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BUSINESS DAY

New Emails in Pradaxa Case Show Concern Over Profit

By KATIE THOMAS FEB. 7, 2014

Employees of Boehringer Ingelheim, the German drug maker, continued to express concern over whether sales of their blood thinner, Pradaxa, could be harmed if the public learned that some patients might need regular testing for safety reasons, according to new documents unsealed by a federal judge in Illinois on Thursday.

The documents, which include a series of internal emails and memos, add to a trove of court records that were made public last week by Chief Judge David R. Herndon, of the United States District Court in East St. Louis, who is overseeing thousands of lawsuits filed by patients and their families, who say that Boehringer Ingelheim failed to properly warn them about the risks of taking Pradaxa.

Since its approval in 2010, the drug, which can cause fatal bleeding, has brought in more than $2 billion in sales in the United States, according to the research firm IMS Health. It has been prescribed to 850,000 patients, but has also been linked to more than 1,000 deaths.

Boehringer Ingelheim has stood by the drug, noting that the Food and Drug Administration has upheld its safety and that its value has been proved in clinical trials.

Many of the documents released last week and Thursday centered on the question of what the company's response should be to internal research showing that some patients could benefit from closer monitoring of their blood. If too little of the drug is absorbed, patients could be at increased risk of stroke. But if too much of it was in the blood, they could be at risk for bleeding.

Testing is a critical issue because Pradaxa and two other recently approved drugs, Xarelto and Eliquis, are in a race to gain market share from warfarin, a generic drug that for decades has been the standard treatment for preventing

blood clots and strokes. Many patients viewed the older warfarin as a nuisance because it required frequent blood tests and careful attention to diet and other drugs.

The new drugs do not require such monitoring, yet claim to be as good, or better, at preventing strokes and blood clots in patients with a heart-rhythm disorder known as atrial fibrillation.

The documents released on Thursday contain several emails from employees at Boehringer Ingelheim expressing concern over the sales impact of testing patients who are using Pradaxa.

In one email, from June 2012, an employee wonders about the implications of internal research showing that blood levels of Pradaxa could vary significantly in a single patient.

"This may not be a onetime test and could result in a more complex message (regular monitoring), and a weaker value proposition ... vs. competitors," wrote the employee, whose name was redacted in accordance with privacy laws in Germany, where the company is based.

In another, an employee — whose name was also removed — asks about whether a newly available blood test in the United States might be useful for doctors treating patients with Pradaxa, which is also known as dabigatran. Another replies that such a test could be developed "in-house," but "2 years ago there was an informed decision NOT to develop this." The employee continued, "this would go against the 'no monitoring' idea/claim."

Employees also continued to question the merits of allowing a research paper to be published showing that some patients could benefit from monitoring of their blood. The paper was published on Tuesday but with some details removed.

"This publication will more harm than be useful for us, neither in the market but be especially harmful in the discussions with regulatory bodies," one email read. "Can't this be avoided?"

One email from a Boehringer Ingelheim employee expressed concern about safety risks in older patients, citing research showing that, in patients over 80, even a lower dose of Pradaxa, which is available in Europe but not the United States, compared unfavorably to warfarin when it came to major bleeding.

The employee says that "there may be a role" for one or two tests of Pradaxa levels in a patient's blood, and recommends that the company conduct a study to examine the issue.

But another employee, in the same email chain, casts doubt on whether measuring a patient's blood levels would help predict the likelihood of bleeding, saying that some people with high levels of the drug in their blood would not experience a problem.

"It's like driving a car," the employee wrote. "220km/h does not mean that one would for sure have an accident." That speed is the equivalent of about 135 miles per hour.

In a statement earlier this week, Boehringer Ingelheim said that the court documents represented "small fragments of the robust discussion and debate that is a vital component in all scientific inquiry, and in the research and development of any important medication such as Pradaxa."
