reveal a cozy and sometimes lucrative relationship between Midei, St. Joseph and Abbott. In one exchange, Abbott officials congratulated Midei for implanting 30 stents in one day, calling it a record and describing the physician as "one of the highest implantors [sic] thus far."

Investigators for the Senate Finance Committee, which has long been concerned about inappropriate relationships between pharmaceutical companies and physicians, said their investigation raises questions about "whether or not Abbott Laboratories indirectly encouraged Dr. Midei to intensify his use of stents, with unfortunate results."

Abbott declined to answer questions Friday, but issued a statement saying, "Dr. Midei has been a highly regarded physician in his field, with whom Abbott had consulted in the past. Our affiliation with Dr. Midei ended early this year."

St. Joseph said it had not seen the report and declined to answer questions Friday, while Midei's attorney, Stephen L. Snyder, dismissed it, saying simply: "Big deal."

Among other details in the Senate report:

• Abbott paid for social events at Midei's home, including a "beers and crabs" dinner and a whole-pig barbeque for employees of the St. Joseph cardiac lab. A company official also lauded an Abbott saleswoman for her business relationship with Midei, calling it the strongest the official has seen in 15 years.

• Abbott officials enlisted Midei as a paid consultant after he was forced out of St. Joseph, calling it the right thing to do because "he helped us so many times over the years." The company paid him more than $30,000 to market its "Xience V" stent in Japan, after the media climate in the United States became "too hot."

• The company noted an "ugly" decline in the volume of stent procedures at hospitals throughout the Baltimore region after the allegations against Midei became public, including a 46 percent drop at St. Joseph.

• One Abbott official suggested that local connections or the "Philly mob" should intervene to silence Baltimore Sun columnist Jay Hancock for his coverage of the scandal, saying "someone needs to take this writer outside and kick his ass!"

The report does not offer recommendations or outline a next step, though some safety measures have already been added through recent legislation, Baucus said.

"Aggressive new tools, like improved screening of medical providers and increased oversight, [were included] in the new health care reform law to root out fraud, waste and abuse like this," Baucus said.

T**he U.S. Senate committee, which oversees the taxpayer-funded Medicare and Medicaid programs,**launched the investigation in February after a story in The Sun about Midei's questionable procedures. The inquiry focused on Midei, St. Joseph and Abbott, which manufactures the stents that Midei typically used during his last year of work at the hospital, which ended in May 2009.

READ THE REST OF THE ARTICE:

# Abbott Labs Accused of Racketeering in Depakote Marketing Suit

By Andrew Harris August 16, 2013

Abbott Laboratories ([ABT:US](http://investing.businessweek.com/research/stocks/snapshot/snapshot.asp?ticker=ABT:US)) allegedly engaged in racketeering when it led an effort to market the epilepsy drug Depakote for unapproved uses, according to a federal court complaint filed in Chicago.

The pharmaceutical company last year agreed to pay $1.6 billion to settle state and federal claims it promoted the drug’s use to treat bi-polar mania and to prevent migraine headaches.

“Unfortunately, these sanctions were insufficient to compensate” for harm caused to injured claimants, according to today’s complaint by three health-benefit plans seeking to represent those claimants as a group.

“Abbott probably calculated both its risk of being caught and its potential civil and criminal exposure assuming its only liability would be to the Medicare, Medicaid and Tricare systems,” the plans alleged, referencing government health benefit programs for the elderly, the indigent, and those in the armed forces.

Last year’s settlement resolved a four-year investigation into the sales practices of the Abbott Park, Illinois-based company.

In addition to its agreement to pay $800 million to resolve civil claims and a $700 million criminal penalty, Abbott said it would pay $100 million to states to resolve consumer protection matters.

## Federal Racketeering

Scott E. Stoffel, a company spokesman, didn’t immediately respond to voice-mail messages seeking comment on today’s allegations.

The plaintiffs are the Sidney Hillman Health Center of Rochester, New York, the Teamsters Health Services & Insurance Plan Local 404 in Springfield, Massachusetts, and Park Ridge, Illinois-based United Food & Commercial Workers Unions and Employers Midwest Health Benefits Fund, each of which allegedly paid for its beneficiaries’ use of Depakote.

Alleging violations of federal racketeering and of being unjustly enriched, the plaintiffs are seeking unspecified money damages.

Chicago federal court Judge Virginia Kendall in June denied a defense request to dismiss a 2011 lawsuit accusing company directors including Chairman Miles D. White of shirking their responsibility to supervise marketing of the drug.

The case is Sidney Hillman Health Center of Rochester, 13-cv-05865, U.S. District Court, Northern District of Illinois (Chicago).

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