ELAN PHARMACEUTICALS INC

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Grade Course:

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This essay aims at analyzing the Elan Pharmaceuticals inc after the U.S Department of Justice announced that it has settled one of the largest ever lawsuit against a pharmaceutical firm. In its analysis, the essay will first analyze how this settlement may be related to ethics and compliance in research, before giving my opinion on whether the CIA will prevent actions similar to Elan's firm from occurring again with other pharmaceutical companies.

This settlement relates to ethics and compliance in research because the company stretched the research findings to cover other unapproved uses. According to United States District Court (2010), the results that FDA based on while approving Zonegran showed that the drug was effective as an adjunctive therapy in treating partial seizures among epilepsy patients aged over 16 years. By this time, it was clear that were concerns about the use of the drug among children as a result of severe side effects, and pediatric uses of this drug. However, the company in 2003 decided to market Zonegran for unapproved uses like use among children, mono-therapy among others as stated by Department of Justice (2010). This implies that though the first results were positive, the company stretched them to give them a significance that was not warranted by the evidence that led to its approval as a combination therapy. The results stretching occurred because Elan Pharmaceutical did not provide other research findings especially the phase 4 clinical studies to the FDA to warrant evidence for approval for other uses.

This implies that the company continued to promote the drug by disseminating false information that is unsupported by available research results. For instance, the company's sales aid and sales training materials contained messages indicating that research has indicated that "the serotonergic and dopaminergic effects of ZONEGRAN are important to

physicians who use AEDs for other purposes beyond epilepsy" (United States District Court 2010).

In addition, Elan Pharmaceutical Inc failed to comply with the anti-kickback, stark, and civil monetary penalty statute and regulations. This is because Elan Pharmaceutical Inc provided indirect remuneration or inducements among physicians to recommend the use and purchase Zonegran drugs based on the research findings that were not approved the FDA.

On the issue of CIA preventing similar actions from occurring, I believe CIA can impact other pharmaceutical firms from acting similarly. This is because the CIA will not only regulate marketing, but also selling of drugs coming into market by promoting respect for the law by deterring criminal conducts in the industry. Basically, the CIA forces the board of directors in conjunction with external experts to review the compliance program of the company to certify its effectiveness (Office of Inspector General 2010). In addition, the senior executives of every department as well as functional areas will also be required to certify there departments annually. These actions of reviewing and certification programs will prevent the occurrence of such actions in the industry as they increase the individual responsibility on board and corporate members. This is important in grabbing attention of company's management level that might have been less responsive in previous instances (Barry 2012).

In addition, the consequences of breaching the CIA are too tough for any pharmaceutical firm to engage in a similar action and find itself in such a situation. This is because being excluded from Federal Health programs like Medicare and Medicaid among other monetary penalties brings financial losses as a result of reduced sales and cancelled

contracts. As a result, CIA will enhance compliance as upon its breach; the OIG has the authority of imposing additional sanctions within his/her powers (Barry 2012).

References

Barry, J. (2012). *CIAs: OIG's Favorite Enforcement Tool.* Retrieved on 29th May 2014 from: http://www.healthreformwatch.com/tag/corporate-integrity-agreement/.

Department of Justice. (2010). *Pharmaceutical Companies to Pay $214.5 Million to Resolve Allegations of Off-Label Promotion of Zonegran*. Retrieved on 29th May 2014 from: http://www.justice.gov/opa/pr/2010/December/10-civ-1444.html.

Office of Inspector General. (2010). *Corporate Integrity Agreement the between Office of Inspector General the Department of Health and Human Services and Elan Corporation, Plc.* Retrieved on 29th May 2014 from: http://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&cad=rja&uact=8&ved=0CCoQFjAA&url=http%3A%2F%2Foig.hhs.gov%2Ffraud%2Fcia%2Fagreements%2Felan_corporation_plc_12152010.pdf&ei=vgOHU4XIGe6V7AbEu4HIBw&usg=AFQjCNERdj7xNzOw4im6DsxuM-4S3loSng&sig2=ornNCY4p_3pkcDkoQWdWQw&bvm=bv.67720277,d.ZGU

United States District Court. (2010). *United States of America vs. Elan pharmaceuticals, Inc. Criminal* . NO. 1:10-cr-10431-MBB.