German drug company covered-up deadly side effects of anticoagulant Pradaxa

By Douglas Lyons
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The *British Medical Journal* (BMJ) has alleged that Boehringer Ingelheim, a transnational pharmaceutical company headquartered in Germany, deliberately withheld important health and safety information concerning its drug Pradaxa from regulators in the UK and US, precipitating unnecessary deaths.

The anticoagulant Pradaxa has been used for patients suffering from atrial fibrillation, a debilitating heart-rhythm disorder causing chest pain, palpitations, fainting, and chronic heart failure, to prevent stroke, but the drug has a grave side-effect, internal and irreversible bleeding.

The Institute for Safe Medication Practices (ISMP) at the University of Ottawa cited four internal reports written by Boehringer Ingelheim scientists, in which they issued concerns about the risks of serious bleeding being ignored by management.

As a result, the ISMP then conducted research on the drug to determine if simply monitoring the levels of it in the blood would reduce bleeding complications, resulting from the casual intake of the drug over time. The results: monitoring blood levels occasionally would have allowed doctors to accordingly adjust, or temporarily stop, the amount of the drug, so that dangerously high levels of Pradaxa would recede.

One of the prime selling points of Pradaxa, making it one of the best-selling drugs for patients with this illness, is that the drug does not require frequent blood plasma monitoring. Older drugs in this genre like Coumadin apply blood monitoring procedures.

In contrast to Boehringer Ingelheim's marketing gimmick, the drug company's internal documents reveal evidence that in up to 40 percent of all severe bleeding episodes, "simple blood testing could have prevented the deaths associated with Pradaxa use." The pharmaceutical giant, according to ISMP, "had been aware of this even before the drug was green-lighted by the FDA [US Food and Drug Administration], but apparently withheld this information during the approval process of Pradaxa."

So almost half of all patients, who had died as a result of the drug, could have been saved if their blood intoxication levels had been checked. In one instance, an 83-year-old man was evaluated for routine problems associated with a fall. His mind was clear and doctors acknowledged that he seemed fine, despite CT scans that showed minor hemorrhaging of the brain. As time elapsed, scans displayed accelerating and extensive brain hemorrhaging. Doctors' efforts to rectify the problem were futile, and the man died from the side effects of Pradaxa.

All in all, there have been hundreds of deaths caused by the drug, and, according to the *Journal of Neurosurgery*, bleeding complications from Pradaxa are generally irremediable. Another study in January 2012 by *Archives of Internal Medicine* evidenced a link between the use of Pradaxa and a higher risk of heart attack—27 to 33 percent higher—when compared to similar medicines.

Boehringer Ingelheim responded to this indictment, saying, "Our company has provided regulators with the complete data set and analyses of clinical evidence demonstrating the efficacy and safety profile of Pradaxa, and FDA and European Medicines Agency (EMA) have affirmed RE-LY's [Randomized Evaluation of Long Term Anticoagulant Therapy] conclusions and stated that Pradaxa provides an important health benefit when used as directed."

They neglected to add that it also causes irreversible internal bleeding when taken as directed!

Government oversight organizations have again demonstrated their subservience to a giant

pharmaceutical company, both of which should be held responsible. The FDA approved the drug in 2010. The next year, however, the FDA acquired post-marketing reports connecting Pradaxa with bleeding problems, issuing a toothless comment about its ongoing safety review. Nevertheless, it said recipients should still maintain their daily regimen of the drug. In May of this year, the FDA had reaffirmed their position on the "positive efficacy-safety profile of the drug."

The criminal corporate indifference to the fatal repercussions of approving and marketing this drug is not unusual. Just this year, the American automobile company, General Motors, has been exposed for its years-long cover-up of defective ignition switches on several of its low-cost models. Even though the company was aware that the defective switches were responsible for the deaths of many drivers, it refused to issue recalls or replace them.

Boehringer Ingelheim is one of the world's 20 leading pharmaceutical companies and operates 142 affiliates globally. It employs 47,400 workers. In 2013, the company's net sales reached about 14.1 billion euros. It has shown, once again, that the profit-making motive directly excludes the consideration of the common good.