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Verdicts & Settlements

$185 Million Settlement Mandates Public Access To Drug Trials


THOMAS DUBBS

By Natalie White

In a massive settlement that includes groundbreaking disclosure rules for clinical trial information, one of the nation's largest pharmaceutical companies has agreed to pay $185 million in a class action securities fraud lawsuit.

As part of the settlement over the hypertension drug Vanlev, Bristol-Myers Squibb will use its website to publicly post clinical trial results for all of its drugs approved for marketing in the United States and abroad.

The settlement, which has yet to be finalized, is part of a trend in which large institutional plaintiffs seek corporate reforms in addition to large monetary awards, said lead plaintiffs' attorney Thomas Dubbs of New York City.

"With this agreement, anyone taking a drug manufactured by BMS will have instant access to crucial information, especially serious side effects," said Dubbs, who represented the LongView Collective Investment Fund of the Amalgamated Bank.

He said the settlement could renew interest in federal legislation that would make it mandatory for all pharmaceutical companies to provide public disclosure of clinical test information. But others said the more likely result is for the industry to initiate its own reforms to ward off government intervention.

"The climate in our country for that kind of legislation hasn't been very strong," said Jerome Kassirer, former editor-in-chief of the New England Journal of Medicine and a professor at Tufts University School of Medicine in Boston. "If anything, I think other pharmaceutical companies may go along with similar disclosure just to avoid Congress getting involved."

Kassirer said the impact of the BMS settlement will depend on how easy the information is to understand. Currently there are several voluntary clinical trial registries where information is available, but there have been complaints about quality of the information provided.

"The more information out there the better, but if the information is obfuscated then it isn't all that helpful," he said. "It will depend on the accuracy and completeness of the data."

Kassirer said the case also highlights a problem that wasn't addressed in the suit because it focused on securities.

"It's clear [from the documents] that the investors were misled, but what I found more interesting was the conflict of interest and the behavior of the physicians who were working for BMS," said Kassirer. "What became apparent to me is that the physicians knew about the complications of Vanlev, yet they were out talking to medical audiences about the potential of the drug, and they were not telling them about the extent of the complications. They were underplaying the serious side effects of the drug."

Meanwhile, the defendant emphasized that the settlement has yet to be finalized.

"The parties have reached an agreement in principle on financial terms and are seeking to finalize non-financial aspects of a potential settlement," the company said in a statement posted on its website.

Withholding Dangers

If approved, the January settlement will end a five-year battle that included more than 200 securities fraud claims filed against Bristol-Myers Squibb for allegedly withholding information about negative side effects of Vanlev, which was being touted as an upcoming "blockbuster" drug.

The lawsuit was filed in 2000 after tests showed dangerous side effects such as angioedema - a rapid swelling of the skin below the surface, often around the eyes, lips, face, hands and feet. It can also include swelling of the throat that blocks the airway.

As a result, the company withdrew its new drug application from the FDA and BMS stock fell nearly 40 percent, according to the suit.

Dubbs said the company harmed investors even though the drug never reached the market.

"Even though it was never mass-produced to the public, this arguably propped up its stock price and damaged class members," he said.

Critics of the industry said this is just another example of pharmaceutical companies putting the public at risk by withholding information about serious side effects.

"We have seen time and again in recent cases such as Vioxx and Paxil the unnecessary health risks posed because a drug company left the public in the dark," said plaintiffs' spokesman Noel Beasley of LongView Collective Investment Fund. "Now, consumers will have access to crucial information about BMS drugs, especially any serious side effects."

Far-Reaching Impact

Dubbs contends that the settlement will have a greater impact than previous pharmaceutical litigation because it marks the first time a drug company has agreed to public disclosure of drug trials prior to FDA approval.

In an earlier settlement involving the antidepressant Paxil, GlaxoSmithKline agreed to release information only about drugs that have been approved for use in the United States.

By requiring BMS to provide easy access to clinical trials and reveal potential side effects of all its approved for market drugs, the settlement seeks to prevent companies from withholding negative information about new drugs during the development stage.

"It will be a deterrent against drug companies failing to disclose negative materials at the same time they are making statements about the financial implications of the drug," Dubbs said.

Congress has tried several times to get drug companies to be more forthcoming and has proposed the "Fair Access to Clinical Trials Act," (S. 479 and HR 5252) - but so far, the legislation has languished.

Dubbs said the settlement incorporates many of the provisions in the bill, which was introduced in the House by John Markey (D-Mass.) and Henry Waxman (D-Calif.), and in the Senate by Christopher Dodd (D-Conn.), Chuck Grassley (R-Iowa),Tim Johnson (D-S.D.) and Ron Wyden (D-Ore.).

Under the agreement, the information will be posted on the BMS website as well as on the leading consumer-oriented prescription drug information website www.clinicaltrials.org

The case involves more than four million pages of documents. Dubbs said that the plaintiffs deposed dozens of former and current BMS employees and officers, securities analysts and others. The case also drew in dozens of experts in fields from cardiology and epidemiology to regulatory matters and securities markets. More than 1,500 exhibits were marked during depositions.

Plaintiffs' Attorney: Thomas Dubbs of Labaton Sucharow & Rudoff in New York City.

Defense Attorney: Evan Chesler of Cravath, Swaine & Moore in New York City.

The Case: *Bristol-Myers Squibb Securities Litigation*; Jan. 23, 2006; U.S. District Court for the District of New Jersey; Judge Stanley Chesler.
